CBP and Trade Automated Interface Requirements

FDA Supplemental Guide for the Automated Commercial Environment/International Trade Data System (ACE/ITDS)

Version 2.5.12 DRAFT

U.S. Customs and Border Protection

Pub # 0875-0419

Table of Contents

Table of Tables

Change Log

Date	Version No.	Commodity	Description
TBD	**2.5.12**	**Appendix E**	Added IUCs to reflect changes listed below for COS, DRU, ADE, CCW products
		Cosmetics	PG01: Updated IUC to mandatory. Added IUC 100.000, 110.000, 130.000, 150.000, 180.000, 920.000, 970.000 and 980.000.
		Drugs	PG01: For Processing Code PHN updated IUC to mandatory and added IUC 110.000, 130.033, 155.000, 180.000, 920.000 and 970.000.For Processing Code PRE added IUC 110.000. For Processing Code OTC added IUC 110.000. PG23, Table 7-20: Added IUC 110.000, 130.033, 155.000, 180.000.
		Food: Stand-alone Prior Notice	PG01, Table 8-5: Updated CFSAN reference to FDA due to agency reorganization.
		Food: Combined Entry	PG01, Table 9-5: Updated CFSAN reference to FDA due to agency reorganization.
		Food: Non-PN Food or PN Requirements Previously Met	PG01: Updated IUC to mandatory for Processing Code CCW added table 10-5 with IUC 130.029, 970.000 and 980.000. Updated table 10-4 to indicate foods, PN previously met.
		Medical Devices	PG23: Updated table 11-18. Removed/Deleted Mandatory AOC “IFE” for IUC 170.000
		Animal Drugs and Devices	PG01:For Processing Code ADE updated IUC to mandatory and added table 14.5 with IUC 085.000. Removed differentiation for ADR and ADE in Note 3.
08/05/2024	**2.5.11**	**Appendix B**	Updated CFR References
		All	Updated all Stand-alone references to align with PE CATAIR.
		All	Updated all Industry Code, Class Code & Subclass references to align with FDA Product Code Builder
12/12/2023	**2.5.10**	**Food: Stand-alone Prior Notice**	PG02: Removed Subclass ‘Y’ for Industry Code 54 in the Prior Notice Requirements logic.
		Food: Combined Entry	PG02: Removed Subclass ‘Y’ for Industry Code 54 in the Prior Notice Requirements logic.
5/5/2023	**2.5.9**	**Food: Combined Entry & Non-PN Food or PN Requirements Previously Met**	PG25: Updated Lot Qualifer Number description to only allow Lot Number Qualifier 3 for Processing Code NSF
4/14/23	**2.5.8**	**DRU**	PG02: Clarified language for the Product Code Subclasses applicable to the various Industry Codes PG23, Table 7-20: Corrected Affirmation Code DLS for Intended Use Code 080.012 to make it conditional PG23, Table 7-18: Added clarifying information to REG to indicate AofC is optional for Government Agency Processing code 804
3/10/2023	**2.5.7**	**Food: Combined Entry & Non-PN Food or PN Requirements Previously Met**	PG01: Renumbered notes to align with Stand-alone Prior Notice Section.

Date	Version No.	Commodity	Description
		Radition Emitting Products	Section 13,Table 13-2: Updated 2877 requirements for Veterinary Therapy Utltrasonic Products and Medical Diagnostic X Ray Equipment
5/30/22	**2.5.6**	**All**	PG02: Corrected references to change Process Identification Code (PIC) to Process Indicator Code (PIC) in the product code structure and additional logic
		DRU	Section 4: Removed reference to indicate Industry Code 58 is for future use PG02: Corrected reference to PIC Code description in the logic for Industry Codes, dependent upon the Government Agency Processing Code PG02: Removed reference to indicate Industry Code 58 is for future use
		Food: Combined Entry	Section 9.1: Removed 'Required" from Data Elements Column to align with Food, Stand-alone Prior Notice Section
		Animal Drugs and Devices	Section 4: Added Industry Code 58 to VME Section
		Point of Contact	Updated FDA ACE Support hours and contact information
9/18/21	**2.5.5**	**All**	PG21: Clarified acceptable email format
		Food: Combined Entry	PG19: Clarified/standardized language for FSVP data requirements PG23: Updated list of optional Affirmations of Compliance to include REG, VFD and VFL
		Non-PN Food or PN Requirements Previously Met	PG19: Clarified/standardized language for FSVP data requirements PG23: Updated list of optional Affirmations of Compliance to include REG, VFD and VFL
		Animal Drugs and Devices	PG23: Updated Syntax for VFL to 7X PG23: Updated description for VFL
4/9/21	**2.5.4**	**All, Except Food: Stand-alone Prior Notice**	PG01: Disclaim Code F is now being accepted. Deleted note: "Disclaim code "F" will not be utilized/accepted until notification via a CSMS message"
		Food: Stand-alone Prior Notice	PG25: Updated list of applicable FDA Industry Codes for PICs: E (Commercially Sterile), F (Aseptic), and I (Acidified)
		Food: Combined Entry	PG23 & PG25: Updated list of applicable FDA Industry Codes for PICs: E (Commercially Sterile), F (Aseptic), and I (Acidified)
		Non-PN Food or PN Requirements Previously Met	PG23: Updated list of applicable FDA Industry Codes for PICs E: (Commercially Sterile), F (Aseptic), and I (Acidified)
1/29/21	**2.5.3**	**All**	Updated Section 1 to indicate that the FDA PGA Message Set, with the exception of Stand-alone Prior Notice (Section 8), must be submitted with an ACE Cargo Release or ACE Entry Summary certified for cargo release transaction. PGA Message Set Exmple Excel file: No content changes. Filename changed to remove version number.
1/29/21	**2.5.3**	**All, Except Food: Stand-alone Prior Notice**	PG01: Added new Disclaim Code "F", for use with FDA Entry Type 21 submissions

1 Introduction

This document is intended to provide supplementary instructions to the CBP Customs and Trade Automated Interface Requirements (CATAIR) and PGA Message Set chapter (also referred to as an implementation guide). The FDA PGA Message Set provides specific instructions for filing FDA-regulated commodities, and, with the exception of Stand-alone Prior Notice (Section 8), must be submitted with an ACE Cargo Release or ACE Entry Summary certified for cargo release transaction (see hyperlinks below for more information). Additional information on import submission requirements for FDA regulated products is available at https://www.fda.gov/industry/entry-submission-process/transmitting-required-information

CBP's ACE CATAIR Cargo Release Chapter is available at: https://www.cbp.gov/document/guidance/ace-catair-cargo-release-chapter

CBP;s ACE CATAIR Entry Summary Create/Update document is available at https://www.cbp.gov/document/technical-documentation/entry-summary-createupdate

The PGA Message Set chapter/implementation guide and its related CBP ACE CATAIR Appendix PGA are available at http://www.cbp.gov/document/guidance/appendix-pga

The ACE ABI CATAIR – CBP and Trade Automated Interface Requirements is available at http://www.cbp.gov/document/guidance/pga-message-set

CBP's ACE CATAIR Appendix V Government Agency Codes is available at http://www.cbp.gov/document/guidance/appendix-v-government-agency-codes

Appendix R Intended Use Codes for ACE are available at http://www.cbp.gov/document/guidance/appendix-r-intended-use-codes-ace

CBP's ACE CATAIR Appendix B Valid Codes are available at https://www.cbp.gov/document/guidance/appendix-b-valid-codes-0

CBP's ACE CATAIR Appendix C Tariff Abbreviations is available at http://www.cbp.gov/document/guidance/appendix-c-tariff-abbreviations

FDA ACE Affirmation of Compliance Codes is available at https://www.fda.gov/industry/entry-submission-process/affirmation-compliance-codes

1.1 FDA Overview

FDA is responsible for:

- Protecting the public health by assuring that foods (except for meat from livestock, poultry and some egg products which are regulated by the U.S. Department of Agriculture) are safe, wholesome, sanitary and properly labeled; ensuring that human and animal drugs, and vaccines and other biological products and medical devices intended for human use are safe and effective
- Protecting the public from electronic product radiation
- Assuring cosmetics and dietary supplements are safe and properly labeled
- Regulating tobacco products
- Advancing the public health by helping to speed product innovations

Primary responsibility for administering the nation's laws related to imports, exports, and collection of duties resides with the United States Customs and Border Protection (CBP). However, FDA is responsible for determining whether an article offered for importation complies or violates the acts enforced by FDA. This includes the responsibility to determine whether a violative article may be brought into compliance with appropriate statutes and/or regulations and authorize reconditioning to bring an article into compliance. CBP and FDA closely collaborate to fulfill their responsibilities.

1.2 Points of Contact

For technical questions about the content of this document, contact FDA's ACE Support, ACE_Support@fda.hhs.gov.
ACE Support Hours:

- Monday – Friday: 8AM-8PM ET (excluding Federal Holidays)

For additional questions or comments about this document or for data examples, contact:

Gayle Gehrman
Consumer Safety Officer
Food and Drug Administration (FDA)
718-662-5708
Gayle.Gehrman@fda.hhs.gov

2 Legend

2.1 Field Requirements

Abbreviation	Name	Description
M	Mandatory	The data element is required under all circumstances
C	Conditional	The data element is required under certain circumstances as defined by corresponding notes
O	Optional	The data element is not required under all circumstances

Table 2-1: Field Requirements Legend

2.2 Field Data Types

Abbreviation	Name	Description
A	Alpha	Letters A-Z
N	Numeric	Numbers 0-9
AN	Alphanumeric	Letters A-Z and Numbers 0-9
X	Alphanumeric and Special Characters	Letters A-Z, Numbers 0-9, special characters such as *, @, !, etc.

Table 2-2: Field Data Types Legend

3 Required (Mandatory and/or Conditional) Data Elements for FDA Commodities

Level of Data	Record ID	Data Element	Length/ Class	Position	Field Type
Line	PG01	PGA Line Number	3N	5-7	Incremental
Line	PG01	Government Agency Code	3AN	8-10	Code
Line	PG01	Government Agency Program Code	3X	11-13	Code
Line	PG01	Government Agency Processing Code	3AN	14-16	Code
Line	PG02	Item Type	1A	5	Code
Line	PG02	Product Code Qualifier	4AN	6-9	Code
Line	PG02	Product Code Number	19X	10-28	Text
Line	PG06	Source Type Code	3AN	5-7	Code
Line	PG06	Country Code	2X	8-9	Code
Line	PG10	Product Description	57X	24-80	Text
Line	PG19	Entity Role Code	3AN	5-7	Code
Line	PG19	Entity Name	32X	26-57	Text
Line	PG19	Entity Address 1	23X	58-80	Text
Line	PG20	Entity City	21X	42-62	Text
Line	PG20	Entity Country	2A	66-67	Code
Line	PG21	Individual Name	23X	8-30	Text
Line	PG21	Telephone Number of the Individual	15X	31-45	Text
Line	PG21	Email Address for the Individual	35X	46-80	Text
Line	PG30	Arrival Information Code	1A	5	Code
Line	PG30	Anticipated Arrival date	8N	6-13	Date
Line	PG30	Anticipated Arrival time	4N	14-17	Time

Table 3-1: Required Data Elements for FDA Commodities

4 FDA Commodities, Commodity Sub-Types, and Corresponding Industry Codes

PG01: Program Code & Commodity	PG01: Processing Code & Commodity Subtype	PG02: Industry Code
BIO - Biologic	ALG - Allergenics	57
	BLO - Blood & Blood Products	
	CGT - Cell and Gene Therapy	
	HCT - Human Cells & Tissue	
	VAC - Vaccines	
	XEN - Xenotransplants	
	BDP - Blood Derivatives	
	BBA - Blood Bag with anti-coagulant	
	BLD - Licensed Devices	
	PVE - Plasma Volume Expanders	
COS - Cosmetic	N/A	50 or 53
DRU – Drug*	PRE - Prescription	54, 56, 58,60, 61, 62, 63, 64, 65, or 66
	OTC - Over the Counter	
	RND - Research & Development	
	INV - Investigational	
	PHN - Pharmaceutical Necessities	55, various codes could apply
	804 – Section 804 Importation Program***	54, 56, 60, 61, 62, 63, 64, 65, or 66
VME - Animal Drug or Device*	ADR - Animal Drug	54, 56, 58, 60, 61, 62, 63, 64, 65, 66 or 67
	ADE - Animal Device	68
FOO – Food*	NSF - Natural State Food	02-05, 07, 09, 12-18, 20-42, 45-46, 50, 52, 54, 69, 70, 71 or 72
	PRO - Processed Food	
	FEE - Animal Feed	
	DSU - Dietary Supplement	
	ADD - Additives and Colors	
	CCW - Ceramicware or Food Contact Substance	52
DEV - Medical Device	NED - Non-Radiation Emitting Device	73-92
	RED - Radiation-Emitting Device	
RAD - Radiation-Emitting Products	REP - Non-Medical Radiation-Emitting Product	94-97
TOB - Tobacco	CSU - Consumer Use	98
	FFM - For further manufacturing	
	INV – Investigational	

Table 4-1: FDA Commodities, Commodity Sub-Types, and Corresponding Industry Codes

* Subject to additional rules based on FDA Program/Processing/Product codes. Refer to PG02 in individual chapters.

***Section 804 Importation Program is limited to a port authorized by FDA. At the time of implementation, the only port authorized by FDA is 3801 (Detroit).

5 Biologics Commodity Data Elements and Values

Biologics commodities are grouped into the following categories using the existing Government Agency data elements available in the PG01 message.

PG01 - Government Agency Code	Commodity Type	PG01 - Government Agency Program Code	Commodity Sub-Type	PG01 - Government Agency Processing Code
FDA	Biologics	BIO	Allergenics	ALG
FDA	Biologics	BIO	Blood Bag with Anti-coagulant	BBA
FDA	Biologics	BIO	Blood Derivatives	BDP
FDA	Biologics	BIO	Licensed Devices	BLD
FDA	Biologics	BIO	Blood and Blood Products	BLO
FDA	Biologics	BIO	Cell & Gene Therapy	CGT
FDA	Biologics	BIO	Human Cells & Tissue	HCT
FDA	Biologics	BIO	Plasma Volume Expanders	PVE
FDA	Biologics	BIO	Vaccines	VAC
FDA	Biologics	BIO	Xenotransplant	XEN

Table 5-1: Biologics Commodity Hierarchy

The following are the potential PGA records associated with Biologics data submission:

PG Record	Description
PG01	FDA program that regulates the product, and the intended use code
PG02	The Item Type and Product Code details
PG04	Product Constituent Active Ingredient
PG06	Product Source information
PG07	Trade/Brand Name
PG10	Product Description (Line level Item Common/Usual/Market Name Description)
PG19	Entity Role (manufacturer, consignee, shipper, etc.) Entity Identification, Entity Name, and Entity Address 1
PG20	Additional address data on the entity in PG19
PG21	Entity of Record's (manufacturer, shipper, etc.) individual point of contact, phone number and email.
PG23	FDA affirmation of Compliance criteria
PG24	Remarks
PG25	Temperature qualifier, Lot Number Qualifier, Lot Number, and PGA Line Value
PG26	Packaging qualifier and quantity of the shipment
PG27	Container number
PG30	Date, time and location of anticipated arrival information
PG55	Additional roles performed by entity or individual
PG60	Additional Information
PG00	Data Substitution

Table 5-2: Biologics PGA Records

5.1 Biologics Example

Biologic Message Set Layout for Sample

Refer to the external file: **FDA SG Example PG Message Sets** Tab: ***Biologics***

The required PGA Records and Data Elements are dependent on the selected agency program and processing code. For an expansive set of examples of FDA PGA Message Sets, refer to the above section.

5.2 Record Identifier PG01 (PGA Identifier)

Mandatory | Not Repeatable per PGA Line

This is a mandatory PGA input record that provides data pertaining to the PGA Line Number, Government Agency Code, Government Agency Program Code, Government Agency Processing Code, Intended Use Code, Intended Use Description, and Disclaimer.

Record Identifier PG01 (*PGA Identifier*)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description/Required Value**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"01"	
PGA Line Number	3N	5-7	M	Begin with "001" and sequentially increment the line number on subsequent PG01 records, if applicable.	
Government Agency Code	3AN	8-10	M	"FDA"	
Government Agency Program Code	3X	11-13	C	"BIO"	1, 2
Government Agency Processing Code	3AN	14-16	C	Allowed values for Biologics sub-types are: ALG, BBA, BDP, BLD, BLO, CGT, HCT, PVE, VAC, XEN	1, 2
Intended Use Code	16X	42-57	C	Refer to the Intended Use Codes table below for allowed values	3,4,5, 6
Intended Use Description	21X	58-78	O	N/A for FDA lines	
Correction Indicator	1X	79	O	For future use	
Disclaimer	1A	80	C	"A" (= product is not regulated by this agency) indicating that there is no agency declaration requirement. This field is left blank for no disclaimer. "F" indicating that the product is manufactured in any state of the US, the District of Columbia, or Puerto Rico and sourced directly to the warehouse without ever leaving the US. **May only be used for FDA on Entry Type 21**. No other codes are accepted	

Table 5-3: Biologics PG01

Note 1
Refer to Table 5-1 above for the commodity hierarchy for Biologics commodity.

Note 2
If the product is to be disclaimed, then the above data elements should be populated with value "FDA". Otherwise the Government Agency Program Code and Government Agency Processing Code are mandatory.

Note 3
Unless the line is disclaimed, Intended Use Code is mandatory.

Note 4

CBP publication, Appendix R - Intended Use Codes for ACE, provides general descriptions of all Intended Use Codes for all Partner Government Agencies (PGAs). For FDA regulated products, use the IUC descriptions as specified per commodity throughout this document. See Appendix E for a mapping of FDA IUC descriptions to CBP Appendix R IUC descriptions. Table 5-4 below shows the Intended Use Codes available for Government Agency Program Code BIO.

Note 5
For entries of human hematopoietic stem cell and reproductive tissue (BIO/HCT/ Product Code 57K and 57M), use Intended Use Code 082.000. Intended Use Code 082.000 is for the immediate use by authorized medical officials in the medical treatment of humans. However, several other Intended Use Codes could also be applicable (Refer to PG23 table for scenario-based use of the AoC codes).

Note 6
If after consultation with the importer, who should know the intended use of the product, the filer still ***does not know*** the intended use of the product, "UNK" may be used in lieu of an IUC. In most cases, the line will be subject to manual review, and may result in a request for documentation and/or additional information about the product as the product offered for import will be treated as a standard import. Ensure the IUC (reason for importation) is transmitted to avoid delays. As per the ACE Rule, if "UNK" is submitted as the IUC for the article, the ACE filer is still responsible for submitting the other required data elements in this rule that are applicable to that article, at the time of entry. In the future, if those other data elements are not submitted in ACE at the time of entry, the entry may be transmitted by ACE to FDA for admissibility review, but FDA may reject the entry. If FDA rejects an entry filing, the ACE filer will need to resubmit the entry with complete and accurate information.

Intended Use Code	CBP Intended Use Name	CBER Regulated Products Import Scenario
080.000	For Human Medical Use as a Non-Food Product under Controlled Distribution	CBER-regulated Final Product (includes licensed biological products, drugs or devices); ready for use
082.000	For Immediate use by authorized medical officials in the medical treatment of humans	Human Cells, tissues, and cellular and tissue based products (HCT/Ps) for implant, transplant, infusion, or transfer into a human recipient
970.000	For Immediate Re-Exportation	CBER-Import for Export (IFE) under the import for export provisions 801(d) (3), & 801(d) (4) of the FD&C Act.
180.016	For processing samples submitted to CBER for lot release testing.	CBER Product Sample for testing or lot release
150.007	For commercial processing as a Non-Food product; for processing into a pharmaceutical product.	Bulk Drug Substance or CBER product for processing into a pharmaceutical product.
155.000	For Commercial Assembly as a Non-Food Product	CBER product for further manufacture of a licensed biological product under a short supply agreement (21 CFR 601.22)
100.000	For private non-commercial use under the FDA personal importation policy (PIP)	Importation for Personal Use
140.000	For Charitable Organization Use as Non-Food Product. Ex: For improving living conditions during a natural disaster.	Standard import of a biological drug or device for non-commercial distribution in government and non-government organization support program
180.009	Biological or chemical for research and development into a pharmaceutical product	Biological or chemical for research and development into a pharmaceutical product – Investigational New Drugs (IND); clinical trials or other human/animal use

Intended Use Code	CBP Intended Use Name	CBER Regulated Products Import Scenario
180.000	For Research and Development as a Non-Food Product	Import of biologic for non-clinical research use only, bench testing, etc. These entries could be disclaimed if the HTS code allows it.
110.000	For Public Exhibition or Display as a Non-Food Product	Import of biological drug or device for trade show
170.000	For repair of a Non-Food Product	For reconditioning or repair of a Non-Food. Product
940.000	Import of a Compassionate Use/Emergency Use Device	Importation of a drug (including a biological product) or device for compassionate use/emergency use
920.000	For return to the US	US Goods Returned

Table 5-4: Biologics Intended Use Codes

5.3 Record Identifier PG02 (Product Identifier)

Mandatory | Not Repeatable per PGA Line

This mandatory PGA input record is used to include information related to a product (P).

Record Identifier PG02 (Product Identifier)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"02"	
Item Type	1A	5	M	Code identifying the following records as pertaining to the product. Enter P for product. No other values are allowed. Only one "P" record is allowed for the same PGA Line # in PG01.	
Product Code Qualifier	4AN	6-9	M	"FDP" (FDA Product)	
Product Code Number	19X	10-28	M	FDA Product Code must be exactly 7 characters	

Table 5-5: Biologics PG02

Product Code Qualifiers and their descriptions can be found in CBP's ACE CATAIR Appendix PGA (PG02 – Product Code Qualifiers). For FDA filings, the Product Code Qualifier is always "FDP".
Only one FDA Product Code Number is allowed per line.

FDA Product Code Structure

Position	1-2	3	4	5	6-7
Name	Industry Code (N)	Class Code (AN)	Subclass Code (A or '-')	Process Indicator Code - PIC (A or '-')	Product (AN)

Legend - N: Numeric; A: Alphabetic; AN: Alphanumeric

Table 5-6: Biologics FDA Product Code Structure

*** Edit to limit Industry Codes, dependent upon the Government Agency Program Code ***

IF Government Agency Program Code = "BIO"
THEN Industry Code = 57

5.4 Record Identifier PG04 (Product Constituent Element)

Optional | Repeatable per PGA Line

This is an optional PGA input record that provides data pertaining to Constituent Active Ingredient Qualifier, Name of the Constituent Element, Quantity of Constituent Element, Unit of Measure, and Percent of Constituent Element for the product identified by Product Code Number in PG02. This record can be repeated.

If opting to transmit this record, Name of the Constituent Element, Quantity, and either Unit of Measure or Percent are required. i.e., the record must be sent with complete information.

Refer to Appendix C: Sample use of PG04 – Product Constituent Element for an example of how PG04 can be used at the Product-level for multiple Constituent Elements.

Record Identifier PG04 (Product Constituent Element)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"04"	
Constituent Active Ingredient Qualifier	1A	5	O	Active ingredient = "*Y*" if yes, blank if no.	1
Name of the Constituent Element	51X	6-56	O		1
Quantity of Constituent Element	12N	57-68	O	2 decimal places are implied. Example: 000000000400	1
Unit of Measure (Constituent Element)	5AN	69-73	O		1
Percent of Constituent Element	7N	74-80	O	4 decimal places are implied. 18.2% is entered as 0182000.	1, 2

Table 5-7: Biologics PG04

Note 1
Some of the Biologics products may not have a defined active ingredient. Even when an active ingredient is known, it may be in a descriptive form. For example, the multiple active ingredients in the MMR Vaccine are expressed in detail in the Prescribing information.

Note 2
Examples of Percentages:

1000000	=	100%
0990000	=	99%
0090000	=	9%
0009000	=	.9%
0000900	=	.09%
0000090	=	.009%
0000009	=	.0009%

5.5 Record Identifier PG06 (Product Origin)

Mandatory |Repeatable per PGA Line

This is a mandatory PGA input record that provides data pertaining to Source Type (Origin) - other than the CBP Country of Origin - for the product identified by Product Code Number in PG02.

Currently, FDA processes PG06-PG07-PG10 records only at the Product-level (when under a PG02).

Record Identifier PG06 (Product Origin)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"06"	
Source Type Code	3AN	5-7	M	Mandatory value is 39 (Country of Production) or 30 (Country of Source). Code 294 may be used to indicate a country has previously refused the line item.	1
Country Code	2X	8-9	M	Country of Production or Source is required for Biologics.	2

Table 5-8: Biologics PG06

Note 1
Source Type Codes and their descriptions can be found in CBP's ACE CATAIR Appendix PGA (PG06 – Source Type Codes).

Note 2
Any of the country codes from CBP's ACE CATAIR Appendix B (Section: Country and Currency Codes) can be entered.

5.6 Record Identifier PG07 (Product Trade Names)

Conditional |Not Repeatable per PGA Line

This is a conditional PGA input record that provides data pertaining to Trade or Brand Name of the product identified by Product Code Number in PG02.

Currently, FDA processes PG06-PG07-PG10 records only at the Product-level (when under a PG02).

Record Identifier PG07 (Product Trade Names)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"07"	
Trade Name/Brand Name	35X	5-39	C	The make of the product by manufacturer or distributor from the label or invoice. For Government Agency Processing Codes ALG, BDP, BLD, BLO, CGT, VAC, XEN, BBA or PVE, Trade Name/Brand Name or Proper Name must be transmitted if it exists. If Government Agency Processing Code = HCT then Trade Name/Brand Name/Proper Name is optional. If Trade/Brand Name requires additional space, continue in a PG60 record with Qualifier Code "TBN".	1,2,3, 4

Table 5-9: Biologics PG07

Note 1
Per 21CFR600.3(k), Proper Name, as applied to a product means the name designated in the license, for use upon each package of the product.

Note 2
Government Agency Processing Codes ALG, BDP, BLD, BLO, CGT, VAC or XEN apply to CBER regulated licensed biological products.

Note 3
Government Agency Processing Codes BBA or PVE apply to drug products regulated by CBER (NDA and ANDA under 505 of the FD&C Act).

Note 4
Government Agency Processing Code HCT applies to Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps) that do not have a Trade Name or Proper Name. Trade Name/Brand Name is optional. Providing description would aid in facilitating the entry admissibility decision.

5.7 Record Identifier PG10 (Product Characteristics)

Mandatory | Not Repeatable per PGA Line

This is a mandatory PGA input record that allows for reporting the description of the product identified by the Product Code in PG02.

Currently, FDA processes PG06-PG07-PG10 records only at the Product-level (when under a PG02).

Record Identifier PG10 (Product Characteristics)					
Data Element	**Length/Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"10"	
Commodity Characteristic Description	57X	24-80	M	Common, market, usual name; free form invoice description; not product code description. For examples, see Appendix A: Use of PG10 Record	

Table 5-10: Biologics PG10

5.8 Record Identifier PG19 (Entity Data)

Mandatory | Repeatable per PGA Line

This is a mandatory PGA input record that provides data pertaining to Entity Role, Entity Name, and Entity Address 1.

Entity Identification Code [16 (DUNS #), 47 (FEI #)] and Entity number are optional data elements. They are listed as conditional because if opting to transmit Entity Identification Code, then Entity Number must also be provided, and vice versa.

Record Identifier PG19 (Entity Data)					
Data Element	**Length/Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"19"	
Entity Role Code	3AN	5-7	M	Code identifying the role of the entity. For example, MF. Each entity role code can only be transmitted once per PGA line.	1
Entity Identification Code	3AN	8-10	C	Code identifying the Entity Identification. For example: 16 (DUNS #), 47 (FEI#). Mandatory, if Entity Number is entered.	2
Entity Number	15X	11-25	C	Identifying Number (DUNS or FEI) for the associated Entity Identification Code. Mandatory if Entity Identification Code is provided	2
Entity Name	32X	26-57	M	The name of the entity is required. If Entity Name requires additional space, continue in a PG60 record with Qualifier Code "ENA". Refer to validation criteria below.	
Entity Address 1	23X	58-80	M	The address of the entity is required. If Entity Address1 requires additional space, continue in a PG60 record with Qualifier Code "AD1".	

Table 5-11: Biologics PG19

Note 1
List of Entity Role codes that are mandatory to FDA Message Set is noted below. One of each of these is mandatory for every line.

Data Element	**Code**	**Description**
Entity Role Codes	MF	Manufacturer of goods
	DEQ	Shipper
	FD1	FDA Importer (Importer of Record)
	DP	Delivered-To Party

Table 5-12: Biologics Entity Role Codes (Mandatory)

List of Entity Role codes that are **optional** to FDA Message Sets are noted below:

Data Element	**Code**	**Description**
Entity Role Codes	PK	Point of Contact (Filer/Broker Contact Information)

Table 5-13: Biologics Entity Role Codes (Optional)

Note 2
Entity Identification Code and Entity Number are optional. However, if opting to transmit an Entity Identification Code, Entity Number must also be provided and vice versa. List of Entity Identification codes applicable to FDA Biologics Message Sets is noted below:

Data Element	Code	Description	Length/ Class
Entity Identification Codes	16	D&B-assigned (DUNS number); must be 9 digits	9N
	47	FDA-assigned (FEI number); must be from 1 to 10 digits	1 -10N

Table 5-14: Biologics Entity Identification Codes

FDA ENTITY IDENTIFICATION CODE AND ENTITY NUMBER SELECTION AND VALIDATION CRITERIA

FDA/CBER prefer the transmission of an FEI number for identifying the entities required to register. The Facility FEI (FDA Establishment Identifier) number is assigned by FDA when the establishment registers with CBER and is made publicly available which is accessible using the links below. If the FEI is unavailable, then the DUNS number may be provided.

Links to FEI numbers for blood establishments can be found in the publicly available Blood Establishment Registration (BER) Database; For HCT/Ps, FEI numbers can be found in the publicly available Human Cell and Tissue Establishment Registration Public Query.

IF Entity Identification Code =16 (DUNS) THEN Entity Number must be Length = 9 and Type = N
ELSE IF Entity Identification Code =47 (FEI) THEN Entity Number must be Length from 1 to 10 and Type = N

5.9 Record Identifier PG20 (Entity Address)

Mandatory | Repeatable per PGA Line

This is a mandatory PGA input record that provides additional data pertaining to Entity identification such as Entity Address line 2, Apartment/Suite, City, State, and Zip/Postal Code. This record is used to transmit additional address information of an entity.

Record Identifier PG20 (Entity Address)					
Data Element	**Length/Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"20"	
Entity Address 2	32X	5-36	C	Address Line 2 of the entity. If an Entity Address2 requires additional space, continue in a PG60 record with Qualifier Code "AD2".	1
Entity Apartment Number/Suite Number	5X	37-41	C	Apartment/Suite number of the entity.	
Entity City	21X	42-62	M	City of the entity. If an Entity City requires additional space, continue in a PG60 record with Qualifier Code "ECI".	
Entity State/Province	3AN	63-65	C	Refer to CBP's ACE CATAIR Appendix B for valid codes.	2
Entity Country	2A	66-67	M	Refer to CBP's ACE CATAIR Appendix B for valid codes.	
Entity Zip/Postal Code	9X	68-76	C	Zip/Postal Code of the entity.	2
Filler	4X	77-80	M	Space fill	

Table 5-15: Biologics PG20

Note 1
If the Entity requires more than 2 address lines, use the optional PG60 records with Qualifier Codes "AD3", "AD4" and "AD5" immediately under the PG20 record for the same Entity.

Note 2
Required for US or Canada based entities.

5.10 Record Identifier PG21 (Point of Contact)

Mandatory | Repeatable per PGA Line

This is a mandatory PGA input record that provides point of contact information.

For each FDA line, at least one PG21 is required with the individual qualifier "FD1" (sent with the preceding PG19 and PG20 FD1 record).

FDA highly encourages the transmission of PG21 with the individual qualifier "PK" which should be the point of contact of the filer/broker. "PK" may be sent in one of the following ways:

1) Under a PG19PK (transmitting PG19PK, PG20PK and PG21PK for the filer), the FDA preferred method, **OR**
2) As a secondary PG21 to FD1 using individual qualifier "PK" (transmitting PG19FD1, PG20FD1, PG21FD1, and PG21PK for the filer), **OR**
3) Under any other required PG19 entity if "PK" is the individual qualifier in PG21

If provided, there should be only one PK per FDA line.

Although the PK (filer/broker contact information) is optional, transmitting this information will enable FDA to expeditiously contact the filer, instead of contacting the Importer of Record. If only the Importer of Record PG21 is transmitted without PK, FDA processing may be delayed.

Record Identifier PG21 (Point of Contact)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"21"	
Individual Qualifier	3AN	5-7	M	Identify the type of party or facility the Individual represents. Only "FD1" and "PK" are allowed values.	
Individual Name	23X	8-30	M	Name of the Individual. If the name exceeds the length, continue in a PG60 record with Qualifier Code "INA".	
Telephone Number of the Individual	15X	31-45	M	Telephone number of the Individual. For example, (713)555-8765 in US or (+65)9052-3529 in Singapore	
Email Address for the Individual	35X	46-80	M	Email Address of the individual. If the Email Address exceeds the length, continue in a PG60 record with Qualifier Code "EMA".	1

Table 5-16: Biologics PG21

Note 1
Only transmit one valid email address as you would in an email program. Do not include names, additional characters, etc.

Valid Example	first.last@company.com
Invalid Example	<first.last@company.com>
Invalid Example	FirstName LastName first.last@company.com
Invalid Example	FirstName LastName <first.last@company.com>
Invalid Example	first.last@company.com, first.last@company.com

5.11 Record Identifier PG23 (Affirmation of Compliance)

Conditional | Repeatable per PGA Line

This is a conditional PGA input record that provides data pertaining to FDA Affirmation of Compliance Criteria. This record is repeatable, but each affirmation of compliance code can only be transmitted once.

Record Identifier PG23 (Affirmation of Compliance)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"23"	
Affirmation of Compliance Code	5X	5-9	C	A code used to affirm compliance with FDA requirements. Refer to CBP's ACE CATAIR Appendix PGA (Food & Drug Affirmation of Compliance Codes) for valid codes.	1
Affirmation of Compliance Qualifier	30X	10-39	C	Text describing the information required by the FDA. For AoC codes with "no qualifier code", this field is left blank. All other qualifiers must follow the syntax instructions for each code as specified in CBP's ACE CATAIR Appendix PGA.	
Filler	1X	80	C	Space fill	

Table 5-17: Biologics PG23

Note 1
Below is the list of Affirmation of Compliance codes for FDA-Biologics Message Sets, followed by the scenarios when the AoCs are provided: N= Numeric Digits; X = Alphanumeric including special characters.

AoC Code	**Description**	**Syntax**
DA	Biologics New Drug Application Number or Abbreviated New Drug Application Number (NDA or ANDA)	BA+4-6N or BN + 5-6 N or 6N
HRN	Biologics Human Cells, Tissues/ Cellular and Tissue-Based Product Establishment Registration Number (HCT/P Registration Numbers)	10N
IND	Biologics Investigation New Drug Application Number	4-6N (No Leading Zeros for CBER IND)
HCT	Human Cells & Tissue	Indicator only
BLN	Biologics License Number	4N
STN	Biologics Submission Tracking Number	6N
CPT	Component Identifier	Indicator only
IFE	Import For Export	Indicator only
REG	Drug Registration Number	4-10N
DLS	Drug Listing Number	10N

Table 5-18: Biologics AoC Codes

Scenario based use of the above AoC codes:

#	Government Agency Processing Codes for BIO	CBER Regulated Products Import Scenario	Intended Use Codes§	CBP Intended Use Name	Mandatory	Optional
1	ALG, BBA, BDP, BLD, CGT, PVE, VAC, BLD or XEN	Biological or chemical for research and development into a pharmaceutical product – Investigational New Drugs (IND); clinical trials or other human/animal use	180.009	For Research and Development of a pharmaceutical product	IND	REG
2	ALG, BDP, BLD, BLO, CGT, VAC, or XEN	CBER-regulated Final product; ready for use. Importation of a licensed biological product. The Biologics License number (BLN) is the U.S. License Number. The Submission Tracking Number (STN) is associated with the manufacturer and a specific product and the first six digits represent the original submission tracking number.	080.000	For Human Medical Use as a Non-Food Product under Controlled Distribution	BLN or STN or both	REG, DLS
3	BBA, PVE	CBER-regulated Final product; ready for use. Importation of drug regulated by CBER.	080.000	For Human Medical Use as a Non-Food Product under Controlled Distribution	DA, REG, (DA includes NDA and ANDAs only)	DLS
4	HCT	Human Cells, tissues, and cellular and tissue based products (HCT/Ps) for implant, transplant, infusion, or transfer into a human recipient. The HCT affirmation should be used to indicate the HCT/Ps being importer or offered for import in compliance with all applicable requirements of 21 CFR 1271.	082.000	For Immediate use by authorized medical officials in the medical treatment of humans	HCT (No Qualifier Needed for HCT)	
5	HCT	Human Cells, tissues, and cellular and tissue based products (HCT/Ps) for implant, transplant, infusion, or transfer into a human recipient. The HRN Affirmation should be used for Importation of human cells, tissues and cellular and tissue-based product where the establishment is registered with the FDA.	082.000	For Immediate use by authorized medical officials in the medical treatment of humans	HRN	HCT
6	ALG, BDP, BLD, BLO,	CBER Product sample for testing or lot release	180.016	For processing	BLN or STN or both	REG, DLS

#	Government Agency Processing Codes for BIO	CBER Regulated Products Import Scenario	Intended Use Codes§	CBP Intended Use Name	Mandatory	Optional
	CGT, VAC, or XEN			samples submitted to CBER for lot release testing.		
7	ALG, BLO, BLD, BDP, VAC, XEN, or CGT.	CBER product for further manufacture of a licensed biological product under a short supply agreement (21 CFR 601.22)*****	155.000	For processing into a pharmaceuti cal product	BLN or STN or both	REG, DLS
8	ALG, BBA, BDP, BLD, BLO, CGT, PVE, VAC, or XEN	Importation for personal use	100.000	For private non-commercial use under the FDA Personal importation policy (PIP)		
9a	ALG, BDP, BLD, BLO, CGT, VAC, or XEN	Bulk biological drug substance for processing into a pharmaceutical product	150.007	For commercial processing as a non-food product; for processing into a pharmaceuti cal product.	BLN or STN or both	IND, REG, DLS
9b	BBA or PVE	Bulk drug substance for processing into a pharmaceutical product	150.007	For commercial processing as a non-food product; for processing into a pharmaceuti cal product.	DA	IND, REG, DLS
10	ALG, BBA, BDP, BLD, BLO, CGT, PVE, VAC, or XEN	Standard import of a biological drug or device for non-commercial distribution in government and non-government support program.	140.000*	For improving living conditions during a natural disaster.		BLN, STN, DA, IND
11	ALG, BBA, BDP, BLD, BLO, CGT, PVE, VAC, or XEN	Import of a biological drug or device for trade show	110.000*	For public exhibition or display as a non-food product.		BLN, STN, DA, IND
12	ALG, BBA, BDP, BLD, BLO, CGT, HCT, PVE, VAC, or XEN	For reconditioning or repair of a non-food product	170.000*	For repair of a non-food product.		BLN, STN, DA, IND, HCT, HRN,

#	Government Agency Processing Codes for BIO	CBER Regulated Products Import Scenario	Intended Use Codes§	CBP Intended Use Name	Mandatory	Optional
13	ALG, BBA, BDP, BLD, BLO, CGT, PVE, VAC, or XEN	Importation of non-compliant articles (including blood, blood components, source plasma and source leukocytes) under the import for export provisions 801(d) (3), & 801(d) (4) of the FD&C Act.	970.000*	Import for Export	IFE (No qualifier required)	
14	BLO, ALG, BBA, BDP, BLD, CGT, HCT, PVE, VAC, or XEN	Import of a biologic for non-clinical research use only, bench testing, etc. These entries could be disclaimed if the HTS code allows it.	180.000	For Research and Development as a Non-food product.		
15	ALG, BLO, CGT, HCT, VAC, XEN, BDP, BLD, BBA, PVE	Importation of a drug (including a biological product) or device for compassionate use/emergency use	940.000*	Compassionate Use/Emergency Device		BLN, STN, DA, IND, HCT, HRN
16	ALG, BLO, CGT, HCT, VAC, XEN, BDP, BLD, BBA, PVE	Import of US Goods Returned	920.000	For return to the United States (US Goods Returned).		

Table 5-19: Biologics Scenario Bases use of AoC Codes

§ If after consultation with the importer, who should know the intended use of the product, the filer still ***does not know*** the intended use of the product, "UNK" may be used in lieu of an IUC. In most cases, the line will be subject to manual review, and may result in a request for documentation and/or additional information about the product as the product offered for import will be treated as a standard import. Ensure the IUC (reason for importation) is transmitted to avoid delays. As per the ACE Rule, if "UNK" is submitted as the IUC for the article, the ACE filer is still responsible for submitting the other required data elements in this rule that are applicable to that article, at the time of entry. In the future, if those other data elements are not submitted in ACE at the time of entry, the entry may be transmitted by ACE to FDA for admissibility review, but FDA may reject the entry. If FDA rejects an entry filing, the ACE filer will need to resubmit the entry with complete and accurate information.

Note
The Government Agency Processing Code BRD, the corresponding Intended Use Code, and Affirmation of Compliance Codes (PM# and IDE) have been removed from the Biologics Commodity Data Elements and Values section. These devices will be handled using the Medical Device Commodity Data Elements and Values in the ACE/ITDS environment.

The list of AoC codes that are **optional** to FDA Message Sets is noted below:

Data Element	Code	Description	Syntax	Business Rules
AoC Code	ERR	Entry Review Requested	indicator only	ERR is just used as an indicator, no data will follow

Table 5-20: Biologics AoC Codes (Optional)

5.12 Record Identifier PG24 (Remarks)

Optional | Not Repeatable per PGA Line

This is an optional PGA input record that provides data pertaining to Remarks Type Code and Remarks Text.

PG24 cannot be repeated and only one PG24 is allowed for the same FDA line.

If entered, the GEN is the only allowed value for Remarks Type Code under the PG02.

Currently, FDA processes PG24 record only at the Product-level (when under a PG02).

Record Identifier PG24 (Remarks)					
Data Element	**Length/Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"24"	
Remarks Type Code	3X	5-7	O	FDA uses only "GEN" as its valid value.	
Remarks Text	68X	13-80	O	Free form text relevant to the shipment or the commodity.	

Table 5-21: Biologics PG24

5.13 Record Identifier PG25 (Product Condition)

Optional | Repeatable per PGA Line

This is an optional PGA input record that provides data pertaining to Temperature Qualifier, Lot Number, and PGA Line Value. This record is repeatable for multiple Lot Numbers. If transmitting a line value, the PGA Line Value must be included on the first PG25 record.

Record Identifier PG25 (Product Condition)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"25"	
Temperature Qualifier	1A	5	O	Temperature Category for quality control or preservation purposes. A=Ambient, F=Frozen R=Refrigerated/Chilled, D=Dry Ice H=Fresh, U=Uncontrolled P=Flashpoint	
Lot Number Qualifier	1N	15	O	Code of the entity that assigned the Lot number. The only valid value is: 1=Manufacturer In the case of multiple PG25 records for a given FDA line, enter Lot Number Qualifier only in the first PG25 record.	
Lot Number	25X	16-40	O	The lot number that the manufacturer assigned to the product.	
PGA Line Value	12N	57-68	O	Although Line Value is optional, transmitting the value will assist in product review in a timely manner. Failure to transmit the value may result in delays associated with gathering the missing information. If entered: • in the case of multiple PG25 records, enter value only in the first PG25 record • value should be in US Dollars, and enter whole dollars only • must be greater than zero and be right justified with preceding zeros.	

Table 5-22: Biologics PG25

5.14 Record Identifier PG26 (Product Packaging)

Optional | Repeatable per PGA Line

This is an optional PGA Record that provides data pertaining to Packaging Qualifier, Quantity, and Unit of Measure. If included, the following rules apply:

This record can be repeated up to six times per unique package size. The first record is used to describe the largest container (outermost container) and the number of containers. The second record is used to describe the contents of the next smallest container. If needed, records 2-6 are used in a similar manner (largest to smallest container). The last quantity record used must describe the actual amount of the product in the smallest container and should be a code from the table of base units listed below.

When reporting a different package size of the same product, repeat this record using the method described above.

The appearance of any 'Packaging Qualifier' number level requires all levels under it to be represented. For instance, level 3 cannot be present without levels 1 and 2. The same unit of measure cannot be used multiple times on the same PGA line. Although product packaging is an optional data element, the record is listed as conditional because if opting to transmit the PG26 data, all positions must be sent (Control Identifier, Record Type, Packaging Qualifier, Quantity, and Unit of Measure).

Record Identifier PG26 (Product Packaging)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"26"	
Packaging Qualifier	1N	5	C	This code identifies the level of packaging for the product. Outermost (largest=1) packages to the innermost (smallest=6) packages. Maximum of 6 levels of packaging are allowed. If reporting only one level, show the total quantity for the item and report that as level 1.	1,4
Quantity	12N	6-17	C	Although quantity is optional, transmitting the quantity accurately and following the rules below will assist in reviewing the product in a timely manner. Failure to transmit the quantity records may result in delays associated with gathering missing information. If entered, this is the total quantity for the packaging level. Must be greater than zero. Two decimal places are implied. Example: 000000000400 The base quantity must always be the last quantity transmitted. **Transmitting Quantity requires transmitting Packaging Qualifier and the Unit of Measure. Last unit transmitted must be a base unit and only one base unit is allowed.**	2,4
Unit of Measure (Packaging Level)	5X	18-22	C	Type of packaging / packaging level. For example, BX. Cannot be repeated among the PG26 records.	3,4

Table 5-23: Biologics PG26

Note 1

This code identifies the level of packaging for the product. Valid values are 1, 2, 3, 4, 5 and 6: Outermost (largest=1) packages to the innermost (smallest=6) packages. There can be up to 6 levels of packaging.

Note 2
There are two implied decimal points when writing the quantity in Units of Measure for all packaging levels. For example, 4 pieces are represented as 000000000400, with the nine leading zeroes as "fill" and two decimal places following the value.

Note 3
List of Unit of Measure codes applicable to FDA-Biologics Message Sets are noted below:
FDA Units of Measure (UoM) for the Packaging Containers and Base Unit (Last Quantity Transmitted) that apply to Biologics are listed below:

Valid FDA/CBER - Units of Measure for Packaging Containers	
Code	**Description**
AE	Aerosol
AM	Ampoule, Nonprotected
AP	Ampoule, Protected
AT	Atomizer
BA	Barrel
BC	Bottle crate, Bottle rack
BG	Bag
BO	Bottle, Non-Protected, Cyl
BQ	Bottle, Protected, Cylindrical
BS	Bottle, Nonprotected, Bulbous
BV	Bottle, Protected Bulbous
BX	Box
CA	Can, Rectangular
CI	Canister
CON	Container
CS	Case
CT	Carton
CX	Can, Cylindrical
CY	Cylinder
DR	Drum
EN	Envelope
FD	Framed Crate
GB	Gas Bottle
MB	Bag, Multi-ply
PAL	Pallet
PC	Parcel
PK	Package
SY	Syringe
VI	Vial
TU	Tube
VP	Vacuum Packed
VL	Bulk Liquid

Table 5-24: Biologics UoM for Packaging Containers

Note: Last unit of measure transmitted must be a Base Unit and only one base unit is allowed.

Valid FDA/CBER - Units of Measure for the Base Unit (Last Quantity Transmitted)		
Code	**Description**	**Measure Type**
AU	Allergy Units (ml or tablet)	Dosage
BAU	Bioequivalent Allergy Units (ml or tablet)	Dosage
CAP	Capsule	Dosage
CG	Centigrams	Weight
FOZ	Ounces, fluid	Volume
G	Grams	Weight
GAL	Gallons (US)	Volume
KG	Kilograms	Weight
L	Liters	Volume
LB	Pounds (avdp)	Weight
MG	Milligrams	Weight
ML	Milliliters	Volume
MCG	Micrograms	Weight
NO	Number	Count
OZ	Ounces, weight (avdp)	Weight
PCS	Pieces	Count
PNU	Protein Nitrogen Units	Dosage
PTL	Pints, liquid (US)	Volume
QTL	Quarts, liquid (US)	Volume
TAB	Tablets	Dosage

Table 5-25: Valid FDA/CBER UoM for Base Unit

Note 4

Quantity data provides additional information to FDA about the product and how it is packaged. The basic format for Quantity data is in multiple pairs of data; quantity and unit of measure, i.e., 500 cases, 12 ounces, fluid, 1000 cartons, etc. Up to 6 data pairs may be submitted, beginning with the 1st pair for the outermost packaging when Packaging Qualifier = 1. The first pair may describe the largest container and the last pair must describe the amount of product in the smallest container.

For example: Blood Derivatives: 25 boxes, 8 bottles/box, 1pint each bottle:

Units 1-Quantity= 25
Units 1-Measure =BX
Units 2-Quantity=8
Units 2-Measure=BO
Units 3-Quantity=1
Units 3-Measure=PTL (Note: last unit of measure transmitted must be a base unit).

5.15 Record Identifier PG27 (Shipping Container Information)

Optional | Repeatable per PGA Line

This is an optional PGA input record that provides data pertaining to the shipping Container Number. This record may be repeated.

Record Identifier PG27 (Container Information)					
Data Element	**Length/Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"27"	
Container Number (Equipment ID)	20AN	5-24	O	The number of the shipping container.	
Container Number (Equipment ID)	20AN	28-47	O	The number of the shipping container.	
Container Number (Equipment ID)	20AN	51-70	O	The number of the shipping container.	
Filler	7X	74-80	O	Space fill	

Table 5-26: Biologics PG27

5.16 Record Identifier PG30 (Anticipated Arrival Information)

Mandatory | Repeatable per PGA Line

This is a mandatory PGA input record that provides data pertaining to the date, time, and location of the anticipated arrival/entry information for all FDA products.

For each line a PG30 record with an "A" (Anticipated arrival information) status code, date and time of arrival is mandatory. For entry type 21 coming from a Foreign Trade Zone, a PG30 record with an "F" (Foreign Trade Zone) code and FIRMS code for the FTZ location is required.

Record Identifier PG30 (Anticipated Arrival Information)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"30"	
Anticipated Arrival Information	1A	5	M	A (Anticipated arrival information). If entry type = 21, then repeat PG30 and enter F (Foreign Trade Zone)	1, 2
Anticipated Arrival Date at Port of Entry	8N	6-13	C	A numeric date in MMDDCCYY (month, day, century, year) format. **Mandatory if Status = "A".**	1, 2
Anticipated Arrival Time at Port of Entry	4N	14-17	C	Military time HHMM in (hour, minute) format. (Example: 1015, this represents 10:15 a.m.). For midnight, use 2400 (0000 is invalid). **Mandatory if Status = "A**".	1, 2
Inspection or Arrival Location Code	4AN	18-21	C	Only a value of "4" (=FIRMS Code) is allowed for entry type = 21. For entry type not = 21, this field is left blank.	
Inspection or Arrival Location	50X	22-71	C	Provide FIRMS code here. For valid FIRMS codes, refer to ACS/ACE query. https://www.cbp.gov/document/report/acs-public-firms-code-report	
Filler	8X	72-80	M	Space fill	

Table 5-27: Biologics PG30

Note 1
A= Anticipated Arrival Date and Time at the Anticipated Port of Entry.

Port of Entry:
19 CFR 101.1.
Port and port of entry. The terms "port" and "port of entry" refer to any place designated by Executive Order of the President, by order of the Secretary of the Treasury, or by Act of Congress, at which a Customs officer is authorized to accept entries of merchandise to collect duties, and to enforce the various provisions of the Customs and navigation laws. The terms "port" and "port of entry" incorporate the geographical area under the jurisdiction of a port director. (The Customs ports in the Virgin Islands, although under the jurisdiction of the Secretary of the Treasury, have their own Customs laws (48 U.S.C. 1406(i)). These ports, therefore, are outside the Customs territory of the United States and the ports thereof are not "ports of entry" within the meaning of these regulations).

Note 2
Examples on how to submit PG30:

For all Entry Types other than Entry Type 21 Warehouse for an FTZ Withdrawal	**For Entry Type 21 Warehouse for an FTZ Withdrawal**
PG30 Record • Anticipated Arrival Information status code = "A" (anticipated arrival information) is mandatory • Anticipated Arrival Date at Port of Entry is mandatory • Anticipated Arrival Time at Port of Entry is mandatory	PG30 Record • Anticipated Arrival Information status code = "A" (anticipated arrival information) is mandatory • Anticipated Arrival Date at Port of Entry is mandatory • Anticipated Arrival Time at Port of Entry is mandatory Additional PG30 Record • Anticipated Arrival Information status code = "F" (FTZ) is mandatory • Anticipated Arrival Date at Port of Entry is optional • Anticipated Arrival Time at Port of Entry is optional • Inspection or Arrival Location Code = "4" (FIRMS Code) is mandatory • FTZ Location is mandatory

5.17 Record Identifier PG55 (Additional Entity Roles)

This is an optional PGA input record used to provide additional roles performed by an entity or individual.

Not supported by FDA at this time

Currently, the PG55 record is not supported by FDA. Multiple PG19 records should be used to input more than one Entity-Role combination. Refer to the PG19 section for details.

Record Identifier PG55 (Additional Entity Roles)					
Data Element	**Length/Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"55"	
Entity Role Code	3AN	5-7	O	Additional role of the entity	
Entity Role Code	3AN	8-10	O	Additional role of the entity	
Entity Role Code	3AN	11-13	O	Additional role of the entity	
Entity Role Code	3AN	14-16	O	Additional role of the entity	
Entity Role Code	3AN	17-19	O	Additional role of the entity	
Entity Role Code	3AN	20-22	O	Additional role of the entity	
Entity Role Code	3AN	23-25	O	Additional role of the entity	
Entity Role Code	3AN	26-28	O	Additional role of the entity	
Entity Role Code	3AN	29-31	O	Additional role of the entity	
Entity Role Code	3AN	32-34	O	Additional role of the entity	
Filler	8X	72-80	M	Space fill	

Table 5-28: Biologics PG55

5.18 Record Identifier PG60 (Additional Information)

Optional | Repeatable per PGA Line

This is an optional PGA input record used to provide additional information about data in the PG record that precedes it during the submission of a PGA record set.

This record can follow a PG07, PG19, PG20 or PG21 record, and can only be used to provide the additional information noted by the Additional Information Qualifier Code list.

This record may be repeated.

Record Identifier PG60 (Additional Information)					
Data Element	**Length/Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"60"	
Additional information qualifier code	3AN	5-7	C	Code indicating the type of additional information being provided	1
Additional Information	73X	8-80	C	Text of the additional information related to the additional reference qualifier code	

Table 5-29: Biologics PG60

Note 1
Valid PG60 Additional Information Qualifier Codes applicable to FDA Message Sets are listed below:

Code	Description
ENA	Continuation of Entity Name for PG19
AD1	Continuation of Entity Address Line 1 for PG19
AD2	Continuation of Entity Address Line 2 for PG20
AD3	Entity address Line 3 for PG20
AD4	Entity address Line 4 for PG20
AD5	Entity address Line 5 for PG20
ECI	Continuation of Entity City for PG20
INA	Continuation of Individual Name for PG21
EMA	Continuation of Email Address for PG21
TBN	Continuation of Trade/Brand Name for PG07

Table 5-30: Biologics PG60 Additional Information Qualifier Codes

PG60 record should follow immediately after its parent. For example, a PG60: ENA record should follow PG19 and a PG60: TBN record should follow PG07.

5.19 Record Identifier PG00 (Data Substitution)

This is an optional record used at the CBP entry (or entry summary) header, CBP entry (or entry summary) line and/or PGA message set levels to indicate data substitution.

PG00 Substitution Grouping
In situations where the trade would be supplying identical information more than once within a PGA Message Set, a PG00 substitution grouping can be used instead of repeating the information multiple times. Refer to the 'usage notes' in the ACE ABI CATAIR - Customs and Trade Automated Interface Requirements publication for detailed information.

Record Identifier PG00 (Data Substitution)					
Data Element	**Length/Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"00"	
Substitution Indicator	1X	5	O	Identifies either the start or end of the substitution group, or the location of where to place the substitute data within the PGA Message Set. The following codes are allowed: S=Start of the substitution group E=End of the substitution group R=Replace this record with the substitution group indicated by the Substitution Number	
Substitution Number	4AN	6-9	O	Sequential number assigned to, or referring to, a specific substitution group of data provided at the header level. This data element is mandatory when using the S or R substitution indicator.	
Filler	71X	10-80	M	Space fill	

Table 5-31: Biologics PG00

6 Cosmetics Commodity Data Elements and Values

Cosmetic commodities can only be filed under the following category using the existing Government Agency data elements available in the PG01 message.

PG01 - Government Agency Code	Commodity Type	PG01 - Government Agency Program Code	Commodity Sub-Type	PG01 - Government Agency Processing Code
FDA	Cosmetics	COS	None	None

Table 6-1: Cosmetics Commodity Hierarchy

The following are the potential PGA records associated with submitting Cosmetics data:

PG Record	Description
PG01	FDA program that regulates the product.
PG02	The Item Type and Product Code details.
PG06	Product Source information
PG07	Trade/Brand Name
PG10	Product Description (Line level Item Common/Usual/Market Name Description)
PG19	Entity Role (manufacturer, consignee, shipper, etc.) Entity Identification, Entity Name, and Entity Address 1
PG20	Additional address data on the entity in PG19 (Address line 2, Apartment/Suite, City, State, and Zip/Postal Code).
PG21	Entity of Record's (manufacturer, shipper, etc.) individual point of contact, phone number and email.
PG23	FDA's Affirmation of Compliance criteria.
PG24	Remarks
PG25	Temperature Qualifier, Lot Number Qualifier, Lot Number, and PGA Line Value
PG26	Packaging qualifier and quantity of the shipment
PG27	Container Number
PG30	Date, time and location of anticipated arrival information
PG55	Additional roles performed by entity or individual
PG60	Additional Information
PG00	Data Substitution

Table 6-2: Cosmetics PGA Records

6.1 Cosmetics Example

Cosmetics Message Set Layout for Sample

Refer to the external file: **FDA SG Example PG Message Sets** **Tab: *Cosmetics***

PGA Records and Data Elements required are dependent on the agency program and processing code selected. For a more expansive set of examples of FDA PGA Message Sets, refer to the above document.

6.2 Record Identifier PG01 (PGA Identifier)

Mandatory | Not Repeatable per PGA Line

This is a mandatory PGA input record that provides data pertaining to the PGA Line Number, Government Agency Code, Government Agency Program Code, Intended Use Code, Intended Use Description, and Disclaimer.

Record Identifier PG01 (PGA Identifier)					
Data Element	**Length /Class**	**Position**	**Status**	**Description/Required Value**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"01"	
PGA Line Number	3N	5-7	M	Begin with "001" and sequentially increment the line number on subsequent PG01 records, if applicable	
Government Agency Code	3AN	8-10	M	"FDA"	
Government Agency Program Code	3X	11-13	C	"COS"	1, 2
Government Agency Processing Code	16AN	14-16	O	No Processing Code applies for Cosmetics.	1, 2
Intended Use Code	16X	42-57	C	Refer to the Intended Use Code table for valid values.	3, 4
Intended Use Description	21X	58-78	O	N/A for FDA lines	
Correction Indicator	1X	79	O	For future use	
Disclaimer	1A	80	C	"A" (= product is not regulated by this agency) indicating there is no agency declaration requirement. Leave it blank for no disclaimer. "F" indicating that the product is manufactured in any state of the US, the District of Columbia, or Puerto Rico and sourced directly to the warehouse without ever leaving the US. **May only be used for FDA on Entry Type 21**. No other codes are accepted	

Table 6-3: Cosmetics PG01

Note 1
Refer to the Table 6-1 above for the commodity hierarchy for Cosmetic commodity.

Note 2
If the product is to be disclaimed, then these data elements should both be populated with "FDA". Otherwise, the Government Agency Program Code is mandatory.

Note 3
Note that CBP publication, Appendix R - Intended Use Codes for ACE, provides general descriptions of all Intended Use Codes for all Partner Government Agencies (PGAs). For FDA regulated products, use the FDA Import Scenario as specified per commodity throughout this document. See Appendix E for a mapping of FDA IUC descriptions to CBP Appendix R IUC descriptions. List of Intended Use Codes available for Government Agency Program Code = "COS" are below.

Intended Use Code	FDA Import Scenario
100.000	Importation for Personal Use
110.000	For Public Exhibition or Display as a Non-Food Product
130.000	For Consumer Use as a Non- Food Product
150.000	For Commercial Processing as a Non-Food Product
180.000	For Research and Development as a Non-Food Product
920.000	US Goods Returned
970.000	Import for Export
980.000	For Other Use

Table 6-4: Cosmetics Intended Use Codes

Note 4
If after consultation with the importer, who should know the intended use of the product, the filer still ***does not know*** the intended use of the product, "UNK" may be used in lieu of an IUC. In most cases, the line will be subject to manual review, and may result in a request for documentation and/or additional information about the product as the product offered for import will be treated as a standard import. Ensure the IUC (reason for importation) is transmitted to avoid delays. As per the ACE Rule, if "UNK" is submitted as the IUC for the article, the ACE filer is still responsible for submitting the other required data elements in this rule that are applicable to that article, at the time of entry. In the future, if those other data elements are not submitted in ACE at the time of entry, the entry may be transmitted by ACE to FDA for admissibility review, but FDA may reject the entry. If FDA rejects an entry filing, the ACE filer will need to resubmit the entry with complete and accurate information.

6.3 Record Identifier PG02 (Product Identifier)

Mandatory | Not Repeatable per PGA Line

This mandatory PGA input record is used to include information related to a product (P).

Record Identifier PG02 (Product Identifier)					
Data Element	**Length/Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"02"	
Item Type	1A	5	M	Code identifying the following records as pertaining to P=Product. No other values accepted. Only one "P" record is allowed for the same PGA Line # in PG01.	
Product Code Qualifier	4AN	6-9	M	"FDP"	1
Product Code Number	19X	10-28	M	FDA Product Code must be exactly 7 characters	1

Table 6-5: Cosmetics PG02

Note 1
Product Code Qualifiers and their descriptions can be found in CBP's ACE CATAIR Appendix PGA (PG02 – Product Code Qualifiers). For FDA filings, the Product Code Qualifier is always "FDP".
Only one FDA Product Code Number is allowed per line.

FDA Product Code Structure

Position	1-2	3	4	5	6-7
Name	Industry Code (N)	Class Code (AN)	Subclass Code (A or '-')	Process Indicator Code - PIC (A or '-')	Product (AN)

Legend - N: Numeric; A: Alphabetic; AN: Alphanumeric

Table 6-6: FDA Product Code Structure

IF Government Agency Program Code = "COS"
THEN Industry Code = 50 or 53

6.4 Record Identifier PG06 (Product Origin)

Mandatory | Repeatable per PGA Line

This is a mandatory PGA input record that provides data pertaining to Source Type (Origin) other than the CBP Country of Origin.

Record Identifier PG06 (Product Origin)					
Data Element	**Length/Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"06"	
Source Type Code	3AN	5-7	M	Mandatory value is 39 (Country of Production). Code 294 may be used to indicate a country has previously refused the line item.	1
Country Code	2X	8-9	M	Country of Production is required for Cosmetics.	2

Table 6-7: Cosmetics PG06

Note 1
Source Type Codes and their descriptions can be found in CBP's ACE CATAIR Appendix PGA (PG06 – Source Type Codes).

Note 2
Any of the country codes from CBP's ACE CATAIR Appendix B (Section: Country and Currency Codes) can be entered.

6.5 Record Identifier PG07 (Product Trade Names)

Optional | Not Repeatable per PGA Line

This is an optional PGA input record that provides data pertaining to Trade or Brand Name.

Record Identifier PG07 (Product Trade Names)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"07"	
Trade Name/Brand Name	35X	5-39	O	Trade or Brand name of the Cosmetic product is entered. If Trade/Brand Name requires additional space, continue in a PG60 record with Qualifier Code "TBN".	

Table 6-8: Cosmetics PG07

6.6 Record Identifier PG10 (Product Characteristics)

Mandatory | Not Repeatable per PGA Line

This is a mandatory PGA input record that allows for reporting the description of the product identified by the Product Code in PG02. For example, this record can be used to provide the specific type of mascara.

Record Identifier PG10 (Product Characteristics)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"10"	
Commodity Characteristic Description	57X	24-80	M	Common, market, usual name; free form invoice description; not product code description. For examples, see Appendix A: Use of PG10 Record.	

Table 6-9: Cosmetics PG10

6.7 Record Identifier PG19 (Entity Data)

Mandatory | Repeatable per PGA Line

This is a mandatory PGA input record that provides FDA with data pertaining to Entity Role, entity name and entity address 1.

Entity Identification Code [16 (DUNS #), 47 (FEI #)] and Entity number are optional data elements, but they are listed as conditional because if opting to transmit Entity Identification Code, then Entity Number must also be provided, and vice versa.

Record Identifier PG19 (Entity Data)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"19"	
Entity Role Code	3AN	5-7	M	Code identifying the role of the entity being provided. For example: MF, DP. Each entity role code can only be transmitted once per PGA line.	1
Entity Identification Code	3AN	8-10	C	Code identifying the Entity Identification is entered. For example: 16 (DUNS #), 47 (FEI #). Mandatory, if Entity Number is entered.	2
Entity Number	15X	11-25	C	Identifying Number (DUNS or FEI) for the associated Entity Identification Code. Mandatory if Entity Identification Code is provided.	2
Entity Name	32X	26-57	M	The name of the entity is required. If Entity Name requires additional space, continue in a PG60 record with Qualifier Code "ENA". Refer to the validation criteria below.	
Entity Address 1	23X	58-80	M	Must be entered. If Entity Address1 requires additional space, continue in a PG60 record with Qualifier Code "AD1".	

Table 6-10: Cosmetics PG19

Note 1
List of Entity Role codes that are mandatory to FDA Message Sets is noted below:

Data Element	**Code**	**Description**
Entity Role Codes	MF	Manufacturer of goods
	DEQ	Shipper
	FD1	FDA Importer (Importer of Record)
	DP	Delivered-To Party

Table 6-11: Cosmetics Entity Role codes (Mandatory)

List of Entity Role codes that are **optional** to FDA Message Sets is noted below:

Data Element	**Code**	**Description**
Entity Role Codes	PK	Point of Contact (Filer/Broker Contact Information)

Table 6-12: Cosmetics Entity Role codes (Optional)

Note 2
Entity Identification Codes and their descriptions can be found in CBP's ACE CATAIR Appendix PGA (PG19 – Entity Identification Codes). List of Entity Identification codes applicable to FDA Cosmetics Message Sets is noted below:

Data Element	Code	Description	Length/ Class
Entity Identification Codes	16	D&B-assigned (DUNS number); must be 9 digits	9N
	47	FDA-assigned (FEI number); must be from 1 to 10 digits	1 -10N

Table 6-13: Cosmetics Entity Identification codes

FDA ENTITY IDENTIFICATION CODE AND ENTITY NUMBER SELECTION AND VALIDATION CRITERIA

IF Entity Identification Code =16 (DUNS) THEN Entity Number must be Length = 9 and Type = N
ELSE IF Entity Identification Code =47 (FEI) THEN Entity Number must be Length from 1 to 10 and Type = N

6.8 Record Identifier PG20 (Entity Address)

Mandatory | Repeatable per PGA Line

This is a mandatory PGA input record that provides additional data pertaining to Entity identification such as Entity Address line 2, Apartment/Suite, City, State, and Zip/Postal Code. This record is used when there is additional address information for the entity.

Record Identifier PG20 (Entity Address)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"20"	
Entity Address 2	32X	5-36	C	Address Line 2 for the Entity. If Entity Address2 requires additional space, continue in a PG60 record with Qualifier Code "AD2".	1
Entity Apartment Number/Suite Number	5X	37-41	C	Apartment/Suite number of the entity.	
Entity City	21X	42-62	M	City of the entity. If Entity City requires additional space, continue in a PG60 record with Qualifier Code "ECI".	
Entity State/Province	3AN	63-65	C	Refer to CBP's ACE CATAIR Appendix B for valid codes.	2
Entity Country	2A	66-67	M	Refer to CBP's ACE CATAIR Appendix B for valid codes.	
Entity Zip/Postal Code	9X	68-76	C	Zip/Postal Code of the entity.	2
Filler	4X	77-80	M	Space fill	

Table 6-14: Cosmetics PG20

Note 1
If the Entity requires more than 2 address lines, use the optional PG60 records with Qualifier Codes "AD3", "AD4" and "AD5" immediately under the PG20 record for the same Entity.

Note 2
Required for US or Canada based entities

6.9 Record Identifier PG21 (Point of Contact)

Mandatory | Repeatable per PGA Line

This is a mandatory PGA input record that provides point of contact information.

For each FDA line, at least one PG21 is required with the individual qualifier "FD1" (FDA Importer of Record) sent with the preceding PG19 and PG20 FD1 record.

FDA also highly encourages the transmission of PG21 with the individual qualifier "PK" which should be the point of contact for the filer/broker. "PK" may be sent in one of the following ways:

1) Under a PG19PK (transmitting PG19PK, PG20PK and PG21PK for the filer), the FDA preferred method, **OR**
2) As a secondary PG21 to FD1 using individual qualifier "PK" (transmitting PG19FD1, PG20FD1, PG21FD1, and PG21PK for the filer), **OR**
3) Under any other required PG19 entity as long as "PK" is the individual qualifier in PG21.

If provided, there should be only one PK per FDA line.

Although the PK (filer/broker contact information) is optional, transmitting this information will enable FDA to expeditiously contact the filer, instead of contacting the Importer of Record. If only the Importer of Record PG21 is transmitted and PK is not, FDA processing may be delayed.

Record Identifier PG21 (Point of Contact)					
Data Element	**Length /Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"21"	
Individual Qualifier	3AN	5-7	M	Identify the type of party or facility the Individual represents. Only "FD1" and "PK" are allowed.	
Individual Name	23X	8-30	M	Name of the Individual. If the name will not fit, continue in a PG60 record with Qualifier Code "INA".	
Telephone Number of the Individual	15X	31-45	M	Telephone number of the Individual. For example, (713)555-8765 in US or (+65)9052-3529 in Singapore	
Email Address for the Individual	35X	46-80	M	Email Address of the individual. If the Email Address exceeds in length, continue in a PG60 record with Qualifier Code "EMA".	1

Table 6-15: Cosmetics PG21

Note 1
Only transmit one valid email address as you would in an email program. Do not include names, additional characters, etc.

Valid Example	first.last@company.com
Invalid Example	<first.last@company.com>
Invalid Example	FirstName LastName first.last@company.com
Invalid Example	FirstName<LastName first.last@company.com>
Invalid Example	first.last@company.com, first.last@company.com

6.10 Record Identifier PG23 (Affirmation of Compliance)

Optional | Repeatable per PGA Line

This is an optional PGA input record that provides data pertaining to FDA Affirmation of Compliance Criteria. This record is repeatable, but each affirmation of compliance code can only be transmitted once.

Record Identifier PG23 (Affirmation of Compliance)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"23"	
Affirmation of Compliance Code	5X	5-9	O	A code used to affirm compliance with FDA requirements. Refer to CBP's ACE CATAIR Appendix PGA (Food & Drug Affirmation of Compliance Codes) for valid codes.	1
Affirmation of Compliance Qualifier	30X	10-39	C	Text describing the information allowed by the PGA. For 'indicator only' AoC codes, this field is left blank. All other qualifiers must follow the syntax instructions for each code as specified in CBP's ACE CATAIR Appendix PGA.	1
Filler	1X	80	O	Space fill	

Table 6-16: Cosmetics PG23

Note 1
The FDA Affirmation of Compliance Codes and their descriptions are listed in CBP's ACE CATAIR Appendix PGA, FDA Affirmation of Compliance Codes.

The list of AoC codes that are optional to FDA Message Sets is noted below:

Data Element	**Code**	**Description**	**Syntax**	**Business Rules**
Affirmation of Compliance Code	COS	Cosmetic Registration Number	7N or 10N	If Government Agency Program Code = "COS", then COS is optional.
	ERR	Entry Review Requested	indicator only	ERR is just used as an indicator, no data will follow.

Table 6-17: Cosmetics List of AoC codes (Optional)

6.11 Record Identifier PG24 (Remarks)

Optional | Not Repeatable per PGA Line

This is an optional PGA input record that provides data pertaining to Remarks Type Code and Remarks Text.

PG24 cannot be repeated and only one PG24 is allowed for the same FDA line.

If entered, the Remarks Type Code should be GEN and must be under the PG02.

Currently, FDA processes PG24 record only at the Product-level (when under a PG02)

Record Identifier PG24 (Remarks)					
Data Element	**Length /Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"24"	
Remarks Type Code	3X	5-7	O	FDA uses only "GEN" as its valid value.	
Remarks Text	68X	13-80	O	Free form text relevant to the shipment or the commodity.	

Table 6-18: Cosmetics PG24

6.12 Record Identifier PG25 (Product Condition)

Optional | Repeatable per PGA Line

This is an optional PGA input record that provides data pertaining to Temperature Qualifier, Lot Number and PGA Line Value. This record is repeatable for multiple Lot Numbers. If opting to transmit line value, the PGA Line Value must be included on the first PG25 record.

Record Identifier PG25 (Product Condition)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"25"	
Temperature Qualifier	1A	5	O	Temperature Category being reported for quality control or preservation purposes. A=Ambient, F=Frozen, D=Dry Ice, R=Refrigerated/Chilled, H=Fresh, U=Uncontrolled, P=Flashpoint	
Lot Number Qualifier	1N	15	O	Code of the entity that assigned the Lot number. For Cosmetics the only valid value is: 1=Manufacturer In the case of multiple PG25 records for a given FDA line, enter Lot Number Qualifier only in the first PG25 record	
Lot Number	25X	16-40	O	The lot number that the manufacturer assigned to the product.	
PGA Line Value	12N	57-68	O	Although Line Value is optional, transmitting the value will assist in reviewing the product in a timely manner. Failure to transmit the value may result in delays associated with gathering missing information. If entered: • in the case of multiple PG25 records, enter value only in the first PG25 record • value should be in US Dollars, and enter whole dollars only • must be greater than zero and be right justified with preceding zero	

Table 6-19: Cosmetics PG25

6.13 Record Identifier PG26 (Product Packaging)

Optional | Repeatable per PGA Line

This is an optional PGA input record that provides FDA with data pertaining to Packaging Qualifier, Quantity and Unit of Measure. If included, the following rules apply:

This record can be repeated up to six (6) times, once for each unique packaging level. The first record is used to describe the largest (outermost) container and the number of containers at this packaging level. The second record is used to describe the contents of the next smallest container. If needed, qualifiers 2-6 are used in a similar manner (largest to smallest container). The final record must describe the actual amount of the product in the smallest container (base unit) in Appendix D: FDA Unit of Measurement Codes in this guide.

The appearance of any 'Packaging Qualifier' number level requires all levels under it to be represented. For instance, level 3 cannot be present unless levels 1 and 2 are present. The same Unit of Measure cannot be used multiple times on the same PGA line.

Record Identifier PG26 (Product Packaging)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"26"	
Packaging Qualifier	1N	5	C	This code identifies the level of packaging for the product. Outermost (largest=1) packages to the innermost (smallest=6) packages. There can be up to 6 levels of packaging. If reporting only one level, show the total quantity for the item and report that as level 1.	1, 4
Quantity	12N	6-17	C	Although quantity is optional, transmitting the quantity accurately and following the rules below will assist in reviewing the product in a timely manner. Failure to transmit the quantity records may result in delays associated with gathering missing information. If entered, this is the Quantity of the packaging level and Two decimal places are implied. Must be greater than zero. Example: 000000000400 **Transmitting Quantity requires transmitting Packaging Qualifier and the Unit of Measure. Last unit transmitted must be a base unit and only one base unit is allowed.**	2, 4
Unit of Measure (Packaging Level)	5X	18-22	C	Type of packaging / packaging level. For example, BX. Cannot be repeated among the PG26 records.	3, 4

Table 6-20: Cosmetics PG26

Note 1
This code identifies the level of packaging for the product. Valid values are 1, 2, 3, 4, 5 and 6: Outermost (largest=1) packages to the innermost (smallest=6) packages. There can be up to 6 levels of packaging. The same unit of measure cannot be used multiple times on the same PGA line.

Note 2

There are two implied decimal points when writing the quantity in Units of Measure for all packaging levels. In this example, 4 pieces are represented as 000000000400, with the nine leading zeroes as “fill” and two decimal places following the value.

Note 3
For a list of Unit of Measure codes applicable to FDA-Cosmetics Message Sets, refer to Appendix D of this document.

Note 4
Quantity Data provides additional information to FDA about the product and how it is packaged. The basic format for Quantity Data is in multiple pairs of data – quantity and unit of measure, i.e., 500 cases, 12 ounces, fluid, 1000 cartons, etc. Up to 6 data pairs may be submitted, beginning with the 1st pair for the outermost packaging when Packaging Qualifier = 1. The first pair may describe the largest container and the last pair must describe the amount of product in the smallest container (Base Unit).

For example: Bubble bath: 25 boxes, 4 bottles/box, 28 fluid oz. each bottle:

Units 1-Quantity= 25
Units 1-Measure =BX
Units 2-Quantity=4
Units 2-Measure=BO
Units 3-Quantity=28
Units 3-Measure=FOZ (Last Unit of Measure transmitted must be a base unit)

6.14 Record Identifier PG27 (Shipping Container Information)

Optional | Repeatable per PGA Line

This is an optional PGA input record that provides data pertaining to the shipping Container Number. This record may be repeated.

Record Identifier PG27 (Container Information)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"27"	
Container Number (Equipment ID)	20AN	5-24	O	The number of the shipping container.	
Container Number (Equipment ID)	20AN	28-47	O	The number of the shipping container.	
Container Number (Equipment ID)	20AN	51-70	O	The number of the shipping container.	
Filler	7X	74-80	O	Space fill	

Table 6-21: Cosmetics PG27

6.15 Record Identifier PG30 (Anticipated Arrival Information)

Mandatory | Repeatable per PGA Line

This is a mandatory PGA input record that provides data pertaining to the date, time and location of the anticipated arrival/entry information for all FDA products.

For each line a PG30 record with an "A" (Anticipated arrival information) status code, date and time of arrival is mandatory. For entry type 21 coming from a Foreign Trade Zone, a PG30 record with an "F" (Foreign Trade Zone) code and FIRMS code for the FTZ location is required.

Record Identifier PG30 (Anticipated Arrival Information)					
Data Element	**Length/Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"30"	
Anticipated Arrival Information	1A	5	M	A (Anticipated Arrival Information). If entry type = 21, then repeat PG30 and enter F (Foreign Trade Zone).	1, 2
Anticipated Arrival Date at Port of Entry	8N	6-13	C	A numeric date in MMDDCCYY (month, day, century, year) format. **Mandatory if Status = 'A'**.	1, 2
Anticipated Arrival Time at Port of Entry	4N	14-17	C	Military time HHMM in (hour, minute) format. (Example: 1015, this represents 10:15 a.m.). For midnight, use 2400 (0000 is invalid). **Mandatory if Status = 'A'**.	1, 2
Inspection or Arrival Location Code	4AN	18-21	C	Only a value of '4' (=FIRMS Code) is allowed for entry type = 21. For entry type not = 21, this field is left blank.	
Inspection or Arrival Location	50X	22-71	C	Provide FIRMS Code here.For valid FIRMS codes, refer to ACS/ACE query. https://www.cbp.gov/document/report/acs-public-firms-code-report	
Filler	8X	72-80	M	Space fill	

Table 6-22: Cosmetics PG30

Note 1
A= Anticipated Arrival Date and Time at the Anticipated Port of Entry.

Port of Entry:
19 CFR 101.1.
Port and port of entry. The terms "port" and "port of entry" refer to any place designated by Executive Order of the President, by order of the Secretary of the Treasury, or by Act of Congress, at which a Customs officer is authorized to accept entries of merchandise to collect duties, and to enforce the various provisions of the Customs and navigation laws. The terms "port" and "port of entry" incorporate the geographical area under the jurisdiction of a port director. (The Customs ports in the Virgin Islands, although under the jurisdiction of the Secretary of the Treasury, have their own Customs laws (48 U.S.C. 1406(i)). These ports, therefore, are outside the Customs territory of the United States and the ports thereof are not "ports of entry" within the meaning of these regulations).

Note 2
Examples on how to submit PG30

For all Entry Types other than Entry Type 21 Warehouse for an FTZ Withdrawal	For Entry Type 21 Warehouse for an FTZ Withdrawal
PG30 Record • Anticipated Arrival Information status code = “A” (anticipated arrival information) is mandatory • Anticipated Arrival Date at Port of Entry is mandatory • Anticipated Arrival Time at Port of Entry is mandatory	PG30 Record • Anticipated Arrival Information status code = “A” (anticipated arrival information) is mandatory • Anticipated Arrival Date at Port of Entry is mandatory • Anticipated Arrival Time at Port of Entry is mandatory Additional PG30 Record • Anticipated Arrival Information status code = “F” (FTZ) is mandatory • Anticipated Arrival Date at Port of Entry is optional • Anticipated Arrival Time at Port of Entry is optional • Inspection or Arrival Location Code = “4” (FIRMS Code) is mandatory • FTZ Location is mandatory

6.16 Record Identifier PG55 (Additional Entity Roles)

This is an optional PGA input record used to provide additional roles performed by an entity or individual.

Not supported by FDA at this time

Currently, the PG55 record is not supported by FDA. Multiple PG19 records should be used to input more than one Entity-Role combination. Refer to the PG19 section for details.

Record Identifier PG55 (Additional Entity Roles)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"55"	
Entity Role Code	3AN	5-7	O	Additional role of the entity.	
Entity Role Code	3AN	8-10	O	Additional role of the entity.	
Entity Role Code	3AN	11-13	O	Additional role of the entity.	
Entity Role Code	3AN	14-16	O	Additional role of the entity.	
Entity Role Code	3AN	17-19	O	Additional role of the entity.	
Entity Role Code	3AN	20-22	O	Additional role of the entity.	
Entity Role Code	3AN	23-25	O	Additional role of the entity.	
Entity Role Code	3AN	26-28	O	Additional role of the entity.	
Entity Role Code	3AN	29-31	O	Additional role of the entity.	
Entity Role Code	3AN	32-34	O	Additional role of the entity.	
Filler	46X	35-80	M	Space fill	

Table 6-23 Cosmetics PG55

6.17 Record Identifier PG60 (Additional Information)

Optional | Repeatable per PGA Line

This is an optional PGA input record used to provide additional information about data in the PG record that precedes it during the submission of a PGA record set.

This record can follow a PG07, PG19, PG20 or PG21 record, and can only be used to provide the additional information noted by the Additional Information Qualifier Code list.

This record may be repeated.

Record Identifier PG60 (Additional Information)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"60"	
Additional information qualifier code	3AN	5-7	C	Code indicating the type of additional information being provided	1
Additional Information	73X	8-80	C	Text of the additional information related to the additional reference qualifier code	

Table 6-24: Cosmetics PG60

Note 1
Valid PG60 Additional Information Qualifier Codes applicable to FDA Message Set are:

Code	Description
ENA	Continuation of Entity Name for PG19
AD1	Continuation of Entity address Line 1 for PG19
AD2	Continuation of Entity address Line 2 for PG20
AD3	Entity address Line 3 for PG20
AD4	Entity address Line 4 for PG20
AD5	Entity address Line 5 for PG20
ECI	Continuation of Entity City for PG20
INA	Continuation of Individual Name for PG21
EMA	Continuation of Email Address for PG21
TBN	Continuation of Trade/Brand Name for PG07

Table 6-25: Cosmetics PG60 Additional Information Qualifier Codes

PG60 record should follow immediately after its parent. For example, a PG60: ENA record should follow PG19 and a PG60: TBN record should follow PG07.

6.18 Record Identifier PG00 (Data Substitution)

This is an optional record used at the CBP entry (or entry summary) header, CBP entry (or entry summary) line and/or PGA message set levels to indicate data substitution.

PG00 Substitution Grouping
In situations where the trade finds it would be supplying identical information more than once within the PGA Message Set, a PG00 substitution grouping can be used, instead of repeating that information multiple times. Refer to the 'usage notes' in the ACE ABI CATAIR - Customs and Trade Automated Interface Requirements publication for detailed information.

Record Identifier PG00 (Data Substitution)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"00"	
Substitution Indicator	1X	5	O	Identifies either the start or end of the substitution group, or the location of where to place the substitute data within the PGA Message Set. The following codes are allowed: S=Start of the substitution group E=End of the substitution group R=Replace this record with the substitution group indicated by the Substitution Number	
Substitution Number	4AN	6-9	O	Sequential number assigned to, or referring to, a specific substitution group of data provided at the header level. This data element is mandatory when using the S or R substitution indicator.	
Filler	71X	10-80	M	Space fill	

Table 6-26: Cosmetics PG00

7 Drug Commodity Data Elements and Values

Drug commodities can be broken down into the following categories using the existing Government Agency data elements available in the PG01 message

PG01 - Government Agency Code	Commodity Type	PG01 - Government Agency Program Code	Commodity Sub-Type	PG01 - Government Agency Processing Code
FDA	Drugs	DRU	Prescription	PRE
FDA	Drugs	DRU	Over the Counter	OTC
FDA	Drugs	DRU	Pharmaceutical Necessities, Containers, Inactive Pharmaceutical Ingredients and Excipients	PHN
FDA	Drugs	DRU	Research and Development	RND
FDA	Drugs	DRU	Investigational	INV
FDA	Drugs	DRU	Section 804 Importation Program*	804

Table 7-1: Drug Commodity Hierarchy

* Section 804 Importation Program is limited to a port authorized by FDA. At the time of implementation, the only port authorized by FDA is 3801 (Detroit).

The following are the potential PGA records associated with submitting Drug:

PG Record	Description
PG01	FDA program that regulates the product and the intended use code.
PG02	Product Identifier; the item type and Product Code detail.
PG04	Product Constituent Active Ingredient
PG06	Product Source information
PG07	Trade/Brand Name
PG10	Product Description (Line level Item Common/Usual/Market Name Description)
PG19	Entity Role (manufacturer, consignee, shipper, etc.) Entity Identification, Entity Name, and Entity Address 1
PG20	Additional Entity Identification (Address line 2, Apartment/Suite, City, State, and Zip/Postal Code).
PG21	Additional Entity Role
PG23	FDA's Affirmation of Compliance Criteria
PG24	Remarks
PG25	Temperature Qualifier, Degree Type, Actual Temperature, Lot Number, Production Date Range of the Lot, and PGA Line Value
PG26	Packaging qualifier and quantity of the shipment
PG30	Date, time and location of anticipated arrival information
PG55	Additional roles performed by an entity or individual
PG60	Additional Information
PG00	Data Substitution

Table 7-2: Drug PGA Records

7.1 Drug Example

Drug message set layout sample is noted below:

Refer to the external file: **FDA SG Example PG Message Sets** **Tab: *Drugs***

Drugs Message Set Description

PGA Records and Data Elements required are dependent on the agency program and processing code selected. For a more expansive set of examples of FDA PGA Message Sets, refer to the above document.

7.2 Record Identifier PG01 (PGA Identifier)

Mandatory | Not Repeatable per PGA Line

This is a mandatory PGA input record that provides data pertaining to the PGA Line Number, Government Agency Code, Go**v**ernment Agency Program Code, Government Agency Processing Code, Intended Use Code, Intended Use Description, and Disclaimer.

Record Identifier PG01 (PGA Identifier)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description/Required Value**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"01"	
PGA Line Number	3N	5-7	M	Begin with "001" and sequentially increment the line number on subsequent PG01 records, if applicable	
Government Agency Code	3AN	8-10	M	"FDA"	
Government Agency Program Code	3X	11-13	C	"DRU"	1, 2
Government Agency Processing Code	3AN	14-16	C	Allowed values: PRE, OTC, INV, PHN, RND, 804	1, 2
Intended Use Code	16X	42-57	C	Refer to the table below for valid values	3, 4, 5
Intended Use Description	21X	58-78	O	N/A for FDA lines.	
Correction Indicator	1X	79	O	For future use	
Disclaimer	1A	80	C	"A" (= product is not regulated by this agency) indicating there is no agency declaration requirement. Leave it blank for no disclaimer. "F" indicating that the product is manufactured in any state of the US, the District of Columbia, or Puerto Rico and sourced directly to the warehouse without ever leaving the US. **May only be used for FDA on Entry Type 21**. No other codes are accepted	

Table 7-3: Drug PG01

Note 1
Refer to

FDA	Drugs	DRU	Section 804 Importation Program*	804

Table 7-1 above for commodity type and sub-type for Drugs. Section 804 Importation Program is limited to a port authorized by FDA. At the time of implementation, the only port authorized by FDA is 3801 (Detroit).

Note 2
If the product is to be disclaimed, then these data elements should both be populated with 'FDA'. Otherwise the Government Agency Program Code and Government Agency Processing Code are mandatory.

Note 3
If the product is to be disclaimed, then these data elements are left blank; otherwise the Intended Use Code is required.

Note 4

Note that CBP publication, Appendix R - Intended Use Codes for ACE, provides general descriptions of all Intended Use Codes for all Partner Government Agencies (PGAs). For FDA regulated products, use the IUC descriptions as specified per commodity throughout this document. See Appendix E for a mapping of FDA IUC descriptions to CBP Appendix R IUC descriptions. List of Intended Use Codes available for Government Agency Program Code = "DRU" are below.

Intended Use Code	Intended Use Description
080.012	Prescription health or medical product for human use that is the subject of an approved new drug application, abbreviated new drug application, or biologics license application
100.000	Importation for Personal Use
110.000	For public exhibition or display of finished drug products, inactive ingredients, packing components or container closure systems for use with a pharmaceutical product. Excludes active pharmaceutical ingredients, and human drug products intended for distribution in the general public supply chain
130.000	For Consumer Use as a Non- Food Product – Over the Counter (OTC)
130.033	Inactive ingredients and intermediates for use in a pharmaceutical product (PHN only)
150.007	Active Pharmaceutical Ingredient / Bulk Drug Substance for processing into a pharmaceutical product
150.013	Active Pharmaceutical Ingredient / Bulk Drug Substance to be used for Pharmacy Compounding
150.017	Importation of a drug component (API) for use in a medical product regulated under a device (CDRH) application type (e.g., for use in a PMA/510(k) drug-device combination product)
155.000	Packaging component or a container closure system for use in a pharmaceutical product (PHN only). Excludes finished drugs for repacking and relabeling, active pharmaceutical ingredient / bulk drug substance, inactive ingredients, and intermediates
155.009	Importation of a drug constituent part (drug product) for use in a medical product regulated under a device (CDRH) application type (e.g., for use in a PMA/510(k) drug-device combination product)
180.000	For research and development of packaging components, containers closure systems, inactive pharmaceutical ingredients, and intermediates (PHN only).
180.009	Chemical for research and development of a pharmaceutical product – subject of an Investigational New Drug application (IND), including Placebos
180.017	Chemical for research and development of a pharmaceutical product – laboratory testing only, no human/animal use
180.018	Chemical for research and development of a pharmaceutical product – investigational use in animals
180.026	Finished drug or API intended for use in an in vivo bioequivalence or bioavailability study in humans that qualifies under 21 CFR 320.31 for an exemption from the Part 312 requirements; or, finished drug intended for use in clinical investigation in humans that qualifies for an exemption from Part 312 requirements
920.000	US Goods Returned
970.000	Import for Export
980.000	For Other Use: (APIs or Finished Drugs not elsewhere classified)

Table 7-4: Drug Intended Use Codes

Refer to the Intended Use codes applicable for Forms and Types:

Prescription (PRE)

Finished Dosage Form:	
080.012	Prescription health or medical product for human use that is the subject of an approved new drug application, abbreviated new drug application, or biologics license application
100.000	Importation for Personal Use
110.000	For public exhibition or display of finished prescription drug products. Excludes active pharmaceutical ingredients, and human drug products intended for distribution in the general public supply chain.
155.009	Importation of a drug constituent part (drug product) for use in a medical product regulated under a device (CDRH) application type (e.g., for use in a PMA/510(k) drug-device combination product)
920.000	US Goods Returned
970.000	Import for Export
980.000	For Other Use: (APIs or Finished Drugs not elsewhere classified)

Active Pharmaceutical Ingredient / Bulk Drug Substance:	
150.007	Active Pharmaceutical Ingredient / Bulk Drug Substance for processing into a pharmaceutical product
150.013	Active Pharmaceutical Ingredient / Bulk Drug Substance to be used for Pharmacy Compounding
150.017	Importation of a drug component (API) for use in a medical product regulated under a device (CDRH) application type (e.g., for use in a PMA/510(k) drug-device combination product)
920.000	US Goods Returned
970.000	Import for Export
980.000	For Other Use: (APIs or Finished Drugs not elsewhere classified)

Over the Counter (OTC)

Finished Dosage Form:	
100.000	Importation for Personal Use
110.000	For public exhibition or display of finished over the counter drug products. Excludes active pharmaceutical ingredients, and human drug products intended for distribution in the general public supply chain.
130.000	For Consumer Use as a Non-Food Product – Over the Counter (OTC)
155.009	Importation of a drug constituent part (drug product) for use in a medical product, regulated under a device (CDRH) application type (e.g., for use in a PMA/510(k) drug/device combination product)
920.000	US Goods Returned
970.000	Import for Export

Active Pharmaceutical Ingredient / Bulk Drug Substance:	
150.007	Active Pharmaceutical Ingredient / Bulk Drug Substance for processing into a pharmaceutical product
150.013	Active Pharmaceutical Ingredient / Bulk Drug Substance to be used for Pharmacy Compounding
150.017	Importation of a drug component (API) for use in a medical product regulated under a device (CDRH) application type (e.g., for use in a PMA/510(k) drug-device combination product)
920.000	US Goods Returned
970.000	Import for Export

Pharmaceutical Necessities, Containers, Inactive Pharmaceutical Ingredients and Excipients (PHN)

110.000	For Public Exhibition or Display as a Non-Food Product For public exhibition or display of inactive pharmaceutical ingredients packaging component, and container closure systems. Excludes active pharmaceutical ingredients, and human drug products intended for distribution in the general public supply chain.
130.033	Chemical substance for use in a pharmaceutical product. Inactive ingredients and intermediates for use in a pharmaceutical product (PHN only)
155.000	For Commercial Assembly as a Non-Food Product. Packaging component or a container closure system for use with a pharmaceutical product (PHN only). Excludes finished drugs for repacking and relabeling, active pharmaceutical ingredient / bulk drug substance, inactive ingredients, and intermediates.
180.000	For Research and Development as a Non-Food Product. For research and development of packaging components, containers closure systems, and inactive pharmaceutical ingredients and intermediates (PHN only).
920.000	US Goods Returned - Inactive pharmaceutical ingredients, packaging components, and container closure systems of the United States that are exported and returned without having been advanced in value or improved in condition by any manufacturing process or other means while abroad, as per 19 CFR 10.1 (a).
970.000	Import for Export- - Inactive pharmaceutical ingredients, packaging components, and container closure systems product imported for export that is not intended for sale in the US market.

Investigational New Drug (INV)

180.009	Chemical for research and development of a pharmaceutical product – subject of an Investigational New Drug application (IND), including Placebos

180.026	Finished drug or API intended for use in an in vivo bioequivalence or bio-availability study in humans that qualifies under 21 CFR 320.31 for an exemption from the Part 312 requirements; or finished drug intended for use in clinical investigation in humans that qualifies for an exemption from Part 312 requirements
920.000	US Goods Returned

Research and Development (RND)

180.017	Chemical for research and development of a pharmaceutical product – laboratory testing only, no human/animal use
180.018	Chemical for research and development; investigational use in animals

Section 804 Importation Program (804)

080.012	Prescription health or medical product for human use that is the subject of an approved new drug application, abbreviated new drug application, or biologics license application. ***Note that Government Agency Processing Code 804 only applies to prescription drugs for human use and excludes drugs under a Biologics Licensing Application.***

Note 5

If after consultation with the importer, who should know the intended use of the product, the filer still ***does not know*** the intended use of the product, "UNK" may be used in lieu of an IUC. In most cases, the line will be subject to manual review, and may result in a request for documentation and/or additional information about the product as the product offered for import will be treated as a standard import. Ensure the IUC (reason for importation) is transmitted to avoid delays. As per the ACE Rule, if "UNK" is submitted as the IUC for the article, the ACE filer is still responsible for submitting the other required data elements in this rule that are applicable to that article, at the time of entry. In the future, if those other data elements are not submitted in ACE at the time of entry, the entry may be transmitted by ACE to FDA for admissibility review, but FDA may reject the entry. If FDA rejects an entry filing, the ACE filer will need to resubmit the entry with complete and accurate information.

7.3 Record Identifier PG02 (Product Identifier)

Mandatory | Not Repeatable per PGA Line

This mandatory PGA input record is used to include information related to a product (P). For Drugs entries, the Product Code Number is provided within this record.

Record Identifier PG02 (Product Identifier)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1 2	M	"PG".	
Record Type	2N	3-4	M	"02"	
Item Type	1A	5	M	Code identifying the following records as pertaining to P=Product. No other values are allowed. Only one "P" record is allowed for the same PGA Line # in PG01.	
Product Code Qualifier	4AN	6-9	M	"FDP".	1
Product Code Number	19X	10-28	M	FDA Product Code must be exactly 7 characters	

Table 7-5: Drug PG02

Note 1
Product Code Qualifiers and their descriptions can be found in CBP's ACE CATAIR Appendix PGA (PG02 – Product Code Qualifiers). For FDA filings, the Product Code Qualifier is always "FDP".
Only one FDA Product Code Number is allowed per line.

FDA Product Code Structure

Position	1-2	3	4	5	6-7
Name	Industry Code (N)	Class Code (AN)	Subclass Code (A or '-')	Process Indicator Code - PIC (A or '-')	Product (AN)

Legend - N: Numeric; A: Alphabetic; AN: Alphanumeric

Table 7-6: Drug FDA Product Code Structure

*** Edit to limit Industry Codes, dependent upon the Government Agency Processing Code ***

IF Government Agency Processing Code = PRE, OTC, INV or RND
THEN Industry Code should be 54, 56, 58, 60, 61, 62, 63, 64, 65 or 66.

IF Government Agency Processing Code = PHN
THEN Industry Code should be 55 or various other codes could apply.

IF Government Agency Processing Code = 804
THEN Industry Code will be 54, 56, 60, 61, 62, 63, 64, 65, or 66.

IF Government Agency Processing Code = PRE, OTC, INV or RND
AND
IF (Industry Code = '54')
THEN Subclass Code should be ('D', 'E', 'F', 'G', 'I').

*** Edit to limit Subclass, dependent upon the Government Agency Processing Code:***
For Industry Codes 56, 58, and 60-66:
C & D are the Subclasses for PRE products;
A & B are the Subclasses for OTC products;
I is the Subclass for Investigational New Drug products

IF Government Agency Processing Code = INV
AND
IF PG01 Intended Use Code INCLUDES 180.009, 180.026, or 920.000
THEN Subclass Code should be "I".

IF Government Agency Processing Code = PRE
AND
PG01 Intended Use Code INCLUDES 080.012, 100.000, 150.007, 150.017, 155.009, 920.000, 970.000, or 980.000
THEN Subclass Code should be 'C' or 'D'.

IF Government Agency Processing Code = OTC
AND
PG01 Intended Use Code INCLUDES 100.000, 130.000, 150.007, 150.017, 155.009, 920.000 or 970.000
THEN Subclass Code should be 'A' or 'B'.

For Industry Code 54:
F & G are the Subclasses for PRE products;
D & E are the Subclasses for OTC products;
I is the Subclass for Investigational New Drug products

*** Edit to limit Process Indicator Code (PIC) for Active Pharmaceutical Ingredients ***

IF Government Agency Processing Code = PRE or OTC
AND
IF PG01 Intended Use Code = 150.007 or 150.017, (Drug to be used as a component in a Medical Device (Active Pharmaceutical Ingredient / Bulk Drug Substance)
THEN Process Indicator Code (PIC) should be 'S'.

IF Government Agency Processing Code = PRE or OTC
AND
IF PG01 Intended Use Code = 150.013 (Active Pharmaceutical Ingredient to be used in pharmacy compounding)
THEN Process Indicator Code (PIC) should be 'T'.

7.4 Record Identifier PG04 (Product Constituent Element)

Optional | Repeatable per PGA Line

This PGA input record is optional, and it provides data pertaining to Constituent Active Ingredient Qualifier, Name of the Constituent Element, Quantity of Constituent Element, Unit of Measure, and Percent of Constituent Element for the product identified by Product Code Number in PG02. This record can be repeated.

If opting to transmit this record, Name of the Constituent Element, Quantity, and either Unit of Measure or Percent are required. i.e., the record must be sent with complete information.

Using a Drug example, Appendix C: Sample use of PG04 – Product Constituent Element shows how PG04 can be used at the Product-level for multiple Constituent Elements. Currently, FDA processes PG06-PG07-PG10 records only at the Product-level (when under a PG02).

Record Identifier PG04 (Product Constituent Element)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1 2	M	"PG"	
Record Type	2N	3-4	M	"04"	
Constituent Active Ingredient Qualifier	1A	5	O	If commodity sub-type = PRE, OTC, INV or RND then YES = "*Y*" if yes, blank (= NO)	1
Name of the Constituent Element	51X	6-56	O	If FINISHED: Name of Active Ingredient contained in the dosage form If API/BULK DRUG SUBSTANCE: name of the Active Pharmaceutical Ingredient (API)	1, 2 3
Quantity of Constituent Element	12N	57-68	O	If FINISHED – amount of active ingredient per dose if applicable If API/BULK DRUG SUBSTANCE: total volume of API 2 decimal places are implied	1, 2 3
Unit of Measure (Constituent Element)	5AN	69-73	O	If FINISHED: Unit of Measure for Quantity of Constituent Element If API/BULK DRUG SUBSTANCE: Unit of measure for Quantity of Constituent Element	1, 2 3
Percent of Constituent Element	7N	74-80	O	If FINISHED Product - Percent of active ingredient in the product if applicable. If API/BULK Drug Substance – Percent of the Constituent Element = percent identification of the API. 4 decimal places are implied.	1, 3, 4,

Table 7-7: Drug PG04

Note 1
IF Government Agency Program Code = DRU
AND IF Government Agency Processing Code = PRE or OTC or INV or RND
THEN Constituent Active Ingredient Qualifier and Name of the Constituent Element are entered.

Note 2
*** Rules for **Finished Dosage Form Drugs** ***
IF PG01 Intended Use Code =

080.012 Prescription health or medical product for human use that is the subject of an approved new drug application, abbreviated new drug application, or biologics license application
OR
130.000 For Consumer Use as a Non- Food Product – Over the Counter (OTC)
OR
155.009 Importation of a drug constituent part (drug product) for use in a medical product regulated under a device (CDRH) application type (e.g., for use in a PMA/510(k) drug-device combination product)
OR
180.009 Chemical for research and development of a pharmaceutical product – subject of an Investigational New Drug application (IND), including Placebos
OR
180.017 Chemical for research and development of a pharmaceutical product – laboratory testing only, no human/animal
OR
180.018 Chemical for research and development of a pharmaceutical product – investigational use in animals
OR
180.026 Finished drug intended for use in an in vivo bioequivalence or bioavailability study in humans that qualifies under 21 CFR 320.31 for an exemption from the Part 312 requirements; or finished drug intended for use in clinical investigation in humans that qualifies for an exemption from Part 312 requirements
OR
920.000, US Goods Returned
OR
980.000 For Other Use: (APIs or Finished Drugs not elsewhere classified)

THEN

Either the quantity and Unit of Measurement are entered **OR** the Percent Constituent Element is entered.

MAY REPEAT PG04 for EACH Active Pharmaceutical Ingredient in the Finished Dosage form

Example1: Ibuprofen, 200mg tablets
Name of the Constituent Element = Ibuprofen
Quantity of Constituent Element = 200 and Unit of Measure = milligrams

Example2: Antiperspirant Deodorant
Name of the Constituent Element = aluminum zirconium tetrachlorohydrex
Percent of Constituent Element 18.2% (entered as 0182000)

Note 3
*** Rules for **Active Pharmaceutical Ingredients** (API) ***
IF PG01 Intended Use Code =

150.007 Active Pharmaceutical Ingredient / Bulk Drug Substance for processing into a pharmaceutical product
OR
150.013 Active Pharmaceutical Ingredient / Bulk Drug Substance to be used for Pharmacy Compounding
OR
150.017 Importation of a drug component (API) for use in a medical product regulated under a device (CDRH) application type (e.g., for use in a PMA/510(k) drug-device combination product)
OR
180.009 Chemical for research and development of a pharmaceutical product – subject of an Investigational New Drug application (IND), including Placebos
OR
180.017 Chemical for research and development of a pharmaceutical product – laboratory testing only, no human/animal use
OR
180.018 Chemical for research and development of a pharmaceutical product – investigational use

in animals
OR
180.026, Finished drug or API intended for use in an in vivo bioequivalence or bioavailability study in humans that qualifies under 21 CFR 320.31 for an exemption from the Part 312 requirements; or finished drug intended for use in clinical investigation in humans that qualifies for an exemption from Part 312 requirements
OR
920.000 US Goods Returned
OR
980.000 For Other Use: (APIs or Finished Drugs not elsewhere classified)

THEN
The quantity, Unit of Measurement and the Percent Constituent Element are entered.

Name of the Constituent Element = Active Pharmaceutical Ingredient name
Quantity of Constituent Element = Total Amount (by Unit of Measure) of the Active Pharmaceutical Ingredient
Percent of Constituent Element = percent identification of the Active Pharmaceutical Ingredient.

Example: Ephedrine Hydrochloride 99%, USP, 2 – 25 KG drums
Name of the Constituent Element = Ephedrine HCl
Percent of Constituent Element 99% (entered as 0990000)
Quantity of Constituent Element = 50 and Unit of Measure = KG

Note 4
Examples of Percentages:

1000000	=	100%
0990000	=	99%
0090000	=	9%
0009000	=	.9%
0000900	=	09%
0000090	=	.009%
0000009	=	.0009%

7.5 Record Identifier PG06 (Product Origin)

Mandatory | Repeatable per PGA Line

This is a mandatory PGA input record that provides data pertaining to Source Type (Origin) - other than the CBP Country of Origin - for the product identified by Product Code Number in PG02.

Using a Drug example, Appendix C: Sample use of PG04 – Product Constituent Element shows how PG04 can be used at the Product-level for multiple Constituent Elements.

Currently, FDA processes PG06-PG07-PG10 records only at the Product-level (when under a PG02).

Record Identifier PG06 (Product Origin)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1 2	M	"PG"	
Record Type	2N	3-4	M	"06"	
Source Type Code	3AN	5-7	M	Mandatory value is 30 (Country of Source) or 39 (Country of Production). Code 294 may be used to indicate a country has previously refused the line item.	1
Country Code	2X	8-9	M	Country of Production or Source is required for Drugs.	2

Table 7-8: Drug PG06

Note 1
Source Type Codes and their descriptions can be found in CBP's ACE CATAIR Appendix PGA (PG06 – Source Type Codes).

Note 2
Any of the country codes from CBP's ACE CATAIR Appendix B (Section: Country and Currency Codes) can be entered.

7.6 Record Identifier PG07 (Product Trade Names)

Optional | Not Repeatable per PGA Line

This is an optional PGA input record that provides data pertaining to Trade or Brand Name for the product identified by Product Code Number in PG02.

Using a Drug example, Appendix C: Sample use of PG04 – Product Constituent Element shows how PG04 can be used at the Product-level for multiple Constituent Elements. **Currently, FDA processes PG06-PG07-PG10 records only at the Product-level (when under a PG02).**

Record Identifier PG07 (Product Trade Names)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1 2	M	"PG"	
Record Type	2N	3-4	M	"07"	
Trade Name/Brand Name	35X	5-39	O	If Trade/Brand Name requires additional space, continue in a PG60 record with Qualifier Code "TBN".	

Table 7-9: Drug PG07

7.7 Record Identifier PG10 (Product Characteristics)

Mandatory | Not Repeatable per PGA Line

This is a mandatory PGA input record that allows for reporting the description of the product identified by the Product Code in PG02.
Using a Drug example, Appendix C: Sample use of PG04 – Product Constituent Element shows how PG04 can be used at the Product-level for multiple Constituent Elements. **Currently, FDA processes PG06-PG07-PG10 records only at the Product-level (when under a PG02).**

Record Identifier PG10 (Product Characteristics)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"10"	
Commodity Characteristic Description	57X	24-80	M	Common, market, usual name; free form invoice description; not product code description. For examples, see Appendix A: Use of PG10 Record.	

Table 7-10: Drug PG10

7.8 Record Identifier PG19 (Entity Data)

Mandatory | Repeatable per PGA Line

This is a mandatory PGA input record, requiring Entity Role, Entity Name, and Entity Address 1.

Entity Identification Code [16 (DUNS #), 47 (FEI #)] and Entity number are optional data elements, but they are listed as conditional because if opting to transmit Entity Identification Code, then Entity Number must also be provided, and vice versa.

Record Identifier PG19 (Entity Data)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"19"	
Entity Role Code	3AN	5-7	M	Code identifying the role of the entity being provided. For example, MF. Each entity role code can only be transmitted once per PGA line.	1,2,
Entity Identification Code	3AN	8-10	C	Code identifying the Entity Identification is entered. For example, 16 (DUNS #) or 47 (FEI #). Mandatory, if Entity Number is entered.	3
Entity Number	15X	11-25	C	Identifying Number (DUNS or FEI) for the associated Entity Identification Code. Mandatory if Entity Identification Code is provided.	3
Entity Name	32X	26-57	M	The name of the entity is required. If Entity Name requires additional space, continue in a PG60 record with Qualifier Code "ENA". Refer to the validation criteria below.	3
Entity Address 1	23X	58-80	M	The address of the entity is required. If Entity Address1 requires additional space, continue in a PG60 record with Qualifier Code "AD1".	3

Table 7-11: Drug PG19

Note 1
List of Entity Role codes that are **mandatory** to FDA Message Sets is noted below:

Data Element	**Code**	**Description**
Entity Role Codes	MF	Manufacturer of goods (Final producer for the final drug product). If the product is a bulk API, use "MF" as the Entity Role Code (rather than "GD" – Producer of API); If the product is in finished form, provide MF of final product.
	DEQ	Shipper
	FD1	FDA Importer (Importer of Record)
	DP	Delivered-To Party

Table 7-12: Drug Entity Role codes (Mandatory)

Note 2
List of Entity Role codes that are optional to FDA Message Sets is noted below. By providing these optional data elements when needed, will assist in an expedited review of the entry:

Data Element	Code	Description
Entity Role Codes	SPO	Sponsor – if different than MF or FD1
	GD	Producer (Producer of the API*)
	PK	Point of Contact (Filer/Broker Contact Information)

Table 7-13: Drug Entity Role codes (Optional)

*API – Active Pharmaceutical Ingredient

*** Rules for Finished Dosage Form Drugs ***
IF PG01 Intended Use Code =
080.012 Prescription health or medical product for human use that is the subject of an approved new drug application, abbreviated new drug application, or biologics license application OR
130.000 For Consumer Use as a Non- Food Product – Over the Counter (OTC) OR
980.000 For Other Use: (APIs or Finished Drugs not elsewhere classified)
THEN: must include one MF and may include one or more GD

REPEAT GD for EACH Active Pharmaceutical Ingredient in the dosage form

Note 3
Entity Identification Codes and their descriptions can be found in CBP's ACE CATAIR Appendix PGA (PG19 – Entity Identification Codes). List of Entity Identification codes applicable to FDA Drug Message Sets is noted below:

Data Element	Code	Description	Length/ Class
Entity Identification Codes	16	D&B-assigned (DUNS number); must be 9 digits	9N
	47	FDA-assigned (FEI number); must be from 1 to 10 digits	1 -10N

Table 7-14: Drug Entity Identification Codes

FDA SELECTION CRITERIA

FDA requires Entity Name and Entity Address.

IF Entity Identification Code =16 (DUNS) THEN Entity Number must be Length = 9 and Type = N
ELSE IF Entity Identification Code =47 (FEI) THEN Entity Number must be length from 1 to10 and Type = N

7.9 Record Identifier PG20 (Entity Address)

Mandatory | Repeatable per PGA Line

This is a mandatory PGA input record that provides additional data pertaining to Entity identification such as Entity Address line 2, Apartment/Suite, City, State, and Zip/Postal Code. This record is used when there is additional address information for the entity.

Record Identifier PG20 (Entity Address)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"20"	
Entity Address 2	32X	5-36	C	Address Line 2 for the Entity. If Entity Address2 requires additional space, continue in a PG60 record with Qualifier Code "AD2".	1
Entity Apartment Number/Suite Number	5X	37-41	C	Apartment/Suite number of the entity.	
Entity City	21X	42-62	M	City of the entity. If Entity City requires additional space, continue in a PG60 record with Qualifier Code "ECI".	
Entity State/Province	3AN	63-65	C	Refer to CBP's ACE CATAIR Appendix B for valid codes.	2
Entity Country	2A	66-67	M	Refer to CBP's ACE CATAIR Appendix B for valid codes.	3
Entity Zip/Postal Code	9X	68-76	C	Zip/Postal Code of the entity.	2

Table 7-15: Drug PG20

Note 1
If the Entity requires more than 2 address lines, use the optional PG60 records with Qualifier Codes "AD3", "AD4" and "AD5" immediately under the PG20 record for the same Entity.

Note 2
Required for US or Canada based entities

Note 3
If the Government Agency Processing Code is 804, then the PG20 Entity Country for DEQ (shipper) must be the Country Code for Canada.

7.10 Record Identifier PG21 (Point of Contact)

Mandatory | Repeatable per PGA Line

This is a mandatory PGA input record that provides point of contact information.

For each FDA line, at least one PG21 is required with the individual qualifier "FD1" (sent with the preceding PG19 and PG20 FD1 record).

FDA also highly encourages the transmission of PG21 with the individual qualifier "PK" which should be the point of contact for the filer/broker. "PK" may be sent in one of the following ways:

1) Under a PG19PK (transmitting PG19PK, PG20PK and PG21PK for the filer), the FDA preferred method, **OR**
2) As a secondary PG21 to FD1 using individual qualifier "PK" (transmitting PG19FD1, PG20FD1, PG21FD1, and PG21PK for the filer), **OR**
3) Under any other required PG19 entity as long as "PK" is the individual qualifier in PG21.

If provided, there should be only one PK per FDA line.

Although the PK (filer/broker contact information) is optional, transmitting this information will enable FDA to expeditiously contact the filer, instead of contacting the Importer of Record. If only the Importer of Record PG21 is transmitted and PK is not, FDA processing may be delayed.

Record Identifier PG21 (Point of Contact)					
Data Element	**Length /Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"21"	
Individual Qualifier	3AN	5-7	M	Identify the type of party or facility the Individual represents. Only "FD1" and "PK" are allowed.	
Individual Name	23X	8-30	M	Name of the Individual. If the name will not fit, continue in a PG60 record with Qualifier Code "INA".	
Telephone Number of the Individual	15X	31-45	M	Telephone number of the Individual. For example, (713) 555-8765 in US or (+65) 9052-3529 in Singapore	
Email Address for the Individual	35X	46-80	M	Email Address of the individual. If the Email Address exceeds in length, continue in a PG60 record with Qualifier Code "EMA".	1

Table 7-16: Drug PG21

Note 1
Only transmit one valid email address as you would in an email program. Do not include names, additional characters, etc.

Valid Example	first.last@company.com
Invalid Example	<first.last@company.com>
Invalid Example	FirstName LastName first.last@company.com
Invalid Example	FirstName LastName <first.last@company.com>
Invalid Example	first.last@company.com, first.last@company.com

7.11 Record Identifier PG23 (Affirmation of Compliance)

Conditional | Repeatable per PGA Line

This is a conditional PGA input record that provides data pertaining to FDA Affirmation of Compliance Criteria. This record is repeatable, but each affirmation of compliance code can only be transmitted once.

Record Identifier PG23 (Affirmation of Compliance)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"23"	
Affirmation of Compliance Code	5X	5-9	C	A code used to affirm compliance with FDA requirements. Refer to CBP's ACE CATAIR Appendix PGA (Food & Drug Affirmation of Compliance Codes) for valid codes..	1
Affirmation of Compliance Qualifier	30X	10-39	C	Text describing the information required by the PGA. For 'indicator only' AoC codes, this field is left blank. All other qualifiers must follow the syntax instructions for each code as specified in CBP's ACE CATAIR Appendix PGA	
Filler	1X	80	C	Space fill	

Table 7-17: Drug PG23

Note 1
The FDA Affirmation of Compliance Codes and their descriptions are listed in the CBP's ACE CATAIR Appendix PGA (Food & Drug Affirmation of Compliance, FDA Affirmation of Compliance Codes). The list of AoC codes applicable to FDA Drugs Message Sets is noted below:

*** Exemptions from providing Affirmations of Compliance ***
*** Pharmaceutical Necessities & Containers and Research & Development products do not need AoCs ***
***
For Government Agency Program Code = DRU and Government Agency Processing Code =
PHN: Pharmaceutical Necessities, Containers, Inactive Pharmaceutical Ingredients and Excipients; or
RND: Research and Development
THEN PG23 is not required

*** Import For Export entries, and Personal Importations do not require AoCs ***
For Government Agency Program Code = DRU and Intended Use Code =

- 100.000: Importation for Personal Use; OR 970.000: Import For Export

THEN PG23 is not required

When several PG23 records are included in the Message Set, the same AoC Code can be entered only once.

CONDITIONAL AoC codes for FDA Drugs Message Sets is noted below:

Data Element	**Code**	**Description**	**Syntax**	**Business Rules**	**Note**
Affirmation of Compliance Code	DA	New Drug Application Number or Abbreviated New Drug Application Number or	6N	If Government Agency Program Code = "DRU" and Government Agency Processing Code = "PRE" and Intended Use Code = 080.012, or 150.007, then DA is mandatory. If Government Agency Program Code = "DRU" and Government Agency Processing Code = "OTC" and	

Data Element	Code	Description	Syntax	Business Rules	Note
		Therapeutic Biologic Application Number		Intended Use Code = 130.000, or 150.007, 150.017, 155.009, or 920.000, then DA is optional. If Government Agency Program Code = “DRU” and Government Agency Processing Code = “PRE” and Intended Use Code = 150.017, 155.009, or 920.000, then DA is optional. If Government Agency Program Code = DRU and Government Agency Processing Code = 804 and Intended Use Code = 080.012, then DA is mandatory. The DA AoC includes all the previous AoC codes, NDA, ANDA and BLA.	
	REG	Drug Registration Number	9N	If Government Agency Program Code = “DRU” and Government Agency Processing Code is “PRE” and Intended Use Code = 080.012, or 980.000, then REG is mandatory. If Government Agency Program Code = “DRU” and If Government Agency Processing Code is “OTC” and Intended Use Code = 130.000, then REG is mandatory. If Government Agency Program Code = “DRU” and Government Agency Processing Code is (“PRE” or “OTC”) and Intended Use Code = 150.007, 150.013, 150.017, or 155.009, then REG is mandatory. If Government Agency Program Code = “DRU” and Intended Use Code = 920.000, then REG is optional. If Government Agency Program Code = “DRU” and If Government Agency Processing Code is “804” and Intended Use Code = 080.012, then REG is optional.	
	DLS	Drug Listing Number	10N	If Government Agency Program Code = “DRU” and Government Agency Processing Code is “PRE” and Intended Use Code = 080.012, or 980.000, then DLS is mandatory unless affirmation “PLR” is declared. If Government Agency Program Code = “DRU” and Government Agency Processing Code is “OTC” and Intended Use Code = 130.000, then DLS is mandatory. If Government Agency Program Code = “DRU” and Government Agency Processing Code is (“PRE” or “OTC”) and Intended Use Code = 150.007, 150.013, 150.017, or 155.009, then DLS is mandatory. If Government Agency Program Code = “DRU” and Intended Use Code = 920.000, then DLS is optional. If Government Agency Program Code = DRU and Government Agency Processing Code = 804 and Intended Use Code = 080.012, then DLS is mandatory.	2

Data Element	Code	Description	Syntax	Business Rules	Note
				The DLS AoC includes both the previous NDC and DLS AoC codes. Refer to the Note 2 below.	
	IND	Investigational New Drug Number	6N	If Government Agency Program Code = “DRU” and Government Agency Processing Code is “INV” and Intended Use Code = 180.009, then IND is mandatory.	
	FSR	Foreign Seller Registration Number	9N	If Government Agency Program Code = DRU and Government Agency Processing Code = 804 and Intended Use Code = 080.012, then FSR is mandatory.	
	PRN	Pre-import Request Number	6-10N	If Government Agency Program Code = DRU and Government Agency Processing Code = 804 and Intended Use Code = 080.012, then PRN is mandatory.	

Table 7-18: Drug AoC codes (Conditional)

Note 2
When importing finished dosage drugs that are imported by a Private Label Distributor (PLD), the Manufacturer in PG19 should be the actual manufacturer of the product being imported. The DLS should be the listing of the product by the Manufacturer who is not the Private Label Distributor.

OPTIONAL AoC codes for FDA Drugs Message Sets is noted below:

Data Element	Code	Description	Syntax	Business Rules
Affirmation of Compliance Code	ERR	Entry Review Requested	Indicator only	ERR is just used as an indicator, no data will follow
	PLR	Used to identify the shipment as a PLAIR import shipment	Indicator only	Used as an indicator, no data will follow.
	LST	Device Listing Number	Any of the following: A+6N; B+6N; C+6N; D+6N; E+6N; L+6N; Q+6N; R+6N	Refer to the IUC-AoC Mapping Table below
	PM#	Device Premarket Number	Any of the following: P+6N; N+4N, 5N, or 6N; D+6N; H+6N; K+6N; DEN+6N;	Refer to the IUC-AoC Mapping Table below
	IDE	Investigational Device Exemption Number	G+6N OR "NSR"	

Table 7-19: Drug AoC codes (Optional)

The mandatory (M), conditional (C), or optional (O) Affirmations of Compliance based on the Intended Use Code/Import Scenarios are listed below:

Intended Use[§] (Refer to PG01 for definition)	Import Scenarios	Mandatory AoC	Conditional AoC	Optional AoC
080.012	Prescription health or medical product for human use that is the subject of an approved new drug application, abbreviated new drug application, or biologics license application	DA	REG, DLS, FSR, PRN	PLR*
100.000	Importation for Personal Use			

Intended Use[§] (Refer to PG01 for definition)	Import Scenarios	Mandatory AoC	Conditional AoC	Optional AoC
110.000	For public exhibition or display of finished drug products, inactive ingredients, or containers/closure products. Excludes active pharmaceutical ingredients, and human drug products intended for distribution in the general public supply chain.			
130.000	For Consumer Use as a Non-Food Product – Over the Counter (OTC)	REG, DLS		DA
130.033	Inactive ingredients and intermediates for use in a pharmaceutical product (PHN only).			
150.007	Active Pharmaceutical Ingredient / Bulk Drug Substance for processing into a pharmaceutical product	REG, DLS	DA	
150.013	Active Pharmaceutical Ingredient / Bulk Drug Substance to be used for Pharmacy Compounding	REG, DLS		
150.017	Importation of a drug component (API) for use in a medical product regulated under a device (CDRH) application type (e.g., for use in a PMA/510(k) drug-device combination product)	REG, DLS		DA, LST, PM#, IDE
155.000	Packaging component or a container closure system for use in a pharmaceutical product (PHN only). Excludes finished drugs for repacking and relabeling, active pharmaceutical ingredient / bulk drug substance, inactive ingredients, and intermediates.			
155.009	Importation of a drug constituent part (drug product) for use in a medical product regulated under a device (CDRH) application type (e.g., for use in a PMA/510(k) drug-device combination product).	REG, DLS		DA, LST, PM#, IDE
180.000	For research and development of packaging components, containers closure systems, and inactive pharmaceutical ingredients and intermediates (PHN only)			
180.009	Chemical for research and development of a pharmaceutical product – subject of an Investigational New Drug application (IND), including Placebos	IND		
180.017	Chemical for research and development of a pharmaceutical product – laboratory testing only, no human/animal use			
180.018	Chemical for research and development; investigational use in animals			
180.026	Finished drug or API intended for use in an in vivo bioequivalence or bioavailability study in humans that qualifies under 21 CFR 320.31 for an exemption from the Part 312 requirements; or finished drug intended for use in clinical investigation in humans that qualifies for an exemption from Part 312 requirements.			
920.000	US Goods Returned			REG, DLS, DA, IND
970.000	Import for Export			
980.000	For Other Use: (APIs or Finished Drugs not elsewhere classified)	REG, DLS		

Table 7-20: Drug Affirmations of Compliance based on Intended Use Codes

§ If after consultation with the importer, who should know the intended use of the product, the filer still ***does not know*** the intended use of the product, "UNK" may be used in lieu of an IUC. In most cases, the line will be subject to manual review, and may result in a request for documentation and/or additional information about the product as the product offered for import will be treated as a standard import. Ensure the IUC (reason for importation) is transmitted to avoid delays. As per the ACE Rule, if "UNK" is submitted as the IUC for the article, the ACE filer is still responsible for submitting the other required data elements in this rule that are applicable to that article, at the time of entry. In the future, if those other data elements are not submitted in ACE at the time of entry, the entry may be transmitted by ACE to FDA for admissibility review, but FDA may reject the entry. If FDA rejects an entry filing, the ACE filer will need to resubmit the entry with complete and accurate information.

* Affirmation of Compliance 'PLR' not permitted under Agency Processing Code '804'.

7.12 Record Identifier PG24 (Remarks)

Optional | Not Repeatable per PGA Line

This is an optional PGA input record that provides data pertaining to Remarks Type Code and Remarks Text.

PG24 cannot be repeated and only one PG24 is allowed for the same FDA line.

If entered, the Remarks Type Code should be GEN and must be under the PG02.

Currently, FDA processes PG24 record only at the Product-level (when under a PG02)

Record Identifier PG24 (Remarks)					
Data Element	**Length /Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"24"	
Remarks Type Code	3X	5-7	O	FDA uses only "GEN" as its valid value.	
Remarks Text	68X	13-80	O	Free form text relevant to the shipment or the commodity.	

Table 7-21: Drug PG24

7.13 Record Identifier PG25 (Product Condition)

Conditional | Repeatable per PGA Line

This is a conditional PGA input record that provides data pertaining to Temperature Qualifier, Degree Type, Actual Temperature, Lot Number, Production Date Range of the Lot, and PGA Line Value. This record is repeatable for multiple Lot Numbers. If opting to transmit the line value, the PGA Line Value must be included on the first PG25 record.

Record Identifier PG25 (Product Condition)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"25"	
Temperature Qualifier	1A	5	O	Temperature Category being reported for quality control or preservation purposes. A=Ambient, F=Frozen R=Refrigerated/Chilled, D=Dry Ice H=Fresh, U=Uncontrolled P=Flashpoint	
Degree Type	1A	6	O	F=Fahrenheit, C=Celsius, K=Kelvin	1
Negative Number	1A	7	O	If the actual temperature is negative use an "X".	1
Actual Temperature	6N	8-13	O	Reported temperature. Two decimals places are implied.	1
Location of Temperature Recording	1A	14	O	Identifies recorded temperature is for A=product B=container C=conveyance	1
Lot Number Qualifier	1N	15	C	Code of the entity that assigned the Lot number. For Drugs the only valid value is: 1=Manufacturer In the case of multiple PG25 records for a given FDA line, enter Lot Number Qualifier only in the first PG25 record	2
Lot Number	25X	16-40	C	The lot number that the manufacturer/ producer/grower assigned to the product.	2
Production Start date of the Lot	8N	41-48	O	The date when the production for the Lot started. A numeric date in MMDDCCYY (month, day, century, year) format.	1
Production End Date of the Lot	8N	49-56	O	The date when the production for the Lot ended. A numeric date in MMDDCCYY (month, day, century, year) format.	1
PGA Line Value	12N	57-68	O	Although Line Value is optional, transmitting the value will assist in reviewing the product in a timely manner. Failure to transmit the value may result in delays associated with gathering missing information. If entered: • in the case of multiple PG25 records, enter value only in the first PG25 record • value should be in US Dollars, and enter whole dollars only	

Record Identifier PG25 (Product Condition)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
				• must be greater than zero and right justified with preceding zeros	

Table 7-22: Drug PG25

Note 1
This information is not currently used for FDA's review and admissibility process of drug products. Reserved for future use.

Note 2
If the Government Agency Processing Code is 804, then Lot or Control Number assigned by the manufacturer of the eligible prescription drug is mandatory.

7.14 Record Identifier PG26 (Product Packaging)

Conditional | Repeatable per PGA Line

This is a conditional PGA input record that provides FDA with data pertaining to Packaging Qualifier, Quantity and Unit of Measure. If included, the following rules apply:

This record can be repeated up to six (6) times, once for each unique packaging level. The first record is used to describe the largest (outermost) container and the number of containers at this packaging level. The second record is used to describe the contents of the next smallest container. If needed, qualifiers 2-6 are used in a similar manner (largest to smallest container). The final record must describe the actual amount of the product in the smallest container and must be selected from the list of base units below.

The appearance of any 'Packaging Qualifier' number level requires all levels under it to be represented. For instance, level 3 cannot be present unless levels 1 and 2 are present. The same Unit of Measure cannot be used multiple times on the same PGA line.

Record Identifier PG26 (Product Packaging)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"26"	
Packaging Qualifier	1N	5	C	This code identifies the level of packaging for the product. Outermost (largest=1) packages to the innermost (smallest=6) packages. There can be up to 6 levels of packaging. If reporting only one level, show the total quantity for the item and report that as level 1.	1,4, 5
Quantity	12N	6-17	C	Although quantity is optional, transmitting the quantity accurately and following the rules below will assist in reviewing the product in a timely manner. Failure to transmit the quantity records may result in delays associated with gathering missing information. If entered, this is the Quantity of the packaging level and two decimal places are implied. Must be greater than zero. Example: 000000000400 **Transmitting Quantity requires transmitting Packaging Qualifier and the Unit of Measure. Last unit transmitted must be a base unit and only one base unit is allowed.**	2,4, 5
Unit of Measure (Packaging Level)	5X	18-22	C	Type of packaging / packaging level. For example, BX. Cannot be repeated among the PG26 records.	3,4, 5

Table 7-23: Drug PG26

Note 1
This code identifies the level of packaging for the product. Valid values are 1, 2, 3, 4, 5 and 6: Outermost (largest=1) packages to the innermost (smallest=6) packages. There can be up to 6 levels of packaging

Note 2

There are two implied decimal points when writing the quantity in Units of Measure for all packaging levels. In this example, 4 pieces are represented as 000000000400, with the nine leading zeroes as “fill” and two decimal places following the value.

Note 3
List of Unit of Measure codes applicable to FDA-Drug Message Sets
For a full list of Unit of Measure codes for Packaging Containers, refer to Appendix D: FDA Unit of Measurement Codes in this document.

Valid DRUG Units of Measure (UoM) for the Base Unit (Last Quantity Transmitted) are limited to the chart below:

Code	Code Name	Measure Type
BBL	Barrel (42 Gallons Ea)	Volume
BOL	Boluses	Dosage
CAP	Capsules	Dosage
CFT	Cubic Feet	Volume
CG	Centigrams	Weight
CM	Centimeters	Length
CM3	Cubic Centimeters	Volume
CYD	Cubic Yard	Volume
FOZ	Ounces, fluid	Volume
FT	Feet	Length
G	Grams	Weight
GAL	Gallons	Volume
KG	Kilograms	Weight
KM	Kilometer	Length
KM2	1000 Square Meters	Area
KM3	1000 Cubic Meters	Volume
L	Liter	Volume
LB	Pounds (avdp)	Weight
LNM	Linear Meter	Length
M	Meter	Length
M2	Square Meter	Area
M3	Cubic Meter	Volume
MG	Milligrams	Weight
MCG	Micrograms	Weight
ML	Milliliters	Volume
OZ	Ounces	Volume
PCS	Pieces	Count
PTL	Pints	Volume
QTL	Quarts	Volume
STN	Short Ton	Weight
SUP	Suppositories	Dosage
T	Metric Ton	Weight
TAB	Tablets	Dosage
TON	Long Ton	Weight
TOZ	Ounces, Troy	Weight

Table 7-24 Drug UoM for Base Unit

Note 4
Quantity Data provides additional information to FDA about the product and how it is packaged. The basic format for Quantity Data is in multiple pairs of data – quantity and unit of measure, i.e., 500 cases, 12 ounces, fluid, 1000 cartons, etc. Up to 6 data pairs may be submitted, beginning with the 1st pair for the outermost packaging when Packaging Qualifier = 1. The first pairs may describe the largest container and the last pair must describe the amount of product in the smallest container. For example:

100 Cartons 24 Aspirin 100 tablets 325 mg

Units 1-Quantity	100
Units 1-Measure	CT
Units 2-Quantity	24
Units 2-Measure	BO
Units 3-Quantity	100
Units 3-Measure	TAB

In this case, the invoice description contains the strength of the aspirin tablets. The product quantity is listed using the "Tablets" quantity unit code.

Note 5
If the Government Agency Processing Code is 804, then FDA Quantity, which is the quantity of each eligible prescription drug in an import line delineated by packaging level, including the type of package from the largest packaging unit to the smallest packaging unit; the quantity of each packaging unit; and the volume and/or weight of each of the smallest of the packaging units, is mandatory.

7.15 Record Identifier PG30 (Anticipated Arrival Information)

Mandatory | Repeatable per PGA Line

This is a mandatory PGA input record that provides data pertaining to the date, time and location of the anticipated arrival/entry information for all FDA products.

For each line a PG30 record with an "A" (Anticipated arrival information) status code, date and time of arrival is mandatory. For entry type 21 coming from a Foreign Trade Zone, a PG30 record with an "F" (Foreign Trade Zone) code and FIRMS code for the FTZ location is required.

Record Identifier PG30 (Anticipated Arrival Information)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"30"	
Anticipated Arrival Information	1A	5	M	A (Anticipated Arrival Information). If entry type = 21, then repeat PG30 and enter F (Foreign Trade Zone).	1, 2
Anticipated Arrival Date at Port of Entry	8N	6-13	C	A numeric date in MMDDCCYY (month, day, century, year) format. **Mandatory if Status = 'A'**.	1, 2
Anticipated Arrival Time at Port of Entry	4N	14-17	C	Military time HHMM in (hour, minute) format. (Example: 1015, this represents 10:15 a.m.). For midnight, use 2400 (0000 is invalid). **Mandatory if Status = 'A'**.	1, 2
Inspection or Arrival Location Code	4AN	18-21	C	Only a value of '4' (=FIRMS Code) is allowed for entry type = 21. For entry type not = 21, this field is left blank.	
Inspection or Arrival Location	50X	22-71	C	Provide FIRMS Code here.For valid FIRMS codes, refer to ACS/ACE query. https://www.cbp.gov/document/report/acs-public-firms-code-report	
Filler	8X	72-80	M	Space fill	

Table 7-25: Drug PG30

Note 1
A= Anticipated Arrival Date and Time at the Anticipated Port of Entry.

Port of Entry:
19 CFR 101.1.
Port and port of entry. The terms "port" and "port of entry" refer to any place designated by Executive Order of the President, by order of the Secretary of the Treasury, or by Act of Congress, at which a Customs officer is authorized to accept entries of merchandise to collect duties, and to enforce the various provisions of the Customs and navigation laws. The terms "port" and "port of entry" incorporate the geographical area under the jurisdiction of a port director. (The Customs ports in the Virgin Islands, although under the jurisdiction of the Secretary of the Treasury, have their own Customs laws (48 U.S.C. 1406(i)). These ports, therefore, are outside the Customs territory of the United States and the ports thereof are not "ports of entry" within the meaning of these regulations).

Note 2
Examples on how to submit PG30

For all Entry Types other than Entry Type 21 Warehouse for an FTZ Withdrawal	For Entry Type 21 Warehouse for an FTZ Withdrawal
PG30 Record • Anticipated Arrival Information status code = “A” (anticipated arrival information) is mandatory • Anticipated Arrival Date at Port of Entry is mandatory • Anticipated Arrival Time at Port of Entry is mandatory	PG30 Record • Anticipated Arrival Information status code = “A” (anticipated arrival information) is mandatory • Anticipated Arrival Date at Port of Entry is mandatory • Anticipated Arrival Time at Port of Entry is mandatory Additional PG30 Record • Anticipated Arrival Information status code = “F” (FTZ) is mandatory • Anticipated Arrival Date at Port of Entry is optional • Anticipated Arrival Time at Port of Entry is optional • Inspection or Arrival Location Code = “4” (FIRMS Code) is mandatory • FTZ Location is mandatory

7.16 Record Identifier PG55 (Additional Entity Roles)

This is an optional PGA input record used to provide additional roles performed by an entity or individual.

Not supported by FDA at this time

Currently, the PG55 record is not supported by FDA. Multiple PG19 records should be used to input more than one Entity-Role combination. Refer to the PG19 section for details.

Record Identifier PG55 (Additional Entity Roles)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"55"	
Entity Role Code	3AN	5-7	O	Additional role of the entity.	
Entity Role Code	3AN	8-10	O	Additional role of the entity.	
Entity Role Code	3AN	11-13	O	Additional role of the entity.	
Entity Role Code	3AN	14-16	O	Additional role of the entity.	
Entity Role Code	3AN	17-19	O	Additional role of the entity.	
Entity Role Code	3AN	20-22	O	Additional role of the entity.	
Entity Role Code	3AN	23-25	O	Additional role of the entity.	
Entity Role Code	3AN	26-28	O	Additional role of the entity.	
Entity Role Code	3AN	29-31	O	Additional role of the entity.	
Entity Role Code	3AN	32-34	O	Additional role of the entity.	
Filler	8X	72-80	M	Space fill	

Table 7-26: Drug PG55

7.17 Record Identifier PG60 (Additional Information)

Optional | Repeatable per PGA Line

This is an optional PGA input record used to provide additional information about data in the PG record that precedes it during the submission of a PGA record set.

This record can follow a PG07, PG19, PG20 or PG21 record, and can only be used to provide the additional information noted by the Additional Information Qualifier Code list.

This record may be repeated.

Record Identifier PG60 (Additional Information)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"60"	
Additional information qualifier code	3AN	5-7	C	Code indicating the type of additional information being provided	1
Additional Information	73X	8-80	C	Text of the additional information related to the additional reference qualifier code	

Table 7-27: Drug PG60

Note 1
Valid PG60 Additional Information Qualifier Codes applicable to FDA Message Set are:

Code	Description
ENA	Continuation of Entity Name for PG19
AD1	Continuation of Entity address Line 1 for PG19
AD2	Continuation of Entity address Line 2 for PG20
AD3	Entity address Line 3 for PG20
AD4	Entity address Line 4 for PG20
AD5	Entity address Line 5 for PG20
ECI	Continuation of Entity City for PG20
INA	Continuation of Individual Name for PG21
EMA	Continuation of Email Address for PG21
TBN	Continuation of Trade/Brand Name for PG07

Table 7-28: Drug PG60 Additional Information Qualifier Codes

PG60 record should follow immediately after its parent. For example, a PG60: ENA record should follow PG19 and a PG60: TBN record should follow PG07.

7.18 Record Identifier PG00 (Data Substitution)

This is an optional record used at the CBP entry (or entry summary) header, CBP entry (or entry summary) line and/or PGA message set levels to indicate data substitution

PG00 Substitution Grouping
In situations where the trade finds it would be supplying identical information more than once within the PGA Message Set, a PG00 substitution grouping can be used, instead of repeating that information multiple times. Refer to the 'usage notes' in the ACE ABI CATAIR - Customs and Trade Automated Interface Requirements publication for detailed information.

Record Identifier PG00 (Data Substitution)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"00"	
Substitution Indicator	1X	5	O	Identifies either the start or end of the substitution group, or the location of where to place the substitute data within the PGA Message Set. The following codes are allowed: S=Start of the substitution group E=End of the substitution group R=Replace this record with the substitution group indicated by the Substitution Number	
Substitution Number	4AN	6-9	O	Sequential number assigned to, or referring to, a specific substitution group of data provided at the header level. This data element is mandatory when using the S or R substitution indicator.	
Filler	71X	10-80	M	Space fill	

Table 7-29: Drug PG00

8 Stand-alone Prior Notice Submission Data Elements and Values

This chapter describes the data elements for a Stand-alone Prior Notice submission. This chapter consists of Prior Notice Submission (801m) requirements and the PE record requirements for FDA PE/PX.

8.1 Prior Notice Stand-alone PE/PGA Data Elements by Mode of Transportation (Refer to the Note)

The following table makes references to select **entry-level data elements** from the PE10/PE15 to provide the context and to identify from which data source FDA expects to receive the required prior notice data elements for the specific modes of transportation. For additional information on the data elements found within the PE10/PE15 record, refer to the Stand-alone Filing for Prior Notice Data (PE/PX) CATAIR . This document describes only **line-level data** within the structure of the FDA PG Message Set.

Mode of Transportation (MOT)	Data Elements	Mapping	Mapping - Data Elements
AIR	Carrier	PE10	Carrier IATA - position 61-64
	Airway Bill Number	PE10/ PE15	Bill Type Indicator – R or M **PE10** Ref Qual Code = AWB Ref ID Num – bill number Including AWB prefix **PE15** BOL Number - bill number Including AWB prefix
	Express Carrier Tracking Number	PE10/ PE15	Bill Type Indicator T **PE10** Ref Qual Code = AWB Ref ID Num – tracking number Including AWB prefix **PE15** BOL Number - tracking number Including AWB prefix
	Flight Number	PG23	AoC - VFT - Voyage/Flight/Trip Number
	Container Number	PG27	Container Number
	Carrier Name	PG23	AoC - CAN – Carrier Name; If using a PG13 record OR if the IATA is not provided in the PE10 this AoC value is required.
OCEAN	Bill of Lading Number	PE10/ PE15	**PE10** Ref. Qual. Code 'BOL' Bill Type Indicator 'R' or 'M' Reference Id Number - report BOL number **PE15** Bill Type Indicator 'R' or 'M' BOL Number- report BOL number
	Issuer Code of BOL	PE10/ PE15	**PE10** – Code representing the BOL issuer **PE15** – Code representing the BOL issuer
	Express Carrier Tracking Number	PG28	Tracking number Carrier SCAC
	Carrier	PE10/ PE15	Carrier SCAC
	Carrier Name	PG23	AoC - CAN – Carrier Name Name If using a PG13 record OR if the SCAC is not provided in the PE10 this AoC value is required.
	Vessel Name	PG23	AoC – VES – Vessel Name

Mode of Transportation (MOT)	Data Elements	Mapping	Mapping - Data Elements
	Voyage Number	PG23	AoC - VFT - Voyage/Flight/Trip Number
	Container Number	PG27	Container Number
LAND - Bus, Truck	Bill of Lading	PE10/ PE15	**PE10** Ref. Qual. Code 'BOL,' Bill Type Indicator 'R' or 'M' Reference Id Number - report BOL number **PE15** Bill Type Indicator 'R' or 'M' BOL Number- report BOL number
	Issuer Code of BOL	PE10/ PE15	**PE10** Code representing the BOL issuer **PE15** Code representing the BOL issuer
	Express Carrier Tracking Number	PG28	Tracking number Carrier SCAC
	Trip Number	PG23	AoC - VFT - Voyage/Flight/Trip Number
	Carrier	PE10	Carrier SCAC
	Carrier Name	PG23	AoC - CAN – Carrier Name If the carrier SCAC is not reported in the PE10 or PG28, this field is required
	Container Number*	PG27	Container Number
	Bill of Lading Number	PE10/ PE15	**PE10** Ref. Qual. Code 'BOL,' Bill Type Indicator 'R' or 'M' Reference Id Number - report BOL number **PE15** Bill Type Indicator 'R' or 'M' BOL Number- report BOL number
LAND - Rail	Issuer Code of BOL	PE 10/ PE15	**PE10** - position 10-13 **PE15** - position 6-9
	Bill of Lading Number	PE10/ PE15	**PE10** Ref. Qual. Code 'BOL,' Bill Type Indicator 'R' or 'M' Reference Id Number - report BOL number **PE15** Bill Type Indicator 'R' or 'M' BOL Number- report BOL number
	Express Carrier Tracking Number	PG28	Tracking number Carrier SCAC
	Carrier	PE10	Carrier SCAC
	Carrier Name	PG23	PG23 AoC - CAN – Carrier Name If the carrier SCAC is not reported in the PE10 or PG28, this field is required
	Rail Car Number	PG23	AoC – RNO - Rail Car Number
	Container Number*	PG27	Container Number
	Trip Number	PG23	AoC - VFT - Voyage/Flight/Trip Number

*if applicable

Table 8-1: Stand-alone Prior Notice Non-PGA Data Elements by MOT

8.2 Food Commodity Data Elements and Values

Food commodities can be broken down into the following categories using the existing government agency data elements available in the PG01 message:

PG01 - Government Agency Code	Commodity Type	PG01 - Government Agency Program Code	Commodity Sub-Type	PG01 - Government Agency Processing Code
FDA	Food	FOO	Natural State Food	NSF
FDA	Food	FOO	Processed Food	PRO
FDA	Food	FOO	Animal Food (includes pet food, medicated feed and feeds)	FEE
FDA	Food	FOO	Additives and Colors	ADD
FDA	Food	FOO	Dietary Supplements	DSU

Table 8-2: Stand-alone Prior Notice Food Commodity Hierarchy

The following are the potential PGA records associated with submitting Prior Notice:

PG Record	Description
PG01	FDA program that regulates the product
PG02	Item Type and Product Code details
PG06	Product Origin (FDA Country of Production, Shipment, and Refusal)
PG10	Product Description (Line level Item Common/Usual/Market Name Description)
PG13	License Plate Issuer for Privately Owned Vehicle (POV)
PG14	License Plate Number for Privately Owned Vehicle (POV)
PG19	Entity Role (manufacturer, consignee, shipper, etc.) Entity Identification, Entity Name, and Entity Address 1
PG20	Additional address data on the entity in PG19(Address line 2, Apartment/Suite, City, State, and Zip/Postal Code).
PG21	Entity of Record's (manufacturer, shipper, etc.) individual point of contact, phone number and email.
PG23	FDA's Affirmation of Compliance Criteria
PG24	Remarks
PG25	Lot Number Qualifier and Lot Number
PG26	Packaging qualifier and quantity of the shipment
PG27	Container Number
PG28	Express Courier Tracking Number§
PG30	Date, time and location of anticipated arrival information
PG55	Additional Role(s) (for future use)
PG60	Additional Information following a PG07, PG19, PG20 or PG21
PG00	Data Substitution

Table 8-3: Stand-alone Prior Notice PGA Records

§ CBP confirmed that the PE header can only be used to submit express courier tracking numbers approved by Air Cargo Advanced Screening (ACAS) pilot in the air environment. Express courier tracking numbers for PNs for food shipments in the ground/air environment are to be reported in the PG28.

8.3 Prior Notice Example

Stand-alone Prior Notice message set layout sample below:

Refer to the external file: **FDA SG Example PG Message Sets** **Tab:** ***PN Only***

PGA records and data elements required are dependent on the agency program and processing code selected. For a more expansive set of examples of FDA PGA Message Sets, refer to the above document.

8.4 Record Identifier PG01 (PGA Identifier)

Mandatory | Not Repeatable per PGA Line

For Stand-alone Prior Notice, this is a mandatory input record that provides data pertaining to the PGA Line Number, Government Agency Code, Government Agency Program Code, Government Agency Processing Code and Intended Use Code.

Record Identifier PG01 (PGA Identifier)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"01"	
PGA Line Number	3N	5-7	M	Begin with "001" and sequentially increment the line number on subsequent PG01 records, if applicable	
Government Agency Code	3X	8-10	M	"FDA"	
Government Agency Program Code	3X	11-13	M	"FOO"	1
Government Agency Processing Code	3X	14-16	M	For allowed values Codes for Food, refer to the Note 1 below.	1
Intended Use Code	16X	42-57	O	Refer to the table below for valid optional values.	2, 3
Intended Use Description	21X	58-78	O	N/A for FDA lines	
Correction Indicator	1X	79	O	For future use	

Table 8-4: Stand-alone Prior Notice PG01

Note 1
Refer to Table 8-2 above for the commodity for Human Food and Animal Food commodities applicable for Prior Notice.

Note 2
Note that CBP publication, Appendix R - Intended Use Codes for ACE, provides general descriptions of all Intended Use Codes for all Partner Government Agencies (PGAs). For FDA regulated products, use the IUC descriptions as specified per commodity throughout this document. See Appendix E for a mapping of FDA IUC descriptions to CBP Appendix R IUC descriptions. The submission of an Intended Use Code is not a requirement for Food. If providing an Intended Use Code, the following are the applicable options:

FDA Import Scenario	Intended Use Code	CBP Intended Use Name
For Research Use as Human Food	260.000	For Research Use as Human Food
For Research Use as an Animal Food	015.000	For Research Use as an Animal Food
Personal Importation	210.000	For Personal Use as Human Food

Table 8-5: Stand-alone Prior Notice Intended Use Codes

Note 3
If after consultation with the importer, who should know the intended use of the product, the filer still ***does not know*** the intended use of the product, "UNK" may be used in lieu of an IUC. In most cases, the line will be subject to manual review, and may result in a request for documentation and/or additional information about the product as the product offered for import will be treated as a standard import. Ensure the IUC (reason for importation) is transmitted to avoid delays. As per the ACE Rule, if "UNK" is submitted as the IUC for the article, the ACE filer is still responsible for submitting the other required data elements in this rule that are applicable to that article, at the time of entry. In the future, if those other data elements are not submitted in ACE at the time of entry, the entry may be transmitted by ACE to FDA for admissibility review, but FDA may reject the entry. If FDA rejects an entry filing, the ACE filer will need to resubmit the entry with complete and accurate information.

8.5 Record Identifier PG02 (Product Identifier)

Mandatory | Not Repeatable per PGA Line

For Stand-alone Prior Notice, this mandatory input record is used to include information related to a product (P). The Product Code Qualifier and Number are used to provide FDA Product Code.

Record Identifier PG02 (Product Identifier)					
Data Element	**Length /Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"02"	
Item Type	1A	5	M	Code identifying the following records as pertaining to P=Product. No other values accepted. Only one "P" record is allowed for the same PGA Line # in PG01	
Product Code Qualifier	4X	6-9	M	"FDP"	1
Product Code Number	19X	10-28	M	The FDA Product Code must be exactly 7 characters	

Table 8-6: Stand-alone Prior Notice PG02

Note 1
Product Code Qualifiers and their descriptions can be found in CBP's ACE CATAIR Appendix PGA (PG02 – Product Code Qualifiers). For FDA filings, the Product Code Qualifier is always "FDP".
Only one Product Code Number is allowed per line.

FDA Product Code Structure

Position	1-2	3	4	5	6-7
Name	Industry Code (N)	Class Code (AN)	Subclass Code (A or '-')	Process Indicator Code - PIC (A or '-')	Product (AN)

Legend - N: Numeric; A: Alphabetic; AN: Alphanumeric

Table 8-7: Stand-alone Prior Notice FDA Product Code Structure

A product is subject to Prior Notice requirements if any of the following conditions is satisfied.

if Industry Code IN ('07', '09', '69', '70', '71', '72')
OR if Industry Code BETWEEN '02' and '05'
OR if Industry Code BETWEEN '12' and '18'
OR if Industry Code BETWEEN '20' and '42'
OR if Industry Code BETWEEN '45' and '46'
OR if (Industry Code = '50' and Class Code in ('C', 'D', 'E', 'F', 'G', 'L')
OR if (Industry Code = '52' and Class Code = 'D'
OR if (Industry Code = '54' and Subclass Code in ('A','B','C','L','M')

8.6 Record Identifier PG06 (Product Origin)

Mandatory | Repeatable per PGA Line

For Stand-alone Prior Notice, this is a mandatory input record that provides data pertaining to Source Type (FDA country of production/growth and country from which the article was shipped) for the article of food. This record also provides the conditional PN data concerning the Country (or Countries) who previously refused entry of the article of food. This record can be repeated to submit the countries required for PN as described in Note 1.

Record Identifier PG06 (Product Origin)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	”PG”	
Record Type	2N	3-4	M	”06”	
Source Type Code	3X	5-7	M	Source Type Code must be selected using the following logic. IF Government Agency Program Code = “FOO” and natural state food/feed THEN use 262 (Place of Growth) ELSE use 39 (Country of Production). IF Government Agency Program Code = “FOO”, THEN requires CSH (Country of Shipment). IF refused by another country, use 294.	1
Country Code	2X	8-9	M	Must match the country code in PG19-PG20 record based on the value entered for Source Type Code: Source Type Code — Entity Role Code 39 — MF 262 — DFI or FDC	2

Table 8-8: Stand-alone Prior Notice PG06

Note 1
Source Type Codes and their descriptions can be found in CBP’s ACE CATAIR Appendix PGA (PG06 – Source Type Codes).
Prior Notice requires the following data elements:

1. Country of Shipment, Source Type Code = CSH
2. All Natural State Human Food and Animal Food requires the
   - Country of Growth**,** Source Type Code = 262 –the country where the article of food was grown - for fish/seafood caught outside the waters of the US = country in which the vessel who caught the fish/seafood is registered.
3. Non-Natural State Human Food and Animal Food requires the
   - Country of Production, Source Type Code = 39 - the country where the article of food was made - if made from fish/seafood aboard a vessel = country in which the vessel is registered.
4. Country of Entry Refusal, if the article of food was refused by other country (countries), provide the country code(s) as a part of the Prior Notice submission. (Source Code Type = 294)

Note 2
Any of the country codes from CBP’s ACE CATAIR Appendix B (Section: Country and Currency Codes) can be entered.

8.7 Record Identifier PG10 (Product Characteristics)

Mandatory | Not Repeatable per PGA Line

This is a mandatory PGA input record that allows for reporting the description of the product identified by the Product Code in PG02.

Record Identifier PG10 (Product Characteristics)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	”PG”	
Record Type	2N	3-4	M	”10”	
Commodity Characteristic Description	57X	24-80	M	Common, market, usual name; free form invoice description; not product code description. For examples, see Appendix A: Use of PG10 Record.	1

Table 8-9: Stand-alone Prior Notice PG10

Note 1
For PN at least one common, market or usual name in PG10 must be provided.

8.8 Record Identifier PG13 (License Plate Issuer)

Conditional | Not Repeatable per PGA Line

This is a conditional input record that provides data pertaining to Licenses, Permits, Certificates, or Other (LPCO). For Prior Notice submission, this PG record is only required when the carrier is a privately-owned vehicle and does not have a SCAC or IATA. For this situation, this PG record allows for the submission of some of the license plate information for the subject privately owned vehicle. The data elements included in this record are Issuer and location of issuer of the LPCO. If using this record, a PG14 and PG23 (Carrier Name – CAN) are mandatory.

Record Identifier PG13 (License Plate Issuer)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	”PG”	
Record Type	2N	3-4	M	”13”	
Issuer of LPCO	35X	5-39	O	Identifies the entity that issued the LPCO. Leave blank - not required (reserved for future use)	1
LPCO Issuer - Government Geographic Code Qualifier	3A	40-42	C	The code relating to the location of the issuer of the Privately-Owned Vehicle (POV) license plate. Select one: Canadian Province = PR Country Code = ISO Mexican State = MS US State = US	1
Location (Country/State/Province) of Issuer of the LPCO	3A	43-45	C	Identifies the location of the issuer of the POV license plate (ex: the US, Mexico or Canadian Province/State code or Foreign Country Code). Enter the appropriate code from CBP’s ACE CATAIR Appendix B.	1
Regional description of location of Agency Issuing the LPCO	25X	46-70	C	This description allows for the submission of a License Plate Issuer location when the Issuer is reported as an ISO and State or Province other than those from the US, Canada, or Mexico.	1
Filler	10X	71-80	M	Space fill	

Table 8-10: Stand-alone Prior Notice PG13

Note 1
When the Carrier is a privately-owned vehicle (POV), the following Prior Notice data requirements should be submitted using PG13 and PG14 in place of a SCAC or IATA.

License Plate Number	**PG14** – LPCO Number
License State (US)	**PG13** - LPCO Issuer - Location (Country/State/Province) of Issuer of the LPCO
License Province	**PG13** - LPCO Issuer - Location (Country/State/Province) of Issuer of the LPCO
License Country	**PG13** - LPCO Issuer - Government Geographic Code Qualifier

8.9 Record Identifier PG14 (License Plate Number)

Conditional | Not Repeatable per PGA Line

This is a conditional input record applicable for Stand-alone Prior Notice. Where the carrier is a privately-owned vehicle, provide the Privately-Owned Vehicle license plate information.

Record Identifier PG14 (License Plate Number)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	”PG”	
Record Type	2N	3-4	M	”14”	
LPCO Transaction Type	1N	5	O	Leave blank - not required (reserved for future use)	
LPCO Type	3AN	6-8	C	Identifies Type Code for Privately-Owned Vehicle (POV) license plate number as applicable. Use “POV” for Type	1
LPCO Number (or Name)	33X	9-41	C	Identifies the number that corresponds to the Privately-Owned Vehicle license plate number.	

Table 8-11: Stand-alone Prior Notice PG14

Note 1
When the Carrier is a privately-owned vehicle (POV), the above Prior Notice data requirements should be submitted using PG13 and PG14 in place of a SCAC or IATA.

8.10 Record Identifier PG19 (Entity Data)

Mandatory | Repeatable per PGA Line

This is a mandatory PGA input record requiring Entity Role, Entity Name, and Entity Address 1.

Entity Identification Code [16 (DUNS #), 47 (FEI #)] and Entity number are optional data elements, but they are listed as conditional because if opting to transmit Entity Identification Code, then Entity Number must also be provided, and vice versa.

Record Identifier PG19 (Entity Data)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"19"	
Entity Role Code	3X	5-7	M	Code identifying the role of the entity being provided. For example: MF (Manufacturer), UC (Ultimate Consignee). Each entity role code can only be transmitted once per PGA line.	1
Entity Identification Code	3X	8-10	C	Code identifying the Entity Type is entered. For example: 16 (DUNS #), 47 (FEI #). Mandatory, if Entity Number is entered. Optional otherwise.	2
Entity Number	15X	11-25	C	Identifying Number (DUNS or FEI) for the associated Entity Identification Code. Mandatory if Entity Identification Code is provided.	2
Entity Name	32X	26-57	M	The name of the entity is entered. If Entity Name requires additional space, continue in a PG60 record with Qualifier Code "ENA". Refer to the validation criteria below.	2
Entity Address 1	23X	58-80	C	Conditional only for the Manufacturer (MF), PN Transmitter (PNT), and/or PN Submitter (PNS) entities if a Food Facility Registration number is included in PG23. Mandatory for all other required entities. If Entity Address1 requires additional space, continue in a PG60 record with Qualifier Code "AD1".	1, 2, 3

Table 8-12: Stand-alone Prior Notice PG19

Note 1
Entity Role Codes that are mandatory to FDA Prior Notice Message Sets are noted below:

Data Element	**Code**	**Description**	**Additional Information**
Entity Role Codes	PNS	PN Submitter	If the facility is registered, then Submitter Food Facility Registration Number (SRN) may be provided in PG23 with Name, City and Country or provide full address in PG19 and PG20, see Note 3
	PNT	PN Transmitter	If the facility is registered, the Transmitter Food Facility Registration Number(TFR) may be provided in PG23 with Name, City and Country or provide full address in PG19 and PG20, see Note 3

Data Element	Code	Description	Additional Information
Entity Role Codes	MF[2] **-OR-** FDC[2] **-OR-** DFI[2]	Manufacturer[1]	Provide the Manufacturer Food Facility Registration Number (PFR) in PG23 with Name, City and Country or provide full address in PG19 and PG20, see Note 3
		FDA Consolidator[1]	Full address of the firm or person (if individual) who consolidated the articles of food from the grower(s) is required when the food/feed is in its natural state and the grower(s) is/are unknown. If registered, then Consolidator Food Facility Registration Number (CFR) may be provided in PG23 with Name, City and Country or provide full address in PG19 and PG20, see Note 3.
		Grower[1]	Full address of the growing location of the grower or person (if individual) is required when the food/feed is in its natural state. If registered, then the Grower Food Facility Registration Number (GFR)may be provided (if available) in PG23.
	DEQ	Shipper	If registered, then Shipper Food Facility Registration Number (SFR)may be provided in PG23 Full address of Shipper is required. See Note 3

Table 8-13: Stand-alone Prior Notice Entity Role Codes (Mandatory)

[1] The PN regulation requires **ONLY ONE** of the following Entity Role Codes:
IF the food/feed is not in natural state THEN Manufacturer (MF)
IF the food/feed is in natural state THEN Grower (DFI)
IF the food/feed is in natural state, and Grower is unknown THEN Consolidator (FDC)

[2] Only one of the Entity Role Codes MF/FDC/DFI is permitted.

List of Entity Role codes that are **conditionally** required to FDA Prior Notice Message Sets is noted below:

Data Element	Code	Description	Condition
Entity Role Codes	LG	Location of Goods (Secure Holding Facility for PN Purposes)	This entity is only required for PN when the article of food/feed was refused for inadequate PN and moved under CBP Supervision. This entity is the location and address where refused food is held.
	FD1	FDA Importer (Importer of Record)	Except for Transportation & Exportation (T&E) entries, full address of the Importer is required. If registered, the Importer's Food Facility Registration Number (IFR) may be provided in PG23.
	UC	Ultimate Consignee (Delivered to Party)	Except for Transportation & Exportation (T&E) entries, full address of the UC is required. If registered, the Ultimate Consignee Food Facility Registration Number (UFR) may be provided in PG23.
	DFP	Owner	Except for Transportation & Exportation (T&E) entries, full address of the Owner is required. If registered, the Owner's Food Facility Registration Number (ORN) may be provided in PG23.

Table 8-14: Stand-alone Prior Notice Entity Role Codes (Conditional)

List of Entity Role codes that are **optional** to FDA Prior Notice Message Sets is noted below. These codes may not be used as a substitute for the mandatory or conditional entities listed above.

Data Element	Code	Description
Entity Role Codes	PK	Point of Contact (Filer/Broker Contact Information)

Table 8-15: Stand-alone Prior Notice Entity Role Codes (Optional)

Note 2

Entity Identification Codes and their descriptions can be found in CBP's ACE CATAIR Appendix PGA "PG19 – Entity Identification Codes". List of Entity Identification codes applicable to FDA Prior Notice Message Sets is noted below:

Data Element	Code	Description	Length/ Class
Entity Identification Codes[1]	16	D&B-assigned (DUNS number); must be 9 digits	9N
	47	FDA-assigned (FEI number); must be from 1 to 10 digits	1 - 10N

Table 8-16: Stand-alone Prior Notice Entity Identification Codes.

IF Entity Identification Code =16 (DUNS) THEN Entity Number must be Length = 9 and Type = N
ELSE IF Entity Identification Code =47 (FEI) THEN Entity Number must be Length from 1 to 10 and Type = N

Note 3:
Use PG19 & PG20 to provide full address information, which includes entity street name and number; suite/unit number, as appropriate; City; Province or State as appropriate; mail code as appropriate; and Country.

8.11 Record Identifier PG20 (Entity Address)

Mandatory | Repeatable per PGA Line

This is a mandatory PGA input record that provides additional data pertaining to Entity identification such as Entity Address line 2, Apartment/Suite, City, State, and Zip/Postal Code. This record is used with the PG19 and may be repeated if PG19 is repeated.

Record Identifier PG20 (Entity Address)					
Data Element	**Length /Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	”PG”	
Record Type	2N	3-4	M	”20”	
Entity Address 2	32X	5-36	C	Address Line 2 for the Entity. If Entity Address2 requires additional space, continue in a PG60 record with Qualifier Code “AD2”.	1
Entity Apartment Number/Suite Number	5X	37-41	C	Apartment/Suite number of the entity.	
Entity City	21X	42-62	M	City of the entity. If Entity City requires additional space, continue in a PG60 record with Qualifier Code “ECI”.	
Entity State/Province	3X	63-65	C	Refer to CBP’s ACE CATAIR Appendix B for valid codes.	2
Entity Country	2A	66-67	M	Refer to CBP’s ACE CATAIR Appendix B for valid codes.	
Entity Zip/Postal Code	9X	68-76	C	Zip/Postal Code of the entity.	2
Filler	4X	77-80	M	Space fill	

Table 8-17: Stand-alone Prior Notice PG20

Note 1
If the Entity requires more than 2 address lines, use the optional PG60 records with Qualifier Codes “AD3”, “AD4” and “AD5” immediately under the PG20 record for the same Entity.

Note 2
Required for US or Canada based entities

8.12 Record Identifier PG21 (Point of Contact)

Mandatory | Repeatable per PGA Line

This is a mandatory PGA input record that provides point of contact information.

For all FDA lines with 801(m) data, at least two PG21 records are required with the individual qualifiers: "PNS" (PN Submitter) and PNT" (PN Transmitter) (sent with the preceding PG19 and matching individual qualifier in the PG21 records). An optional PG21 with the individual qualifier "FD1" may be transmitted with the preceding PG19FD1 and PG20FD1.

FDA also highly encourages the transmission of PG21 with the individual qualifier "PK" which should be the point of contact for the filer/broker. "PK" may be sent in one of the following ways:

1) Under a PG19PK (transmitting PG19PK, PG20PK and PG21PK for the filer), the FDA preferred method, **OR**
2) As a secondary PG21 to FD1 using individual qualifier "PK" (transmitting PG19FD1, PG20FD1, PG21FD1, and PG21PK for the filer), **OR**
3) Under any other required PG19 entity as long as "PK" is the individual qualifier in PG21

If provided, there should be only one PK per FDA line.

Although the PK (filer/broker contact information) is optional, transmitting this information will enable FDA to expeditiously contact the filer, instead of contacting the Importer of Record. If only the Importer of Record PG21 is transmitted and PK is not, FDA processing may be delayed. An optional PG21 with a fax is allowed for the Submitter and Transmitter.

Record Identifier PG21 (Point of Contact)					
Data Element	**Length /Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"21"	
Individual Qualifier	3X	5-7	M	Identify the type of party or facility the Individual represents. For example, person is associated to the PN Submitter and PN Transmitter. Only the values of "PNS", "PNT", "FD1" or "PK" are allowed.	
Individual Name	23X	8-30	M	Name of the Individual. If the name will not fit, continue in a PG60 record with Qualifier Code "INA".	
Telephone Number of the Individual	15X	31-45	M	Telephone number of the Individual. For example, (713)555-8765 in US or (+65)9052-3529 in Singapore	
Email Address or fax for the Individual	35X	46-80	M	Enter the email Address or the fax number of the individual. If the Email Address exceeds in length, continue in a PG60 record with Qualifier Code "EMA".	1

Table 8-18: Stand-alone Prior Notice PG21

Note 1
When transmitting an email address only transmit one valid email address as you would in an email program. Do not include names, additional characters, etc.

Valid Example	first.last@company.com
Invalid Example	<first.last@company.com>
Invalid Example	FirstName LastName first.last@company.com
Invalid Example	FirstName LastName <first.last@company.com>
Invalid Example	first.last@company.com, first.last@company.com

8.13 Record Identifier PG23 (Affirmation of Compliance)

Conditional | Repeatable per PGA Line

This is a conditional or optional PGA input record that provides data pertaining to FDA Affirmation of Compliance Criteria. This record is repeatable, but each affirmation of compliance code can only be transmitted once unless the code is RNO. RNO may be repeated to report multiple rail car numbers if necessary and applicable.

Record Identifier PG23 (Affirmation of Compliance)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	”PG”	
Record Type	2N	3-4	M	”23”	
Affirmation of Compliance Code	5X	5-9	C	A code used to affirm compliance with FDA requirements. If the merchandise is subject to BTA, use this field to report the appropriate affirmation of compliance information, not reported elsewhere. Refer to CBP’s ACE CATAIR Appendix PGA (Food & Drug Affirmation of Compliance Codes) for valid codes.	1,2
Affirmation of Compliance Qualifier	30X	10-39	C	Text describing the information required by the PGA. For ‘indicator only’ AoC codes, this field is left blank. When free text is allowed, Affirmation of Compliance Qualifiers cannot exceed 30X. All other qualifiers must follow the syntax instructions for each code as specified in CBP’s ACE CATAIR Appendix PGA.	1
Filler	1X	80	C	Space fill	

Table 8-19: Stand-alone Prior Notice PG23

Note 1

The list of **CONDITIONAL** AoC codes for the FDA Prior Notice Message Set is noted below:

Data Element	**Code**	**Description**	**Syntax**	**Business Rules**
Affirmation of Compliance Code	PFR§	Manufacturer Food Facility Registration number	11N	Manufacturer registration number is required unless: • Food Processing Facility Registration Exemption (FME) and Reason code is submitted OR • Consolidator (FDC)/Grower (DFI) role code is submitted in lieu of Manufacturer (MF) for food/feed in its natural state. If both FME and PFR are submitted, FME is not used by the FDA.
	RNO	Rail Car Number		Required if MOT = Rail or MOT = Containerized Rail. For multiple Rail Car Numbers, repeat PG23 as needed. If Rail Car Number is unavailable, enter ‘Does Not Exist’.
	CAN	Carrier Name		Required if using a PG13 record OR if the SCAC or IATA are not provided.

Data Element	Code	Description	Syntax	Business Rules
Affirmation of Compliance Code	VFT	Voyage, Trip, Flight Number		Required if MOT = Air, Rail, Truck or Ocean, if it exists. If article of food is arriving by Express Consignment Operator or Carrier AND neither the PN submitter nor PN transmitter is the Express Consignment Operator or Carrier, the Express Consignment Operator or Carrier Tracking Number may be submitted in lieu of the Flight Number. If the Trip Number is unavailable, enter 'Does Not Exist'.
	VES	Vessel Name		Required if MOT = Ocean
	FME§	Food Processing Facility Registration Exemption	1A	Refer to Appendix B: Food Facility Registration Exemption (FME) at the end of this document for valid codes. Required if PG19 Entity Role Code = MF AND PFR is not provided. If both FME and PFR are submitted with Entity Role Code = MF, FDA will review the registration (PFR). When food or feed is in a natural state and the entity role code DFI (Grower) or FDC (Consolidator) is entered in lieu of manufacturer, FME and Food Facility Registration (PFR) Number are not required.

Table 8-20: Stand-alone Prior Notice AoC Codes (Conditional)

Note 2
The list of **OPTIONAL** AoC codes for the FDA Prior Notice Message Set is noted below:

Data Element	Code	Description	Syntax	Business Rules
Affirmation of Compliance Code	SFR	Shipper Food Facility Registration number	11N	Optional
	UFR	Ultimate Consignee Food Facility Registration number	11N	Optional
	IFR	Importer Food Facility Registration number	11N	Optional
	TFR	Transmitter Food Facility Registration number	11N	Optional
	ORN	Owner Food Facility Registration number	11N	Optional
	SRN	Submitter Food Facility Registration number	11N	Optional
	CFR§	Consolidator Food Facility Registration number	11N	Optional
	GFR§	Grower Food Facility Registration number	11N	Optional
	LFR	Location of Goods (Holding Facility Registration number)	11N	Optional

Table 8-21: Stand-alone Prior Notice AoC Codes (Optional)

§ When AoC codes are entered on the PG23 record for Entity Role Codes MF/FDC/DFI in PG19, then only a PFR or FME shall be used along with MF; only a GFR may be used in conjunction with DFI; and only a CFR may be used in conjunction with FDC.

8.14 Record Identifier PG24 (Remarks)

Optional | Not Repeatable per PGA Line

This is an optional PGA input record that provides data pertaining to Remarks Type Code and Remarks Text.

PG24 cannot be repeated and only one PG24 is allowed for the same FDA line.

If entered, the Remarks Type Code should be GEN and must be under the PG02.

Currently, FDA processes PG24 record only at the Product-level (when under a PG02)

Record Identifier PG24 (Remarks)					
Data Element	**Length /Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"24"	
Remarks Type Code	3X	5-7	C	FDA uses only "GEN" as its valid value.	
Remarks Text	68X	13-80	C	Free form text relevant to the shipment or the commodity.	

Table 8-22: Stand-alone Prior Notice PG24

8.15 Record Identifier PG25 (Product Condition)

Conditional | Repeatable per PGA Line

This is a conditional input record that provides data pertaining to Lot Number required by FDA regulations for Infant formula, Acidified Foods, and LACF products. This record is repeatable for multiple Lot Numbers.

Record Identifier PG25 (Product Condition)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	”PG”	
Record Type	2N	3-4	M	”25”	
Lot Number Qualifier	1N	15	C	Includes Lots and/or Batches. Mandatory for Infant formula, Acidified Foods, and LACF/AF products. In the case of multiple PG25 records for a given FDA line, enter Lot Number Qualifier only in the first PG25 record. Code of the entity that assigned the Lot number. 1=Manufacturer.	
Lot Number	25X	16-40	C	The lot number that the manufacturer assigned to the product. Mandatory for Infant formula, Acidified Foods, and LACF products. Required, if more than one PG25 record is entered.	1

Table 8-23: Stand-alone Prior Notice PG25

Note 1
Using the FDA Product Code in PG02, the following classifications are made where specific imported food/feed products require the submission of lot or code numbers or other identifier with prior notice. These include:

LACF and Acidified:

LACF: Industry Codes: 02-05, 07, 09, 12-18, 20-41, 71, & 72 with PIC: **F** (Aseptic) and **E** (Commercially Sterile)
AF: Industry Codes: 02-05, 07, 09, 12-18, 20-41, 71, & 72 with PIC: **I** (Acidified)

Infant Formula:

Industry Code: 40
With Class:

- C-Formula Prod (Baby)
- N-Ready to Feed Formula Product
- O-Liquid Concentrate Formula Product
- P-Powder Formula Products
- R-Infant Formula for Sample Testing (not for sale)

8.16 Record Identifier PG26 (Product Packaging)

Mandatory | Repeatable per PGA Line

For Stand-alone Prior Notice, this is a mandatory input record that provides FDA with estimated quantity of food to be shipped by describing the Packaging Qualifier, Quantity and Unit of Measure. The following rules apply:

This record can be repeated up to six (6) times, once for each unique packaging level. The first record is used to describe the largest (outermost) container and the number of containers at this packaging level. The second record is used to describe the contents of the next smallest container. If needed, qualifiers 2-6 are used in a similar manner (largest to smallest container). The final record must describe the actual amount of the product in the smallest container.

The appearance of any 'Packaging Qualifier' number level requires all levels under it to be represented. For instance, level 3 cannot be present unless levels 1 and 2 are present.

Record Identifier PG26 (Product Packaging)					
Data Element	**Length /Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"26"	
Packaging Qualifier	1N	5	M	This code identifies the level of packaging for the product. Outermost (largest=1) packages to the innermost (smallest=6) packages. There can be up to 6 levels of packaging. If reporting only one level, show the total quantity for the item and report that as level 1.	1, 4
Quantity	12N	6-17	M	"Quantity of the packaging level, For example, 000000000400. Two decimal places are implied. Must be greater than zero. **Transmitting Quantity requires transmitting Packaging Qualifier and the Unit of Measure. Last unit transmitted must be a base unit and only one base unit is allowed.**	2, 4
Unit of Measure (Packaging Level)	5X	18-22	M	Type of packaging / packaging level. For example, BX. Cannot be repeated among the PG26 records. **Last unit transmitted must be a base unit and only one base unit is allowed.**	3, 4

Table 8-24: Stand-alone Prior Notice PG26

Note 1
This code identifies the level of packaging for the product. Valid values are 1, 2, 3, 4, 5 and 6: Outermost (largest=1) packages to the innermost (smallest=6) packages. There can be up to 6 levels of packaging.

Note 2
There are two implied decimal points when writing the quantity in Units of Measure for all packaging levels. In this example, 4 pieces are represented as 000000000400, with the nine leading zeroes as "fill" and two decimal places following the value.

Note 3
Below is the list of Unit of Measure codes applicable to FDA-Prior Notice Message Sets. Last unit transmitted must be a base unit.
Valid FDA Food Units of Measure (UoM) for **Packaging Containers** are noted below:

Code	Description
AE	Aerosol
AM	Ampoule, Non-Protected
AP	Ampoule, Protected
AT	Atomizer
BA	Barrel (Container)
BB	Bobbin
BC	Bottle crate, Bottle rack
BE	Bundle
BF	Balloon, Non-Protected
BG	Bag
BH	Bunch
BI	Bin
BJ	Bucket
BK	Basket
BL	Bale, Compressed
BN	Bale, Non-Compressed
BO	Bottle, Non-Protected, Cyl
BP	Balloon, Protected
BQ	Bottle, Protected, Cylnd
BR	Bar
BS	Bottle, Non-Prot Bulbous
BU	Butt
BV	Bottle, Protected Bulbous
BX	Box
BZ	Bars in Bundle/Bunch/Trus
CA	Can, Rectangular
CAG	Cage
CB	Crate, Beer
CC	Churn
CE	Creel
CF	Coffer
CH	Chest
CI	Canister
CJ	Coffin
CK	Cask
CL	Coil
CO	Carboy, Non-Protected
CON	Container
CP	Carboy, Protected
CR	Crate
CS	Case
CT	Carton
CU	Cup
CV	Cover
CX	Can, Cylindrical
CY	Cylinder
CZ	Canvas
DJ	Demijohn, Non-Protected
DP	Demijohn, Protected
DR	Drum
EN	Envelope
FC	Crate, Fruit
FD	Crate, Framed
FI	Firkin
FL	Flask
FO	Footlocker
FR	Frame
GB	Bottle, Gas
HG	Hogshead
HR	Hamper
JC	Jerri can, Rectangular
JG	Jug
JR	Jar
JT	Jute bag
JY	Jerri can, Cylindrical
KEG	Keg
KIT	Kit
MB	Bag, Multi-ply
MC	Crate, Milk
MS	Sack, Multiwall
MT	Mat
NE	Unpacked or Unpackaged
NS	Nest
NT	Net
PA	Packet
PAL	Pallet
PC	Parcel
PH	Pitcher
PK	Package
PL	Pail
PO	Pouch
PT	Pot
PU	Tray or Tray Pack
PY	Plates in Bndl/Bnch/Truss
RG	Ring
RO	Roll
SA	Sack
SC	Crate, Shallow
SD	Spindle
SE	Sea-chest
SH	Sachet
SK	Case, Skeleton
SL	Slipsheet
SU	Suitcase
SW	Shrinkwrapped
SZ	Sheets in Bndl/Bnch/Truss
TB	Tub
TC	Tea-Chest
TD	Tube, Collapsible
TK	Tank, Rectangular
TN	Tin
TO	Ton
TR	Trunk
TS	Truss
TU	Tube
TY	Tank, Cylindrical
TZ	Tubes in Bndl/Bnch/Truss
VA	Vat
VG	Bulk Gas at 1031 MBAR
VI	Vial
VL	Bulk Liquid
VO	Bulk, Solid, Lg Particles
VP	Vacuum-packed
VQ	Bulk Liquefied Gas
VR	Bulk, Solid, Granular Parti
VY	Bulk, Solid, Fine Particle
WB	Wickerbottle

Table 8-25: Stand-alone Prior Notice UoM for Packaging Containers

Valid FDA Food Units of Measure for the Base Unit (Last Quantity Transmitted) are noted below:

Code	Description	Measure Type
BBL	Barrels (42 Gallons Ea)	Volume
BOL	Boluses	Dosage
CAR	Carats	Weight
CAP	Capsules	Dosage
CFT	Cubic Feet	Volume
CG	Centigrams	Weight
CM3	Cubic Centimeters	Volume
CYD	Cubic Yards	Volume
DOZ	Dozen	Count
DPC	Dozen Pieces	Count
DPR	Dozen Pairs	Count
FOZ	Ounces, fluid	Volume
G	Grams	Weight
GAL	Gallons (US)	Volume
GR	Gross	Count
KG	Kilograms	Weight
KM3	1,000 Cubic Meters	Volume
L	Liters	Volume
LB	Pounds (avdp)	Weight
M3	Cubic Meters	Volume
MCG	Micrograms	Weight
MG	Milligrams	Weight
ML	Milliliters	Volume
NO	Number	Count
OZ	Ounces, (avdp)	Weight
PCS	Pieces	Count
PRS	Pairs	Count
PTL	Pints, liquid (US)	Volume
QTL	Quarts, liquid (US)	Volume
STN	Short ton (2000 LB)	Weight
T	Metric Ton	Weight
Tab	Tablets	Dosage
TON	Long Ton (2240 LB)	Weight
TOZ	Ounces, Troy or Apoth	Weight

Table 8-26: Stand-alone Prior Notice UoM for Base Unit

Note 4
Quantity Data provides additional information to FDA about the product and how it is packaged. The basic format for Quantity Data is in multiple pairs of data – quantity and unit of measure, i.e., 500 cases, 12 ounces, fluid, 1000 cartons, etc. Up to 6 data pairs may be submitted, beginning with the 1st pair for the outermost packaging when Packaging Qualifier = 1. The first pair may describe the largest container and the last pair must describe the amount of product in the smallest container.

For example:
Product: 1000 cases of mineral water, 24/12 ounce bottles in each case
Packaging Qualifier =1: 1000 CS (Case)
Packaging Qualifier =2: 24 BO (Bottle, Non-protected, Cyl)
Packaging Qualifier =3: 12 FOZ (Ounces, fluid)

8.17 Record Identifier PG27 (Shipping Container Information)

Conditional | Repeatable per PGA Line

This is a conditional PGA input record that provides data pertaining to the Shipping Container Number. Data provided should match the Container Number info included on the Bill. This record is repeatable.

Record Identifier PG27 (Container Information)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"27"	
Container Number (Equipment ID)	20AN	5-24	C	The number of the shipping container as entered on the Bill based on the Mode of Transportation (MOT). This is applicable for food arriving as containerized cargo by water, air, rail, or land, the container number(s) is required for prior notice.	
Container Number (Equipment ID)	20AN	28-47	C	The number of the shipping container as entered on the Bill based on the Mode of Transportation (MOT). This is applicable for food arriving as containerized cargo by water, air, rail, or land, the container number(s) is required for prior notice.	
Container Number (Equipment ID)	20AN	51-70	C	The number of the shipping container as entered on the Bill based on the Mode of Transportation (MOT). This is applicable for food arriving as containerized cargo by water, air, rail, or land, the container number(s) is required for prior notice.	
Filler	7X	74-80	M	Space fill	

Table 8-27: Stand-alone Prior Notice PG27

8.18 Record Identifier PG28 (Express Courier Tracking Number)

Conditional | Not Repeatable per PGA Line

For Stand-alone Prior Notice if the Mode of Transportation is mail or express courier then Package Tracking Number Code and Package Tracking Number are conditionally required, on the PG28 record in lieu of the airway bill or bill of lading and in lieu of the flight number in PG23.

Record Identifier PG28 (Express Courier Tracking Number)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"28"	
Package Tracking Number Code	4AN	17-20	C	Enter SCAC or an AWB prefix for Express Consignment Carrier/Courier. For those express consignment carriers without a SCAC or an AWB prefix, leave blank & enter carrier name in PG23	
Package Tracking Number	50AN	21-70	C	Tracking numbers used by Express Consignment Carrier	

Table 8-28: Stand-alone Prior Notice PG28

8.19 Record Identifier PG30 (Anticipated Arrival Information and Port of Arrival)

Mandatory | Not Repeatable per PGA Line

This is a mandatory PGA input record that provides data pertaining to the date, time and location of the anticipated arrival information for all FDA products.

This is a mandatory PGA input record with status code A in position 5, that provides data pertaining to the date, time and location of anticipated arrival information for FDA BTA.

For each line a PG30 record with an "A" (Anticipated arrival information) code, date, time and location of arrival is mandatory.

Record Identifier PG30 (Anticipated Arrival Information and Port of Arrival)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	”PG”	
Record Type	2N	3-4	M	”30”	
Anticipated Arrival Information	1A	5	M	A = Anticipated arrival information.	1
Anticipated Arrival Date at Port of Arrival	8N	6-13	M	A numeric date in MMDDCCYY (month, day, century, year) format.	1
Anticipated Arrival Time at Port of Arrival	4N	14-17	M	Military time HHMM in (hour, minute) format. (Example: 1015, this represents 10:15 a.m.). For midnight, use 2400 (0000 is invalid).	1
Anticipated Arrival Location Code	4AN	18-21	M	Location type code from CBP’s ACE CATAIR Appendix PGA; only the value of 2 (= Schedule D Port codes) is allowed.	
Anticipated Port of Arrival	50X	22-71	M	For valid port codes, refer to note 2.	2
Filler	9X	72-80	M	Space fill	

Table 8-29: Stand-alone Prior Notice PG30

Note 1
For PN shipments, A = Anticipated Arrival Date and Time at the Anticipated Port of Arrival.

Port of Arrival:
21 CFR 1.276 (b)
(11) **Port of arrival** means the water, air, or land port at which the article of food is imported or offered for import into the United States. For an article of food arriving by water or air, this is the port of unloading. For an article of food arriving by land, this is the port where the article of food first crosses the border into the United States. The port of arrival may be different than the port where consumption or warehouse entry or foreign trade zone admission documentation is presented to the U.S. Customs and Border Protection (CBP).

Note 2
Refer to list of valid Port Codes at https://www.cbp.gov/sites/default/files/assets/documents/2020-Jan/ACE%20Appendix%20E%20Schedule%20D%20January%202020%20%281%29.pdf

8.20 Record Identifier PG55 (Additional Roles)

This is an optional input record used to provide additional roles performed by an entity or individual identified in PG19.

Record not supported by FDA at this time

Currently, the PG55 record is not supported by FDA. Multiple PG19 records should be used to input more than one Entity-Role combination. Refer to the PG19 section for details.

Record Identifier PG55 (Additional Roles)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	Must always equal PG	
Record Type	2N	3-4	M	Must always be 55	
Entity Role Code	3AN	5-7	C	Additional role of the entity.	
Entity Role Code	3AN	8-10	C	Additional role of the entity.	
Entity Role Code	3AN	11-13	C	Additional role of the entity.	
Entity Role Code	3AN	14-16	C	Additional role of the entity.	
Entity Role Code	3AN	17-19	C	Additional role of the entity.	
Entity Role Code	3AN	20-22	C	Additional role of the entity.	
Entity Role Code	3AN	23-25	C	Additional role of the entity.	
Entity Role Code	3AN	26-28	C	Additional role of the entity.	
Entity Role Code	3AN	29-31	C	Additional role of the entity.	
Entity Role Code	3AN	32-34	C	Additional role of the entity.	
Filler	46X	35-80	M	Space fill	

Table 8-30: Stand-alone Prior Notice PG55

8.21 Record Identifier PG60 (Additional Information)

Optional | Repeatable per PGA Line

This is an optional PGA input record used to provide additional information about data in the PG record that precedes it during the submission of a PGA record set.

This record can follow a PG07, PG19, PG20 or PG21 record, and can only be used to provide the additional information noted by the Additional Information Qualifier Code list.

This record may be repeated.

Record Identifier PG60 (Additional Information)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"60"	
Additional information qualifier code	3AN	5-7	C	Code indicating the type of additional information being provided	1
Additional Information	73X	8-80	C	Text of the additional information related to the additional reference qualifier code	

Table 8-31: Stand-alone Prior Notice PG60

Note 1
Valid PG60 Additional Information Qualifier Codes applicable to FDA Message Set are noted below:

Code	Description
ENA	Continuation of Entity Name for PG19
AD1	Continuation of Entity address Line 1 for PG19
AD2	Continuation of Entity address Line 2 for PG20
AD3	Entity address Line 3 for PG20
AD4	Entity address Line 4 for PG20
AD5	Entity address Line 5 for PG20
ECI	Continuation of Entity City for PG20
INA	Continuation of Individual Name for PG21
EMA	Continuation of Email Address for PG21
TBN	Continuation of Trade/Brand Name for PG07

Table 8-32: Stand-alone Prior Notice PG60 Additional Information Qualifier Codes

PG60 record should follow immediately after its parent. For example, a PG60: ENA record should follow PG19 and a PG60: TBN record should follow PG07.

8.22 Record Identifier PG00 (Data Substitution)

This is an optional record used at the CBP entry (or entry summary) header, CBP entry (or entry summary) line and/or PGA message set levels to indicate data substitution.

PG00 Substitution Grouping
In situations where the trade finds it would be supplying identical information more than once within the PGA Message Set, a PG00 substitution grouping can be used, instead of repeating that information multiple times. Refer to the 'usage notes' in the ACE ABI CATAIR - Customs and Trade Automated Interface Requirements publication for detailed information.

Record Identifier PG00 (Data Substitution)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"00"	
Substitution Indicator	1X	5	O	Identifies either the start or end of the substitution group, or the location of where to place the substitute data within the PGA Message Set. The following codes are allowed: S=Start of the substitution group E=End of the substitution group R=Replace this record with the substitution group indicated by the Substitution Number	
Substitution Number	4AN	6-9	O	Sequential number assigned to, or referring to, a specific substitution group of data provided at the header level. This data element is mandatory when using the S or R substitution indicator.	
Filler	71X	10-80	M	Space fill	

Table 8-33: Stand-alone Prior Notice PG00

9 Food Commodity Combined Entry Submission - Data Elements and Values

In this scenario, both 801a and 801m data elements will be submitted as a single message for an Entry.
Food commodities can be broken down into the following categories using the existing Government Agency data elements available in the PG01 message.

PG01 - Government Agency Code	Commodity Type	PG01 - Government Agency Program Code	Commodity Sub-Type	PG01 - Government Agency Processing Code
FDA	Food	FOO	Natural State Food	NSF
FDA	Food	FOO	Processed Food	PRO
FDA	Food	FOO	Animal Food (includes pet food, medicated feed and feeds)	FEE
FDA	Food	FOO	Additives and Colors	ADD
FDA	Food	FOO	Dietary Supplements	DSU

Table 9-1: Food Commodity Combined Entry Hierarchy

This chapter describes the data elements and their business rules for an 801a entry, with the Government Agency Program Code = “FOO”, which may be subject to PN regulations.

The following are the potential PGA records associated with submitting Foods with PN processing:

PG Record	Description
PG01	FDA program that regulates the product
PG02	Item Type and Product Code details
PG06	Product Origin (FDA Country of Production, Shipment, and Refusal)
PG07	Product Trade/Market/Brand Name
PG10	Product Description (Line level item common/usual name)
PG13	License Plate Issuer for Privately Owned Vehicle (POV) Information
PG14	License Plate Number for Privately Owned Vehicle (POV) Information
PG19	Entity Role (manufacturer, consignee, shipper, etc.) Entity Identification, Entity Name, and Entity Address 1
PG20	Additional address data on the entity in PG19(Address line 2, Apartment/Suite, City, State, and Zip/Postal Code).
PG21	Entity of Record’s (manufacturer, shipper, etc.) individual point of contact, phone number and email.
PG23	FDA’s Affirmation of Compliance Criteria
PG24	Remarks
PG25	Temperature Qualifier, Lot Number, Lot Number Qualifier, PGA Line Value
PG26	Packaging Qualifier and Quantity of the shipment
PG27	Container Number
PG28	Express Courier Tracking Number and Container Dimensions (LACF and AF Only) **§**
PG30	Anticipated Arrival Information
PG55	Additional roles (for future use)
PG60	Additional Information following a PG07, PG19, PG20 or PG21
PG00	Data Substitution

Table 9-2: Combined Entry PGA Records

§ SE header can only be used to submit Express Courier Tracking numbers approved by Air Cargo Advanced Screening (ACAS) pilot in the air environment. Express courier tracking numbers for PNs for food shipments in the ground/air environment are to be reported in the PG28.

9.1 Prior Notice Data Elements by Mode of Transportation (Refer to the Note)

Mode of Transportation (MOT)	Data Elements	Mapping	Mapping - Data Elements
AIR	IATA	SE15	Carrier
	Airway Bill Number	SE15	The prefix of BOL = 'AWB', Reference Identifier Number field
	Flight Number	PG23	AoC - VFT - Voyage/Flight/Trip Number
	Carrier Name	PG23	AoC - CAN - Carrier Name
	Container Number	PG27	Container Number
OCEAN	Bill of Lading	SE15	Bill Type Indicator 'R', and report the Bill of Lading Number in the Reference Identifier Number field
	Vessel Name	PG23	AoC – VES – Vessel Name
	Voyage Number	PG23	AoC - VFT - Voyage/Flight/Trip Number
	Carrier Name	PG23	AoC - CAN - Carrier Name
	Container Number	PG27	Container Number
LAND - Bus, Truck	Bill of Lading	SE15	Bill Type Indicator 'R', and report the Bill of Lading Number in the Reference Identifier Number field
	Trip Number	PG23	AoC - VFT - Voyage/Flight/Trip Number
	SCAC	SE15	Carrier
	Carrier Name	PG23	AoC - CAN - Carrier Name
	Container Number *	PG27	Container Number
LAND - Rail	Bill of Lading	SE15	Bill Type Indicator 'R, and Bill of Lading number in the Reference Identifier Number field
	Trip Number	PG23	AoC - VFT - Voyage/Flight/Trip Number
	SCAC	SE15	Filer/SCAC Code, Reference Identifier Number field
	Rail Car Number	PG23	AoC – RNO - Rail Car Number
	Container Number*****	PG27	Container Number
Express Consignment Carrier	Tracking Number	PG28	Report Express Consignment Carrier/Courier tracking number for the shipment as applicable.
	Carrier Name	PG28 or PG23	SCAC/IATA may be entered in PG28 otherwise use PG23 AoC - CAN – Carrier Name

*****if applicable

Table 9-3: Prior Notice Non-PGA Data Elements by MOT

Note
The above table references select entry-level data elements from the SE15 to provide the context and to identify from which data source FDA expects to receive the required prior notice data elements for the specific modes of transportation. For additional information on the data elements found within the SE15 record, refer to the ACE Cargo Release CATAIR. This document describes only line-level data within the structure of the FDA PG Message Set.

9.2 Prior Notice Combined Entry Example

Prior Notice Combined Entry message set layout sample below:

Refer to the external file: **FDA SG Example PG Message Sets** **Tab: *FOO+PN***

PGA Records and Data Elements required are dependent on the agency program and processing code selected. For a more expansive set of examples of FDA PGA Message Sets, refer to the above document.

9.3 Record Identifier PG01 (PGA Identifier)

Mandatory | Not Repeatable per PGA Line

This is a mandatory PGA input record that provides data pertaining to the PGA Line Number, Government Agency Code, Government Agency Program Code, Government Agency Processing Code, Intended Use Code, Intended Use Description, and Disclaimer. The Intended Use Code allows FDA to identify whether the imported commodity is restricted by a consumption allowance or not.

Record Identifier PG01 (PGA Identifier)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description/Required Value**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"01"	
PGA Line Number	3N	5-7	M	Begin with "001" and sequentially increment the line number on subsequent PG01 records, if applicable.	
Government Agency Code	3AN	8-10	M	"FDA"	
Government Agency Program Code	3X	11-13	C	"FOO"	1, 2
Government Agency Processing Code	3AN	14-16	C	Allowed values: NSF, PRO, FEE, ADD, DSU	1, 2
Intended Use Code	16X	42-57	O	Refer to the table below for valid optional values.	3, 4
Intended Use Description	21X	58-78	O	N/A for FDA lines.	
Correction Indicator	1X	79	O	For future use	
Disclaimer	1A	80	C	A code of A (= product is not regulated by this agency) indicating there is no agency declaration requirement. Leave it blank for no disclaimer. "F" indicating that the product is manufactured in any state of the US, the District of Columbia, or Puerto Rico and sourced directly to the warehouse without ever leaving the US. **May only be used for FDA on Entry Type 21**. No other codes are accepted	

Table 9-4: Food Combined Entry PG01

Note 1
Refer to Table 9-1 above for commodity type and sub-type for Food Combined Entry.

Note 2
If the product is Disclaimed, then these data elements should both be populated with 'FDA'. Otherwise the Government Agency Program Code, Government Agency Processing Code are mandatory.

Note 3
Note that CBP publication, Appendix R - Intended Use Codes for ACE, provides general descriptions of all Intended Use Codes for all Partner Government Agencies (PGAs). For FDA regulated products, use the IUC descriptions as specified per commodity throughout this document. See Appendix E for a mapping of FDA IUC descriptions to CBP Appendix R IUC descriptions. The submission of an Intended Use Code is not a requirement for Food. If providing an Intended Use Code, the following are the applicable options:

FDA Import Scenario	Intended Use Code	CBP Intended Use Name
For Research Use as Human Food	**260.000**	For Research Use as Human Food
For Research Use as an Animal Food	**015.000**	For Research Use as an Animal Food
Personal Importation	**210.000**	For Personal Use as Human Food

Table 9-5: Food Combined Entry Intended Use Codes

Note 4

If after consultation with the importer, who should know the intended use of the product, the filer still ***does not know*** the intended use of the product, "UNK" may be used in lieu of an IUC. In most cases, the line will be subject to manual review, and may result in a request for documentation and/or additional information about the product as the product offered for import will be treated as a standard import. Ensure the IUC (reason for importation) is transmitted to avoid delays. As per the ACE Rule, if "UNK" is submitted as the IUC for the article, the ACE filer is still responsible for submitting the other required data elements in this rule that are applicable to that article, at the time of entry. In the future, if those other data elements are not submitted in ACE at the time of entry, the entry may be transmitted by ACE to FDA for admissibility review, but FDA may reject the entry. If FDA rejects an entry filing, the ACE filer will need to resubmit the entry with complete and accurate information.

9.4 Record Identifier PG02 (Product Identifier)

Mandatory | Not Repeatable per PGA Line

This mandatory PGA input record is used to include information related to a product (P).

Record Identifier PG02 (Product Identifier)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"02"	
Item Type	1A	5	M	Code identifying the following records as pertaining to P=Product. No other values accepted. Only one "P" record is allowed for the same PGA Line # in PG01.	
Product Code Qualifier	4AN	6-9	M	"FDP"	1
Product Code Number	19X	10-28	M	FDA Product Code must be exactly 7 characters	

Table 9-6: Food Combined Entry PG02

Note 1
Product Code Qualifiers and their descriptions can be found in CBP's ACE CATAIR Appendix PGA (PG02 – Product Code Qualifiers). For FDA filings, the Product Code Qualifier is always "FDP".
Only one Product Code Number per line is allowed.

FDA Product Code Structure

Position	1-2	3	4	5	6-7
Name	Industry Code (N)	Class Code (AN)	Subclass Code (A or '-')	Process Indicator Code - PIC (A or '-')	Product (AN)

Legend - N: Numeric; A: Alphabetic; AN: Alphanumeric

Table 9-7: Food Combined Entry FDA Product Code Structure

A product is subject to Prior Notice requirements if the following condition is satisfied.

if Industry_Code IN ('07', '09', '69', '70', '71', '72')
OR if Industry Code BETWEEN '02' and '05'
OR if Industry Code BETWEEN '12' and '18'
OR if Industry Code BETWEEN '20' and '42'
OR if Industry Code BETWEEN '45' and '46'
OR if (Industry Code ='50' and Class Code in ('C', 'D', 'E', 'F', 'G', 'L')
OR if (Industry Code ='52' and Class Code = 'D'
OR if (Industry Code = '54' and Subclass Code in ('A','B','C','L','M')

9.5 Record Identifier PG06 (Product Origin)

Mandatory | Repeatable per PGA Line

For a combined food submission, this is a mandatory input record that provides data pertaining to Source Type (FDA country of production/growth and country from which the article was shipped) for the article of food. This record also provides the conditional data concerning the Country (or Countries) who previously refused entry of the article of food. This record can be repeated to submit the countries required as described in Note 1.

Record Identifier PG06 (Product Origin)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"06"	
Source Type Code	3AN	5-7	M	Source Type Code must be selected using the following logic: IF Government Agency Program Code = "FOO" and natural state food/feed THEN use 262 (Place of Growth) ELSE use 39 (Country of Production). IF Government Agency Program Code = "FOO", THEN requires CSH (Country of Shipment). IF refused by another country, use 294.	1
Country Code	2X	8-9	M	Foods require the harvesting or production location of the product must match the country code in PG19-PG20 record based on the value entered for Source Type Code: Source Type Code — Entity Role Code 39 — MF 262 — DFI or FDC	2

Table 9-8: Food Combined Entry PG06

Note 1
Source Type Codes and their descriptions can be found in CBP's ACE CATAIR Appendix PGA (PG06 – Source Type Codes).
Combined food submissions require the following data elements:

Country of Shipment, Source Type Code = CSH (required for Prior Notice)
All Natural State Human Food and Animal Food requires the

- Country of Growth**,** Source Type Code = 262 - if made from fish/seafood aboard a vessel = country in which the vessel is registered.

Non-Natural State Human Food and Animal Food requires the

- Country of Production, Source Type Code = 39 - if made from fish/seafood aboard a vessel = country in which the vessel is registered.

Country of Entry Refusal, if the article of food has been refused by other country(countries), provide the country code(s) and (Source Code Type = 294)

Note 2
Any of the country codes from CBP's ACE CATAIR Appendix B (Section: Country and Currency Codes) can be entered.

9.6 Record Identifier PG07 (Product Trade Names)

Optional | Not Repeatable per PGA Line

This is an optional PGA input record that provides data pertaining to Trade or Brand Name.

Record Identifier PG07 (Product Trade Names)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"07"	
Trade Name/Brand Name	35X	5-39	O	Trade, or Brand Name that describes the food or feed product at each line level. If Trade/Brand Name requires additional space, continue in a PG60 record with Qualifier Code "TBN".	

Table 9-9: Food Combined Entry PG07

9.7 Record Identifier PG10 (Product Characteristics)

Mandatory | Not Repeatable per PGA Line

This is a mandatory PGA input record that allows for reporting the description of the product identified by the Product Code in PG02.

Record Identifier PG10 (Product Characteristics)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"10"	
Commodity Characteristic Description	57X	24-80	M	Common, market, usual name; free form invoice description; not product code description. For examples, see Appendix A: Use of PG10 Record.	

Table 9-10: Food Combined Entry PG10

9.8 Record Identifier PG13 (License Plate Issuer)

Conditional | Not Repeatable per PGA Line

This is a conditional input record that provides data pertaining to Licenses, Permits, Certificates or Other (LPCO). For a combined food submission, this PG record is only required when the carrier is a privately-owned vehicle and does not have a SCAC or IATA. For this situation, this PG record allows for the submission of some of the license plate information for the subject privately owned vehicle. The data elements included in this record are Issuer and location of issuer of the LPCO. If using this record, a PG14 and PG23 (Carrier Name – CAN) are mandatory.

Record Identifier PG13 (License Plate Issuer)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	”PG”	
Record Type	2N	3-4	M	”13”	
Issuer of LPCO	35X	5-39	O	Identifies the entity that issued the LPCO.	1
LPCO Issuer - Government Geographic Code Qualifier	3A	40-42	C	The code relating to the location of the issuer of the Privately-Owned Vehicle (POV) license plate. Select one: • Canadian Province = PR • Country Code = ISO • Mexican State = MS • US State = US	1
Location (Country/State/Province) of Issuer of the LPCO	3A	43-45	C	Identifies the location of the issuer of the POV license plate (ex: the US, Mexico or Canadian Province/State code or Foreign Country Code). Enter the appropriate code from CBP’s ACE CATAIR Appendix B.	1
Regional description of location of Agency Issuing the LPCO	25X	46-70	C	This description allows for the submission of a License Plate Issuer location when the Issuer is reported as an ISO and State or Province other than those from the US, Canada, or Mexico.	1
Filler	10X	71-80	M	Space fill	

Table 9-11: Food Combined Entry PG13

Note 1
When the Carrier is a privately-owned vehicle (POV), the following Prior Notice data requirements should be submitted using PG13 and PG14 in place of a SCAC or IATA.

License Plate Number	**PG14 –** LPCO Number
License State (US)	**PG13** - LPCO Issuer - Location (Country/State/Province) of Issuer of the LPCO
License Province	**PG13** - LPCO Issuer - Location (Country/State/Province) of Issuer of the LPCO
License Country	**PG13** - LPCO Issuer - Government Geographic Code Qualifier

9.9 Record Identifier PG14 (License Plate Number)

Conditional | Not Repeatable per PGA Line

This is a conditional input record where the carrier is a privately-owned vehicle, provide the Privately-Owned Vehicle license plate information.

Record Identifier PG14 (License Plate Number)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	”PG”	
Record Type	2N	3-4	M	”14”	
LPCO Transaction Type	1N	5	O	Leave blank - not required (reserved for future use)	
LPCO Type	3AN	6-8	C	Identifies Type Code for Privately-Owned Vehicle license plate number as applicable. Use “POV” for Type	1
LPCO Number (or Name)	33X	9-41	C	Privately-Owned Vehicle license plate number.	

Table 9-12: Food Combined Entry PG14

Note 1
When the Carrier is a privately-owned vehicle (POV), the above Prior Notice data requirements should be submitted using PG13 and PG14 in place of a SCAC or IATA.

9.10 Record Identifier PG19 (Entity Data)

Mandatory | Repeatable per PGA Line

This is a mandatory PGA input record requiring Entity Role, Entity Name, and Entity Address 1.

Entity Identification Code [16 (DUNS #), 47 (FEI #)] and Entity number are optional data elements, but they are listed as conditional because if opting to transmit Entity Identification Code, then Entity Number must also be provided, and vice versa.

Record Identifier PG19 (Entity Data)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"19"	
Entity Role Code[3]	3X	5-7	M	Code identifying the role of the entity being provided. For example: MF, UC. Each entity role code can only be transmitted once per PGA line.	1
Entity Identification Code	3X	8-10	C	Code identifying the Entity Type is entered. For example: 16 (DUNS #), 47 (FEI #). Mandatory, if Entity Number is entered. Optional otherwise.	2
Entity Number	15X	11-25	C	Identifying Number (DUNS or FEI) for the associated Entity Identification Code. Mandatory if Entity Identification Code is provided.	2
Entity Name	32X	26-57	M	The name of the entity is entered. If Entity Name requires additional space, continue in a PG60 record with Qualifier Code "ENA". Refer to the validation criteria below.	2
Entity Address 1	23X	58-80	C	Conditional only for the PN Transmitter (PNT) and PN Submitter (PNS) entities if a Food Facility Registration number is included in PG23. Mandatory for all other required entities. If Entity Address1 requires additional space, continue in a PG60 record with Qualifier Code "AD1"	1, 2, 3

Table 9-13: Food Combined Entry PG19

Note 1
Entity Role Codes that are mandatory to FDA Prior Notice Message Sets is noted below:

Data Element	**Code**	**Description**	**Condition**
Entity Role Codes	PNS	PN Submitter	If the facility is registered, then Submitter Food Facility Registration Number (SRN) may be provided in PG23 with Name, City and Country or provide full address in PG19 and PG20, see Note 3
	PNT	PN Transmitter	If the facility is registered, the Transmitter Food Facility Registration Number (TFR) may be provided in PG23 with Name, City and Country or provide full address in PG19 and PG20, see Note 3
	MF[3] **or-**	Manufacturer[2]	Provide the Manufacturer Food Facility Registration Number (PFR) in PG23 with Name, City and Country or provide full address in PG19 and PG20, see Note 3

Data Element	Code	Description	Condition
Entity Role Codes	FDC[3] **-or-** DFI[3]	FDA Consolidator[2,]	Full address of the firm or person (if individual) who consolidated the articles of food from the grower(s) is required when the food/feed is in its natural state and the grower(s) is/are unknown. If registered, then Consolidator Food Facility Registration Number (CFR) may be provided in PG23 with Name, City and Country or provide full address in PG19 and PG20, see Note 3
		Grower[2]	Full address of the growing location of the grower or person (if individual) is required when the food/feed is in its natural state. If registered, then the Grower Food Facility Registration Number (GFR)may be provided (if available) in PG23.
	DEQ	Shipper	Full address of Shipper is required for all combined entries, see Note 3. If registered, then Shipper Food Facility Registration Number (SFR) may be provided in PG23
	FD1	FDA Importer (Importer of Record)	Full address of the Importer is required for combined entries, see Note 3. If registered, the Importer's Food Facility Registration (IFR) Number may be provided PG23.
	DFP	Owner	Full address of the Owner is required for combined entries, see Note 3. If registered, the Owner's Food Facility Registration (ORN) Number may be provided in PG23
	UC	Ultimate Consignee (Deliver to Party)[1]	Full address of the UC is required for combined entries, see Note 3. If registered, the Ultimate Consignee's Food Facility Registration (UFR) Number may be provided in PG23.

Table 9-14: Food Combined Entry Entity Role Codes (Mandatory)

[1] Ultimate Consignee (Deliver to Party – reference guidance).
FDA interprets the Prior Notice requirement for Ultimate Consignee to be synonymous with the "Deliver to Party", the U.S. party that physically receives the good(s).

[2] The PN regulation requires **ONLY ONE** of the following:
IF the food/feed is not in natural state THEN Manufacturer (MF)
IF the food/feed is in natural state THEN Grower (DFI)
IF the food/feed is in natural state, and grower is unknown THEN Consolidator (FDC)

[3] Only one of the Entity Role Codes MF/FDC/DFI is permitted.

List of Entity Role codes that are **CONDITIONALLY** required for combined submission Message Sets is noted below:

Data Element	Code	Description	Condition
Entity Role Codes	LG	Location of Goods (Secure Holding Facility for PN Purposes)	This entity is only required for PN when the article of food/feed was refused for inadequate PN and moved under CBP Supervision. This entity is the location and address where refused food is held.
	FSV	Foreign Supplier Verification Program Importer	The following data elements relate to the Foreign Supplier Verification Program (FSVP). If GOVT Agency program code is FOO and processing code is ADD, DSU, FEE, NSF, or PRO, then the following FSVP-related details are mandatory for all FDA FOO lines, except if PG02 Industry Code = 16 or 32 OR PG23 AofC FSX or RNE is present: 1. DUNS#, Firm Name, Firm Address1 are required in PG19; 2. All the elements, except Apt#, are required in PG20 AND 3. PG20 Country = US and PG20 State can only be 50 US States, DC and PR. 4. Qualifier Code=FSV and email address are required in PG21; individual's name and telephone number are optional in PG21.

Table 9-15: Food Combined Entry Entity Role Codes (Conditional)

List of Entity Role codes that are **OPTIONAL** to FDA Message Sets is noted below. These codes may not be used as a substitute for the mandatory or conditional entities listed above.

Data Element	Code	Description
Entity Role Codes	PK	Point of Contact (Filer/Broker Contact Information)

Table 9-16: Food Combined Entry Entity Role Codes (Optional)

Note 2
Entity Identification Codes and their descriptions can be found in CBP's ACE CATAIR Appendix PGA (PG19 – Entity Identification Codes). List of Entity Identification codes applicable to FDA Food Message Sets is noted below:

Data Element	Code	Description	Length/ Class
Entity Identification Codes	16	D&B-assigned (DUNS number); must be 9 digits	9N
	47	FDA-assigned (FEI number); must be from 1 to 10 digits	1-10N

Table 9-17: Food Combined Entry Entity Identification Codes

IF Entity Identification Code =16 (DUNS) THEN Entity Number must be Length = 9 and Type = N
ELSE IF Entity Identification Code =47 (FEI) THEN Entity Number must be Length from 1 to 10 and Type = N

Note 3:
Use PG19 & PG20 to provide full address information, which includes entity street name and number; suite/unit number, as appropriate; City; Province or State as appropriate; mail code as appropriate; and Country.

9.11 Record Identifier PG20 (Entity Address)

Mandatory | Repeatable per PGA Line

This is a mandatory PGA input record that provides additional data pertaining to the Entity identified in the preceding PG19 record; such as Entity Address line 2, Apartment/Suite, City, State, and Zip/Postal Code. This record is used when additional address for the entity needs to be entered.

Record Identifier PG20 (Entity Address)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"20"	
Entity Address 2	32X	5-36	C	Address Line 2 for the Entity. If Entity Address2 requires additional space, continue in a PG60 record with Qualifier Code "AD2".	1
Entity Apartment Number/Suite Number	5X	37-41	C	For example, 102 A.	
Entity City	21X	42-62	M	For example, SUGARLAND. If Entity City requires additional space, continue in a PG60 record with Qualifier Code "ECI".	
Entity State/Province	3AN	63-65	C	Refer to CBP's ACE CATAIR Appendix B for valid codes.	2, 3
Entity Country	2A	66-67	M	Refer to CBP's ACE CATAIR Appendix B for valid codes.	4
Entity Zip/Postal Code	9X	68-76	C	For example, 77004.	2
Filler	4X	77-80	C	Space fill	

Table 9-18: Food Combined Entry PG20

Note 1
If the Entity requires more than 2 address lines, use the optional PG60 records with Qualifier Codes "AD3", "AD4" and "AD5" immediately under the PG20 record for the same Entity.

Note 2
Required for US or Canada based entities

Note 3
If PG19 Entity Role Code = FSV, Entity State/Province can only be 50 US States, DC and PR

Note 4
If PG19 Entity Role Code = FSV, Entity Country must be US

9.12 Record Identifier PG21 (Point of Contact)

Mandatory | Repeatable per PGA Line

This is a mandatory PGA input record that provides point of contact information.

For all FDA lines with combined 801(a) and 801(m) data, at least two PG21 records are required with the individual qualifiers: PNS (PN Submitter) and PNT (PN Transmitter) (sent with the preceding PG19 and matching individual qualifier in the PG21 records). A conditional PG21 with the individual qualifier "FSV" may be transmitted with the preceding PG19FSV and PG20FSV. An optional PG21 with the individual qualifier "FD1" may be transmitted with the preceding PG19FD1 and PG20FD1.

FDA also highly encourages the transmission of PG21 with the individual qualifier "PK" which should be the point of contact for the filer/broker. "PK" may be sent in one of the following ways:

1) Under a PG19PK (transmitting PG19PK, PG20PK and PG21PK for the filer), the FDA preferred method, **OR**
2) As a secondary PG21 to FD1 using individual qualifier "PK" (transmitting PG19FD1, PG20FD1, PG21FD1, and PG21PK for the filer), **OR**
3) Under any other required PG19 entity as long as "PK" is the individual qualifier in PG21.

If provided, there should be only one PK per FDA line.

Although the PK (filer/broker contact information) is optional, transmitting this information will enable FDA to expeditiously contact the filer, instead of contacting the Importer of Record. If only the Importer of Record PG21 is transmitted and PK is not, FDA processing may be delayed. An optional PG21 with a fax is allowed for the Submitter and Transmitter.

Record Identifier PG21 (Point of Contact)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"21"	
Individual Qualifier	3AN	5-7	M	Identify the type of party or facility the Individual represents. Only codes of "PNS", "PNT", "FD1", "PK" and "FSV" are allowed. PG21 with qualifier code "FSV" must follow PG19 with the qualifier code "FSV". Refer to the PG19 for the details of FSVP (Food Supplier Verification Program).	
Individual Name	23X	8-30	C	Name of the Individual. This is optional if the Individual Qualifier = "FSV" otherwise it is mandatory. If the name will not fit, continue in a PG60 record with Qualifier Code "INA".	
Telephone Number of the Individual	15X	31-45	C	This is optional if the Individual Qualifier = "FSV" otherwise it is mandatory. For example, (713)555-8765 in US or (+65)9052-3529 in Singapore	
Email Address or fax number for the Individual	35X	46-80	M	Enter the Email Address the Individual. If the Email Address exceeds in length, continue in a PG60 record with Qualifier Code "EMA". If sending a FAX number, send an additional PG21 record with "FAX".	1

Table 9-19: Food Combined Entry PG21

Note 1

When transmitting an email address only transmit one valid email address as you would in an email program. Do not include names, additional characters, etc.

Valid Example	first.last@company.com
Invalid Example	<first.last@company.com>
Invalid Example	FirstName LastName first.last@company.com
Invalid Example	FirstName LastName <first.last@company.com>
Invalid Example	first.last@company.com, first.last@company.com

9.13 Record Identifier PG23 (Affirmation of Compliance)

Conditional | Repeatable per PGA Line

This is a conditional or optional PGA input record that provides data pertaining to FDA Affirmation of Compliance Criteria. This record is repeatable, but each affirmation of compliance code can only be transmitted once unless the code is RNO. RNO may be repeated to report multiple railcar numbers if necessary and applicable.

Record Identifier PG23 (Affirmation of Compliance)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"23"	
Affirmation of Compliance Code	5X	5-9	C	A code used to affirm compliance with FDA requirements. Refer to CBP's ACE CATAIR Appendix PGA (Food & Drug Affirmation of Compliance Codes) for valid codes.	1, 2, 3, 4, 5
Affirmation of Compliance Qualifier	30X	10-39	C	Text describing the information required by the PGA. For 'indicator only' AoC codes, this field is left blank. When free text is allowed, Affirmation of Compliance Qualifiers cannot exceed 30X. All other qualifiers must follow the syntax instructions for each code as specified in CBP's ACE CATAIR Appendix PGA.	1
Filler	1X	80	C	Space fill	

Table 9-20: Food Combined Entry PG23

Note 1
The list of conditional AoC codes for the FDA Combined Food Submission Message Set is noted below:

Data Element	**Code**	**Description**	**Syntax**	**Business Rules**	**Note**
Affirmation of Compliance Code	FME§	Food Processing Facility Registration Exemption	1A	Refer to the Appendix B: Food Facility Registration Exemption (FME) at the end of this document for valid codes. When food or feed is in a natural state and the entity role code DFI (Grower) or FDC (Consolidator) is entered in lieu of manufacturer, FME and food facility registration number are not required. Either FME or PFR is required when the Manufacturer is transmitted. If both FME and PFR are submitted, FDA will review the registration.	
	RNO	Rail Car Number		Required If MOT = Rail or MOT = Containerized Rail. For multiple Rail Car Numbers, repeat PG23 as needed. If the Rail Car Number is unavailable, enter 'Does Not Exist'.	
	CAN	Carrier Name		If using a PG13 record OR if the SCAC or IATA are not provided, this AoC value is required.	

Data Element	Code	Description	Syntax	Business Rules	Note
Affirmation of Compliance Code	VFT	Voyage, Trip, Flight Number		If the article of food is arriving by express consignment operator or carrier, and neither the PN submitter nor PN transmitter is the express consignment operator or carrier, the express consignment operator or carrier tracking number may be submitted in lieu of the flight number. Otherwise, VFT is required if MOT = Air, Rail, Truck or Ocean if it exists. If the Trip Number is unavailable, enter 'Does Not Exist'.	
	VES	Vessel Name		Required If MOT = Ocean	
	PFR§	Manufacturers food facility registration number	11N	Manufacturer registration number is required unless FME and Reason code is submitted, or consolidator / grower role code is submitted in lieu of manufacturer for food/feed in its natural state. Refer to the Appendix B: Food Facility Registration Exemption (FME) of this document for valid codes If both FME and PFR are submitted, then FME is not used by the FDA.	
	FCE	Food Canning Establishment Number	5N	If Government Agency Program Code = "FOO" and the product is either LACF or AF, then FCE must be entered.	3
	SID	Schedule Identifier Number	11N	If Government Agency Program Code = "FOO" and the product is LACF or AF, then AoC Code SID must be entered. Format: CCYYMMDDnnn.	3
	VOL	LACF/AF Volume		If Government Agency Program Code = "FOO" and the product is LACF or AF, then either VOL or Container Dimensions (PG28 for details) must be entered.	3
	FSX	Product is exempt from FSVP requirements		Indicator only. This AoC is not required for Industry Codes 16 and 32.	
	RNE	Product is for R&E (Research and Evaluation), therefore exempt from FSVP requirements		Indicator only.	

Table 9-21: Food Combined Entry AoC Codes (Conditional)

Note 2
The list of optional AoC codes for the FDA Combined Food Submission Message Set is noted below:

Data Element	Code	Description	Syntax	Business Rules
Affirmation of Compliance Code	SFR	Shipper Food Facility Registration Number	11N	Optional
	UFR	Ultimate Consignee Food Facility Registration Number	11N	Optional
	IFR	Importer Food Facility Registration Number	11N	Optional
	TFR	Transmitter Food Facility Registration Number	11N	Optional

Data Element	Code	Description	Syntax	Business Rules
Affirmation of Compliance Code	ORN	Owners Food Facility Registration Number	11N	Optional
	SRN	Submitter Food Facility Registration Number	11N	Optional
	CFR§	Consolidator Food Facility Registration Number	11N	Optional
	GFR§	Grower Food Facility Registration Number	11N	Optional
	LFR	Location of Goods (Holding Facility Registration Number)	11N	Optional
	CIN	Color Identification Number	Text 30X max.	If Government Agency Program Code = “FOO” and Government Agency Processing Code = “ADD”, then CIN is allowed.
	ERR	Entry Review Requested	indicator only	ERR is just used as an indicator, no data will follow
	FAP	Food Additive Petition Approval Number	6N	If Government Agency Program Code = “FOO” and Government Agency Processing Code = “ADD”, then FAP is allowed.
	FCC	French Cheese Facility Certification Number	9X or 10X	If Government Agency Program Code = “FOO” and Government Agency Processing Code = “PRO”, then FCC is allowed. If length = 9, then the format should be ‘NN NNN NN’; if length = 10, then the format should be ‘NN NNN NNN’.
	IBP	Indian Black Pepper Certificate	text	If Government Agency Program Code = “FOO”, then IBP is allowed.
	IFE	Import For Export	indicator only	
	PKC	Package/Can Code		If Government Agency Program Code = “FOO”, then PKC is allowed.
	AIN	Food Additive Identification Number	6N or 8N or E+7N	If Government Agency Program Code = “FOO” and Government Agency Processing Code = “ADD”, then AIN is allowed.
	JIF	Juice HACCP Importer Firm	1-10N	If Government Agency Program Code = FOO and the product is HACCP, then JIF is allowed.
	SIF	Seafood HACCP Importer Firm	1-10N	If Government Agency Program Code = FOO and the product is HACCP, then SIF is allowed.
	VQI	Voluntary Qualified Importer	5N	Approved VQIP Application Number Syntax is 5N
	REG	Animal Drug Establishment Registration Number	9N	If Government Agency Program Code =”FOO” and Government Agency Processing Code = “FEE”, then REG is allowed.
	VFL	Medicated Feed Mill License (MFL)	7X	If Government Agency Program Code =”FOO” and Government Agency Processing Code = “FEE”, then VFL is allowed.

Data Element	Code	Description	Syntax	Business Rules
	VFD	Veterinary Feed Directive	Indicator Only	If Government Agency Program Code =”FOO” and Government Processing Code = “FEE”, then VFD is allowed.

Table 9-22: Food Combined Entry AoC Codes (Optional)

§ When AoC codes are entered on the PG23 record for Entity Role Codes MF/FDC/DFI in PG19, then only a PFR or FME shall be used along with MF; only a GFR may be used in conjunction with DFI; and only a CFR may be used in conjunction with FDC.

Note 3
Using the FDA Product Code in PG02, the following classifications are made where specific imported food/feed products require the submission of lot or code numbers or other identifier with prior notice. These include:

LACF and Acidified:

LACF: Industry Codes: 02-05, 07, 09, 12-18, 20-39, 41, 71, & 72 with PIC: **F** (Aseptic) and **E** (Commercially Sterile)
AF: Industry Codes: 02-05, 07, 09, 12-18, 20-39, 41, 71, & 72 with PIC: **I** (Acidified)

If the product is Low-Acid Canned Food (LACF) or Acidified Food (AF), both the AoC codes, FCE and SID must be provided; additionally, one of the following must be provided:

1. Container Measurements in PG28 **OR**
2. Container Volume AoC code VOL

9.14 Record Identifier PG24 (Remarks)

Optional | Not Repeatable per PGA Line

This is an optional PGA input record that provides data pertaining to Remarks Type Code and Remarks Text.

PG24 cannot be repeated and only one PG24 is allowed for the same FDA line.

If entered, the Remarks Type Code should be GEN and must be under the PG02.

Currently, FDA processes PG24 record only at the Product-level (when under a PG02).

Record Identifier PG24 (Remarks)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"24"	
Remarks Type Code	3X	5-7	C	FDA uses only "GEN" as its valid value.	
Remarks Text	68X	13-80	C	Free form text relevant to the shipment or the commodity.	

Table 9-23: Food Combined Entry PG24

9.15 Record Identifier PG25 (Product Condition)

Conditional | Repeatable per PGA Line

This is a conditional PGA input record that provides data pertaining to Temperature Qualifier, Lot Number, and PGA Line Value. Lot Numbers are required by FDA regulations for Infant formula, Acidified Foods, and LACF products. This record is repeatable for multiple Lot Numbers and the PGA Line Value may be included on the first PG25 record.

Record Identifier PG25 (Product Condition)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"25"	
Temperature Qualifier	1A	5	O	Temperature Category being reported for quality control or preservation purposes. A=Ambient, F=Frozen, D=Dry Ice, R=Refrigerated/Chilled, H=Fresh, U=Uncontrolled, P=Flashpoint	
Lot Number Qualifier	1N	15	C	Code of the entity that assigned the Lot number. 1=Manufacturer and 3=Grower. If Government Agency Program Code = "FOO" and Government Agency Processing Code = "NSF" then Lot Number Qualifier=3 else Lot Number Qualifier=1 In the case of multiple PG25 records for a given FDA line, enter Lot Number Qualifier only in the first PG25 record.	
Lot Number	25X	16-40	C	The lot number that the manufacturer assigned to the product. Mandatory for Infant formula, Acidified Foods, and LACF products. Required, if more than one PG25 record is entered.	1
PGA Line Value	12N	57-68	O	Although Line Value is optional, transmitting the value will assist in reviewing the product in a timely manner. Failure to transmit the value may result in delays associated with gathering missing information. If entered: • in the case of multiple PG25 records, enter value only in the first PG25 record • value should be in US Dollars, and enter whole dollars only • must be greater than zero and right justified with preceding zeros	

Table 9-24: Food Combined Entry PG25

Note 1
Using the FDA Product Code in PG02, the following classifications are made where specific imported food/feed products require the submission of lot or code numbers or other identifier with prior notice. These include:

LACF and Acidified:

LACF: Industry Codes: 02-05, 07, 09, 12-18, 20-41, 71, & 72 with PIC: **F** (Aseptic) and **E** (Commercially Sterile)
AF: Industry Codes: 02-05, 07-09, 12-18, 20-41, 71, & 72 with PIC: **I** (Acidified)

Infant Formula:

Industry Code: 40
With Class:

- C-Formula Prod (Baby)
- N-Ready to Feed Formula Product
- O-Liquid Concentrate Formula Product
- P-Powder Formula Products
  R-Infant Formula for Sample Testing (not for sale)

9.16 Record Identifier PG26 (Product Packaging)

Mandatory | Repeatable per PGA Line

This is a mandatory PGA input record that provides FDA with data pertaining to Packaging Qualifier, Quantity and Unit of Measure. If included, the following rules apply:

This record can be repeated up to six (6) times, once for each unique packaging level. The first record is used to describe the largest (outermost) container and the number of containers at this packaging level. The second record is used to describe the contents of the next smallest container. If needed, qualifiers 2-6 are used in a similar manner (largest to smallest container). The final record must describe the actual amount of the product in the smallest container.

The appearance of any 'Packaging Qualifier' number level requires all levels under it to be represented. For instance, level 3 cannot be present unless levels 1 and 2 are present.

Record Identifier PG26 (Product Packaging)					
Data Element	**Length/Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"26"	
Packaging Qualifier	1N	5	M	This code identifies the level of packaging for the product. Outermost (largest=1) packages to the innermost (smallest=6) packages. There can be up to 6 levels of packaging. If reporting only one level, show the total quantity for the item and report that as level 1.	1, 4
Quantity	12N	6-17	M	Quantity of the packaging level, For example, 000000000400. Two decimal places are implied. Must be greater than zero. **Transmitting Quantity requires transmitting Packaging Qualifier and the Unit of Measure. Last unit transmitted must be a base unit and only one base unit is allowed.**	2, 4
Unit of Measure (Packaging Level)	5X	18-22	M	Type of packaging / packaging level. For example, BX. Cannot be repeated among the PG26 records. **Last unit transmitted must be a base unit and only one base unit is allowed.**	3, 4

Table 9-25: Food Combined Entry PG26

Note 1
This code identifies the level of packaging for the product. Valid values are 1, 2, 3, 4, 5 and 6: Outermost (largest=1) packages to the innermost (smallest=6) packages. There can be up to 6 levels of packaging.

Note 2
There are two implied decimal points when writing the quantity in Units of Measure for all packaging levels. In this example, 4 pieces are represented as 000000000400, with the nine leading zeroes as "fill" and two decimal places following the value.

Note 3
List of Unit of Measure codes applicable to FDA-Food Message Sets
For a full list of applicable Unit of Measure codes, refer to Appendix D: FDA Unit of Measurement Codes or to the CBP's ACE CATAIR Appendix PGA (PG26 – Unit of Measure - Valid FDA Units of Measure for Packaging Containers and PG26 – Unit of Measure -Valid FDA Units of Measure for the Base Unit (Last Quantity Transmitted)). Valid FDA Food Units of Measure (UoM) for Packaging Containers is noted below:

Code	Description
AE	Aerosol
AM	Ampoule, Non-Protected
AP	Ampoule, Protected
AT	Atomizer
BA	Barrel (Container)
BB	Bobbin
BC	Bottle crate, Bottle rack
BE	Bundle
BF	Balloon, Non-Protected
BG	Bag
BH	Bunch
BI	Bin
BJ	Bucket
BK	Basket
BL	Bale, Compressed
BN	Bale, Non-Compressed
BO	Bottle, Non-Protected, Cyl
BP	Balloon, Protected
BQ	Bottle, Protected, Cylnd
BR	Bar
BS	Bottle, Non-Prot Bulbous
BU	Butt
BV	Bottle, Protected Bulbous
BX	Box
BZ	Bars in Bundle/Bunch/Trus
CA	Can, Rectangular
CAG	Cage
CB	Crate, Beer
CC	Churn
CE	Creel
CF	Coffer
CH	Chest
CI	Canister
CJ	Coffin
CK	Cask
CL	Coil

Code	Description
CO	Carboy, Non-Protected
CON	Container
CP	Carboy, Protected
CR	Crate
CS	Case
CT	Carton
CU	Cup
CV	Cover
CX	Can, Cylindrical
CY	Cylinder
CZ	Canvas
DJ	Demijohn, Non-Protected
DP	Demijohn, Protected
DR	Drum
EN	Envelope
FC	Crate, Fruit
FD	Crate, Framed
FI	Firkin
FL	Flask
FO	Footlocker
FR	Frame
GB	Bottle, Gas
HG	Hogshead
HR	Hamper
JC	Jerri can, Rectangular
JG	Jug
JR	Jar
JT	Jute bag
JY	Jerri can, Cylindrical
KEG	Keg
KIT	Kit
MB	Bag, Multi-ply
MC	Crate, Milk
MS	Sack, Multiwall
MT	Mat
NE	Unpacked or Unpackaged
NS	Nest
NT	Net
PA	Packet
PAL	Pallet
PC	Parcel

Code	Description
PH	Pitcher
PK	Package
PL	Pail
PO	Pouch
PT	Pot
PU	Tray or Tray Pack
PY	Plates in Bndl/Bnch/Truss
RG	Ring
RO	Roll
SA	Sack
SC	Crate, Shallow
SD	Spindle
SE	Sea-chest
SH	Sachet
SK	Case, Skeleton
SL	Slipsheet
SU	Suitcase
SW	Shrinkwrapped
SZ	Sheets in Bndl/Bnch/Truss
TB	Tub
TC	Tea-Chest
TD	Tube, Collapsible
TK	Tank, Rectangular
TN	Tin
TO	Ton
TR	Trunk
TS	Truss
TU	Tube
TY	Tank, Cylindrical
TZ	Tubes in Bndl/Bnch/Truss
VA	Vat
VG	Bulk Gas at 1031 MBAR
VI	Vial
VL	Bulk Liquid
VO	Bulk, Solid, Lg Particles
VP	Vacuum-packed
VQ	Bulk Liquefied Gas
VR	Bulk, Solid, Granular Parti
VY	Bulk, Solid, Fine Particle
WB	Wickerbottle

Table 9-26: Food Combined Entry UoM for Packaging Containers

Valid FDA Food Units of Measure for the Base Unit (Last Quantity Transmitted) is noted below:

Code	Description	Measure Type
BBL	Barrels (42 Gallons Ea)	Volume
BOL	Boluses	Dosage
CAR	Carats	Weight
CAP	Capsules	Dosage
CFT	Cubic Feet	Volume
CG	Centigrams	Weight
CM3	Cubic Centimeters	Volume
CYD	Cubic Yards	Volume
DOZ	Dozen	Count
DPC	Dozen Pieces	Count
DPR	Dozen Pairs	Count
FOZ	Ounces, fluid	Volume
G	Grams	Weight
GAL	Gallons (US)	Volume
GR	Gross	Count
KG	Kilograms	Weight
KM3	1,000 Cubic Meters	Volume
L	Liters	Volume
LB	Pounds (avdp)	Weight
M3	Cubic Meters	Volume
MCG	Micrograms	Weight
MG	Milligrams	Weight
ML	Milliliters	Volume
NO	Number	Count
OZ	Ounces, (avdp)	Weight
PCS	Pieces	Count
PRS	Pairs	Count
PTL	Pints, liquid (US)	Volume
QTL	Quarts, liquid (US)	Volume
STN	Short ton (2000 LB)	Weight
T	Metric Ton	Weight
TAB	Tablets	Dosage
TON	Long Ton (2240 LB)	Weight
TOZ	Ounces, Troy or Apoth	Weight

Table 9-27: Food Combined Entry UoM for Base Unit

Note 4

Quantity Data provides additional information to FDA about the product and how it is packaged. The basic format for Quantity Data is in multiple pairs of data – quantity and unit of measure, i.e., 500 cases, 12 ounces, fluid, 1000 cartons, etc. Up to 6 data pairs may be submitted, beginning with the 1st pair for the outermost packaging when Packaging Qualifier = 1. The first pair may describe the largest container and the last pair must describe the amount of product in the smallest container.

For example:

Product: 1000 cases of mineral water, 24/12 ounce bottles in each case

Units 1-Quantity	1000
Units 1-Measure	CS
Units 2-Quantity	24
Units 2-Measure	BO
Units 3-Quantity	12
Units 3-Measure	FOZ (Last packaging level transmitted must include a base unit).

9.17 Record Identifier PG27 (Shipping Container Information)

Conditional | Repeatable per PGA Line

This is a conditional PGA input record that provides data pertaining to the Shipping Container Number. Data provided should match the Container Number info included on the Bill. This record is repeatable.

Record Identifier PG27 (Container Information)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"27"	
Container Number (Equipment ID)	20AN	5-24	C	The number of the shipping container as entered on the Bill based on the Mode of Transportation (MOT). This is applicable for food arriving as containerized cargo by water, air, rail, or land; the container number(s) is required for prior notice.	
Container Number (Equipment ID)	20AN	28-47	C	The number of the shipping container as entered on the Bill based on the Mode of Transportation (MOT). This is applicable for food arriving as containerized cargo by water, air, rail, or land, the container number(s) is required for prior notice.	
Container Number (Equipment ID)	20AN	51-70	C	The number of the shipping container as entered on the Bill based on the Mode of Transportation (MOT). This is applicable for food arriving as containerized cargo by water, air, rail, or land, the container number(s) is required for prior notice.	
Filler	7X	74-80	M	Space fill	

Table 9-28: Food Combined Entry PG27

9.18 Record Identifier PG28 (Express Courier Tracking Number and Container Dimensions for AF and LACF)

Conditional | Not Repeatable per PGA Line

For Combined Food submission, Acidified and Low Acid Canned Food (LACF) is a conditional PGA input record that provides data pertaining to reporting Container Dimensions for the Food and Drug Administration. Either the container dimensions or the container volume must be provided, and the measurement type should reflect what is filed in the scheduled process. For Prior Notice if the Mode of Transportation is mail or express courier, then Package Tracking Number Code and Package Tracking Number are conditionally required, on the PG28 record in lieu of the airway bill or bill of lading and in lieu of the flight number in PG23.

Record Identifier PG28 (Express Courier Tracking and Container Dimensions – AF and LACF)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"28"	
Container Dimensions #1	4N	5-8	C	The first dimension of the container. If the container is rectangle, the dimension is in width, height, and length order. If the container is cylindrical, the dimensions are in diameter and height order. Container dimension information is restricted to use with acidified and low acid canned foods. The first two spaces are inches. The second two positions are in 16ths.	1, 2
Container Dimensions #2	4N	9-12	C	The second dimension of the container. If the container is rectangle, the dimension is in width, height, and length order. If the container is cylindrical, the dimensions are in diameter and height order. The first two spaces are inches. The second two positions are in 16ths.	1, 2
Container Dimension #3	4N	13-16	C	The third dimension. If the container is rectangle, the dimension is in width, height, and length order. The first two spaces are inches. The second two positions are in 16ths.	1, 2
Package Tracking Number Code	4AN	17-20	C	Enter SCAC/IATA for Express Consignment Carrier/Courier. For those express consignment carriers without a SCAC or IATA, leave blank & enter carrier name in PG23	3
Package Tracking Number	50AN	21-70	C	Tracking numbers used by Express Consignment Carrier	3

Table 9-29: Food Combined Entry PG28

Note 1
IF Government Agency Program Code = "FOO" and
If the product is Low-Acid Canned Food (LACF) or Acidified Food (AF), one of the following must be provided (whichever measurement type is provided should reflect what is in the scheduled process on file with FDA)

1. Container Measurements in PG28 (either height and diameter or height/length, width and thickness **OR**
2. Container Volume (VOL) in PG23

Note 2
If the container is rectangular, the dimensions are in width, height & length order. Each dimension is expressed as a four-digit number. The first 2 digits give the number of whole inches. The next two digits give the additional fraction of the dimension expressed as sixteenths of an inch.

E.g. 1404 x 0800 x 0608 represents 14 4/16" width, 8" height and 6 8/16" length.

If the container is cylindrical the dimensions are in diameter & height order. Each dimension is expressed as a three-digit number. The first digit gives the number of whole inches. The next two digits give the additional fraction of the dimension expressed as sixteenths of an inch.

E.g. 300 x 108 represents 3” diameter & 1 8/16” height.

If the article of food is arriving by express consignment operator or carrier a tracking number may be submitted in lieu of the Airway Bill number(s) or Bill of Lading number(s), and in lieu of the flight number in PG23.

9.19 Record Identifier PG30 (Anticipated Arrival Information and Port of Arrival / Entry)

Mandatory | Not Repeatable per PGA Line

This is a mandatory PGA input record that provides data pertaining to the date, time and location of the anticipated arrival/entry information for all FDA products.

For each line a PG30 record with an "A" (Anticipated arrival information) status code, date, time and location of arrival is mandatory.

Record Identifier PG30 (Anticipated Arrival Information and Port of Arrival / Entry)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"30"	
Anticipated Arrival Information	1A	5	M	A = Anticipated arrival information.	1
Anticipated Arrival Date at Port of Arrival	8N	6-13	M	A numeric date in MMDDCCYY (month, day, century, year) format.	1
Anticipated Arrival Time at Port of Arrival	4N	14-17	M	Military time HHMM in (hour, minute) format. (Example: 1015, this represents 10:15 a.m.). For midnight, use 2400 (0000 is invalid).	1
Anticipated Arrival Location Code	4AN	18-21	M	Location type code from CBP's ACE CATAIR Appendix PGA; only the value of 2 (= Schedule D Port codes) is allowed.	
Anticipated Port of Arrival	50X	22-71	M	For valid port codes, refer to note 2.	2
Filler	8X	72-80	M	Space fill	

Table 9-30: Food Combined Entry PG30

Note 1
For PN shipments, A = Anticipated Arrival Date and Time at the Anticipated Port of Arrival.

Port of Arrival:
21 CFR 1.276 (b)
(11) **Port of arrival** means the water, air, or land port at which the article of food is imported or offered for import into the United States. For an article of food arriving by water or air, this is the port of unloading. For an article of food arriving by land, this is the port where the article of food first crosses the border into the United States. The port of arrival may be different than the port where consumption or warehouse entry or foreign trade zone admission documentation is presented to the U.S. Customs and Border Protection (CBP).

Note 2
Refer to list of valid Port Codes in https://www.cbp.gov/sites/default/files/assets/documents/2020-Jan/ACE%20Appendix%20E%20Schedule%20D%20January%202020%20%281%29.pdf

9.20 Record Identifier PG55 (Additional Entity Roles)

This is an optional PGA input record used to provide additional roles performed by an entity or individual.

Not supported by FDA at this time

Currently, the PG55 record is not supported by FDA. Multiple PG19 records should be used to input more than one Entity-Role combination. Refer to the PG19 section for details.

Record Identifier PG55 (Additional Entity Roles)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"55"	
Entity Role Code	3AN	5-7	O	Additional role of the entity.	
Entity Role Code	3AN	8-10	O	Additional role of the entity.	
Entity Role Code	3AN	11-13	O	Additional role of the entity.	
Entity Role Code	3AN	14-16	O	Additional role of the entity.	
Entity Role Code	3AN	17-19	O	Additional role of the entity.	
Entity Role Code	3AN	20-22	O	Additional role of the entity.	
Entity Role Code	3AN	23-25	O	Additional role of the entity.	
Entity Role Code	3AN	26-28	O	Additional role of the entity.	
Entity Role Code	3AN	29-31	O	Additional role of the entity.	
Entity Role Code	3AN	32-34	O	Additional role of the entity.	
Filler	46X	35-80	M	Space fill	

Table 9-31: Food Combined Entry PG55

9.21 Record Identifier PG60 (Additional Information)

Optional | Repeatable per PGA Line

This is an optional PGA input record used to provide additional information about data in the PG record that precedes it during the submission of a PGA record set.

This record can follow a PG07, PG19, PG20 or PG21 record, and can only be used to provide the additional information noted by the Additional Information Qualifier Code list.

This record may be repeated.

Record Identifier PG60 (Additional Information)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"60"	
Additional information qualifier code	3AN	5-7	C	Code indicating the type of additional information being provided	1
Additional Information	73X	8-80	C	Text of the additional information related to the additional reference qualifier code	

Table 9-32: Food Combined Entry PG60

Note 1
Valid PG60 Additional Information Qualifier Codes applicable to FDA Message Set are:

Code	Description
ENA	Continuation of Entity Name for PG19
AD1	Continuation of Entity address Line 1 for PG19
AD2	Continuation of Entity address Line 2 for PG20
AD3	Entity address Line 3 for PG20
AD4	Entity address Line 4 for PG20
AD5	Entity address Line 5 for PG20
ECI	Continuation of Entity City for PG20
INA	Continuation of Individual Name for PG21
EMA	Continuation of Email Address for PG21
TBN	Continuation of Trade/Brand Name for PG07

Table 9-33: Food Combined Entry PG60 Additional Information Qualifier Codes

PG60 record should follow immediately after its parent. For example, a PG60: ENA record should follow PG19 and a PG60: TBN record should follow PG07.

9.22 Record Identifier PG00 (Data Substitution)

This is an optional record used at the CBP entry (or entry summary) header, CBP entry (or entry summary) line and/or PGA message set levels to indicate data substitution.

PG00 Substitution Grouping
In situations where the trade finds it would be supplying identical information more than once within the PGA Message Set, a PG00 substitution grouping can be used, instead of repeating that information multiple times. Refer to the 'usage notes' in the ACE ABI CATAIR - Customs and Trade Automated Interface Requirements publication for detailed information.

Record Identifier PG00 (Data Substitution)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"00"	
Substitution Indicator	1X	5	O	Identifies either the start or end of the substitution group, or the location of where to place the substitute data within the PGA Message Set. The following codes are allowed: S=Start of the substitution group E=End of the substitution group R=Replace this record with the substitution group indicated by the Substitution Number	
Substitution Number	4AN	6-9	O	Sequential number assigned to, or referring to, a specific substitution group of data provided at the header level. This data element is mandatory when using the S or R substitution indicator.	
Filler	71X	10-80	M	Space fill	

Table 9-34: Food Combined Entry PG00

10 Non-PN Food Commodity OR PN Requirements Previously Met - Data Elements and Values

This chapter describes the data elements and their business rules for an 801(a) entry for Food, with the Government Agency Program Code = "FOO", which either may not be subject to PN regulations or may have already satisfied PN data requirements. To show that the PN requirements were already satisfied, a PG14 record with the PN Confirmation Number may be included in the PG Message Set in addition to all applicable PG records described in this chapter.

In this scenario 801(a) data elements may be submitted with a PG14 record including the Prior Notice Confirmation Number or if the Government Agency Processing Code is CCW or if food is withdrawn from a Foreign Trade Zone (FTZ). Prior Notice Confirmation Number in PG 14 is not always required. Food commodities can be broken down into the following categories using the existing Government Agency data elements available in the PG01 message

PG01 - Government Agency Code	Commodity Type	PG01 - Government Agency Program Code	Commodity Sub-Type	PG01 - Government Agency Processing Code
FDA	Food	FOO	Natural State Food	NSF
FDA	Food	FOO	Processed Food	PRO
FDA	Food	FOO	Animal Food (includes pet food, medicated feed and feeds)	FEE
FDA	Food	FOO	Additives and Colors	ADD
FDA	Food	FOO	Dietary Supplements	DSU
FDA	Food	FOO	Ceramicware and other food contact substances	CCW

Table 10-1: Non-PN Food Commodity Hierarchy

The following are the potential PGA records associated with submitting Foods:

PG Record	Description
PG01	FDA program that regulates the product
PG02	Item Type and Product Code details
PG06	Source Type(origin) other than the CBP country of origin is provided
PG07	Product Trade/Brand Name
PG10	Product Description (Line level Item Common/Usual/Market Name Description)
PG14	PN Confirmation Number previously filed to meet 801(m) prior notice requirements
PG19	Entity Role (manufacturer, consignee, shipper, etc.) Entity Identification, Entity Name, and Entity Address 1
PG20	Additional address data on the entity in PG19(Address line 2, Apartment/Suite, City, State, and Zip/Postal Code).
PG21	Entity of Record's (manufacturer, shipper, etc.) individual point of contact, phone number and email.
PG23	FDA's Affirmation of Compliance Criteria
PG24	Remarks
PG25	Temperature Qualifier, Lot Number Qualifier, Lot Number, PGA Line Value
PG26	Packaging Qualifier and Quantity of shipment
PG27	Container Number
PG28	Container Dimensions (LACF and AF Only)
PG30	Date, time and location of anticipated arrival information
PG55	Additional roles performed by entity or individual (future use)
PG60	Additional Information following a PG07, PG19, PG20 or PG21
PG00	Data Substitution

Table 10-2: Non-PN Food or PN Requirements Previously Met PGA Records

10.1 Food Example

Food message set layout sample below:

Refer to the external file: **FDA SG Example PG Message Sets** **Tab:** ***FOO+PNC***

PGA Records and Data Elements required are dependent on the agency program and processing code selected. For a more expansive set of examples of FDA PGA Message Sets, refer to the above document.

10.2 Record Identifier PG01 (PGA Identifier)

Mandatory | Not Repeatable per PGA Line

This is a mandatory PGA input record that provides data pertaining to the PGA Line Number, Government Agency Code, Government Agency Program Code, Government Agency Processing Code, Intended Use Code, Intended Use Description, and Disclaimer.

Record Identifier PG01 (PGA Identifier)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description/Required Value**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"01"	
PGA Line Number	3N	5-7	M	Begin with "001" and sequentially increment the line number on subsequent PG01 records, if applicable.	
Government Agency Code	3AN	8-10	M	"FDA"	
Government Agency Program Code	3X	11-13	C	"FOO"	1, 2
Government Agency Processing Code	3AN	14-16	C	Allowed values: NSF, PRO, FEE, ADD, DSU, CCW	1, 2
Intended Use Code	16X	42-57	O	Refer to the table below for valid optional values.	3, 4
Intended Use Description	21X	58-78	O	N/A for FDA lines.	
Correction Indicator	1X	79	O	For future use	
Disclaimer	1A	80	C	"A" (= product is not regulated by this agency) indicating there is no agency declaration requirement. Leave it blank for no disclaimer. "F" indicating that the product is manufactured in any state of the US, the District of Columbia, or Puerto Rico and sourced directly to the warehouse without ever leaving the US. **May only be used for FDA on Entry Type 21**. No other codes are accepted	

Table 10-3: Non-PN Food or PN Requirements Previously Met PG01

Note 1
Refer to Table 10-1 above for commodity type and sub-type for Food Non-PN.

Note 2
If the product is to be disclaimed, then these data elements should both be populated with 'FDA'. Otherwise the Government Agency Program Code and Government Agency Processing Code are mandatory.

Note 3
CBP publication, Appendix R - Intended Use Codes for ACE, provides general descriptions of all Intended Use Codes for all Partner Government Agencies (PGAs). For FDA regulated products, use the IUC descriptions as specified per commodity throughout this document. See Appendix E for a mapping of FDA IUC descriptions to CBP Appendix R IUC descriptions. The submission of an Intended Use Code is not a requirement for foods and food contact surfaces. If providing an Intended Use Code, the following are the applicable options:

FDA Import Scenario	Intended Use Code	CBP Intended Use Name
For Research Use as Human Food	260.000	For Research Use as Human Food
For Research Use as an Animal Food	015.000	For Research Use as an Animal Food
Personal Importation	210.000	For Personal Use as Human Food

Table 10-4: Foods PN Requirements Previously Met Intended Use Codes

Intended Use Code	FDA Import Scenario
130.029	Chemical substance for use as a food addtitive
970.000	US Goods Returned
980.000	Import for Export

Table 10-5: Ceramicware and other food contact substances (CCW) Intended Use Codes

Note 4

If after consultation with the importer, who should know the intended use of the product, the filer still ***does not know*** the intended use of the product, "UNK" may be used in lieu of an IUC. In most cases, the line will be subject to manual review, and may result in a request for documentation and/or additional information about the product as the product offered for import will be treated as a standard import. Ensure the IUC (reason for importation) is transmitted to avoid delays. As per the ACE Rule, if "UNK" is submitted as the IUC for the article, the ACE filer is still responsible for submitting the other required data elements in this rule that are applicable to that article, at the time of entry. In the future, if those other data elements are not submitted in ACE at the time of entry, the entry may be transmitted by ACE to FDA for admissibility review, but FDA may reject the entry. If FDA rejects an entry filing, the ACE filer will need to resubmit the entry with complete and accurate information.

10.3 Record Identifier PG02 (Product Identifier)

Mandatory | Not Repeatable per PGA Line

This mandatory PGA input record is used to include information related to a product (P).

Record Identifier PG02 (Product Identifier)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"02"	
Item Type	1A	5	M	Code identifying the following records as pertaining to P=Product. No other values accepted. Only one "P" record is allowed for the same PGA Line # in PG01 record.	
Product Code Qualifier	4AN	6-9	M	FDP	1
Product Code Number	19X	10-28	M	FDA Product Code must be exactly 7 characters	

Table 10-5: Non-PN Food or PN Requirements Previously Met PG02

Note 1
Product Code Qualifiers and their descriptions can be found in CBP's ACE CATAIR Appendix PGA (PG02 – Product Code Qualifiers). For FDA filings, the Product Code Qualifier is always "FDP".
Only one Product Code Number is allowed per line.

FDA Product Code Structure

Position	1-2	3	4	5	6-7
Name	Industry Code (N)	Class Code (AN)	Subclass Code (A or '-')	Process Indicator Code - PIC (A or '-')	Product (AN)

Legend - N: Numeric; A: Alphabetic; AN: Alphanumeric

Table 10-6: Non-PN Food or PN Requirements Previously Met FDA Product Code Structure

IF Government Agency Program Code = "FOO" and Government Agency Processing Code = "CCW"
THEN Industry Code = 52 and Class Code = ('A', 'B', 'E', or 'Y')

If Class Code is 'B', 'E' or 'Y' under Industry Code 52, the only allowable Subclass Code and Process Indicator Code (PIC) is 'Y'.

10.4 Record Identifier PG06 (Product Origin)

Mandatory | Repeatable per PGA Line

For food filings not subject to PN regulations or PN requirements previously met, this is a mandatory PGA input record that provides data pertaining to Source Type (Origin) other than the CBP Country of Origin.

Record Identifier PG06 (Product Origin)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"06"	
Source Type Code	3AN	5-7	M	IF Government Agency Program Code = "FOO" and natural state food/feed THEN use 262 (Place of growth) ELSE use 39 (Country of Production). Code 294 may be used to indicate a country has previously refused the line items.	1
Country Code	2X	8-9	M	Foods require the harvesting or production location of the product.	2

Table 10-7: Non-PN Food or PN Requirements Previously Met PG06

Note 1
Source Type Codes and their descriptions can be found in CBP's ACE CATAIR Appendix PGA (PG06 – Source Type Codes).

Note 2
Any of the country codes from CBP's ACE CATAIR Appendix B (Section: Country and Currency Codes) can be entered.

10.5 Record Identifier PG07 (Product Trade Names)

Optional | Not Repeatable per PGA Line

This is an optional PGA input record that provides data pertaining to Trade or Brand Name.

Record Identifier PG07 (Product Trade Names)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"07"	
Trade Name/Brand Name	35X	5-39	O	Trade, or Brand Name that describes the food or feed product at each line level. If Trade/Brand Name requires additional space, continue in a PG60 record with Qualifier Code "TBN".	

Table 10-8: Non-PN Food or PN Requirements Previously Met PG07

10.6 Record Identifier PG10 (Product Characteristics)

Mandatory | Not Repeatable per PGA Line

This is a mandatory PGA input record that allows for reporting the description of the product identified by the Product Code in PG02.

Record Identifier PG10 (Product Characteristics)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"10"	
Commodity Characteristic Description	57X	24-80	M	Common, market, usual name; free form invoice description; not product code description. For examples, see Appendix A: Use of PG10 Record.	

Table 10-9: Non-PN Food or PN Requirements Previously Met PG10

10.7 Record Identifier PG14 (PN Confirmation Number)

Conditional | Not Repeatable per PGA Line

For food filings with PN requirements previously met, the *Prior Notice Confirmation Number* information is required.

If declaring FTZ in PG30 for Entry Type 21 OR the Government Agency Processing Code is CCW, this record is not needed.

Record Identifier PG14 (PN Confirmation Number)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	”PG”	
Record Type	2N	3-4	M	”14”	
Transaction Type	1N	5	C	Identifies the transaction type. 1 = single use	1
Code Type	3AN	6-8	C	Identifies Type Codes for PN Confirmation Number PN Confirmation Number = PNC	1
PNC Number	33X	9-41	C	Identifies the number that corresponds to the *PN Confirmation number* Prior Notice Confirmation Number is a 12-digit number (12N)	1

Table 10-10: Non-PN Food or PN Requirements Previously Met PG14

Note 1
Prior notice must be submitted before arrival and admission into an FTZ, prior notice is not required when the food is withdrawn from the FTZ, either as an export or for use within the U.S. However, if the food is withdrawn from the FTZ for consumption entry into the U.S., FDA must be notified and will make the admissibility decision about the consumption entry at that time.

10.8 Record Identifier PG19 (Entity Data)

Mandatory | Repeatable per PGA Line

For food filings, not subject to PN regulations or PN requirements previously met, this is a mandatory PGA input record requiring Entity Role, Entity Name, and Entity Address 1.

Entity Identification Code [16 (DUNS #), 47 (FEI #)] and Entity number are optional data elements, but they are listed as conditional because if opting to transmit Entity Identification Code, then Entity Number must also be provided, and vice versa.

Record Identifier PG19 (Entity Data)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"19"	
Entity Role Code	3AN	5-7	M	Code identifying the role of the entity being provided. For example: MF, DP. Each entity role code can only be transmitted once per PGA line.	1
Entity Identification Code	3AN	8-10	C	Code identifying the Entity Identification is entered. For example: 16 (DUNS #), 47 (FEI #). Mandatory, if Entity Number is entered.	2
Entity Number	15X	11-25	C	Identifying Number (DUNS or FEI) for the associated Entity Identification Code. Mandatory if Entity Identification Code is provided.	2
Entity Name	32X	26-57	M	The name of the entity is required. If Entity Name requires additional space, continue in a PG60 record with Qualifier Code "ENA".	2
Entity Address 1	23X	58-80	M	The address of the entity is required. If Entity Address1 requires additional space, continue in a PG60 record with Qualifier Code "AD1".	1

Table 10-11: Non-PN Food or PN Requirements Previously Met PG19

Note 1
List of Entity Role codes that are mandatory to FDA Message Sets is noted below:

Data Element	**Code**	**Description**
Entity Role Codes	MF	Manufacturer of goods
	DEQ	Shipper
	FD1	FDA Importer (Importer of Record)
	DP	Delivered-To Party

Table 10-12: Non-PN Food or PN Requirements Previously Met Entity Role Codes (Mandatory)

List of Entity Role codes that are conditional to FDA Food Message Sets is noted below:

Data Element	Code	Description	Condition
Entity Role Codes	FSV	Foreign Supplier Verification Program Importer	The following data elements relate to the Foreign Supplier Verification Program (FSVP). If GOVT Agency program code is FOO and processing code is ADD, DSU, FEE, NSF, or PRO, then the following FSVP-related details are mandatory for all FDA FOO lines, except if PG02 Industry Code = 16 or 32 OR PG23 AofC FSX or RNE is present: 1. DUNS#, Firm Name, Firm Address1 are required in PG19; 2. All the elements, except Apt#, are required in PG20 AND 3. PG20 Country = US and PG20 State can only be 50 US States, DC and PR 4. Qualifier Code=FSV and email address are required in PG21; individual's name and telephone number are optional in PG21.

Table 10-13: Non-PN Food or PN Requirements Previously Met Entity Role Codes (Conditional)

Note 2
Entity Identification Codes and their descriptions can be found in CBP's ACE CATAIR Appendix PGA (PG19 – Entity Identification Codes). List of Entity Identification codes applicable to FDA Food Message Sets is noted below:

Data Element	Code	Description	Length/ Class
Entity Identification Codes	16	D&B-assigned (DUNS number); must be 9 digits	9N
	47	FDA-assigned (FEI number); must be from 1 to 10 digits	1 -10N

Table 10-14: Non-PN Food or PN Requirements Previously Met Entity Identification Codes

List of Entity Role codes that are optional FDA Message Sets is noted below:

Data Element	Code	Description
Entity Role Codes	PK	Point of Contact (Filer/Broker Contact Information)

Table 10-15: Non-PN Food or PN Requirements Previously Met Entity Role Codes

IF Entity Identification Code =16 (DUNS) THEN Entity Number must be Length = 9 and Type = N
ELSE IF Entity Identification Code =47 (FEI) THEN Entity Number must be Length from 1 to 10 and Type = N

10.9 Record Identifier PG20 (Entity Address)

Mandatory | Repeatable per PGA Line

This is a mandatory PGA input record that provides additional data pertaining to the Entity identified in the preceding PG19 record; such as Entity Address line 2, Apartment/Suite, City, State, and Zip/Postal Code. This record is used when there is additional address information for the entity.

Record Identifier PG20 (Entity Address)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"20"	
Entity Address 2	32X	5-36	C	Address Line 2 for the Entity. If Entity Address2 requires additional space, continue in a PG60 record with Qualifier Code "AD2".	1
Entity Apartment Number/Suite Number	5X	37-41	C	For example, 102 A.	
Entity City	21X	42-62	M	For example, SUGARLAND. If Entity City requires additional space, continue in a PG60 record with Qualifier Code "ECI".	
Entity State/Province	3AN	63-65	C	Refer to CBP's ACE CATAIR Appendix B for valid codes.	2, 3
Entity Country	2A	66-67	M	Refer to CBP's ACE CATAIR Appendix B for valid codes.	4
Entity Zip/Postal Code	9X	68-76	C	For example, 77004.	2
Filler	4X	77-80	C	Space fill	

Table 10-16: Non-PN Food or PN Requirements Previously Met PG20

Note 1
If the Entity requires more than 2 address lines, use the optional PG60 records with Qualifier Codes "AD3", "AD4" and "AD5" immediately under the PG20 record for the same Entity.

Note 2
Required for US or Canada based entities

Note 3
If PG19 Entity Role Code = FSV, Entity State/Province can only be 50 US States, DC and PR

Note 4
If PG19 Entity Role Code = FSV, Entity Country must be US

10.10 Record Identifier PG21 (Point of Contact)

Mandatory | Repeatable per PGA Line

This is a mandatory PGA input record that provides point of contact information.

For FDA lines with processing code CCW (ceramic ware and other food contact surfaces), at least one PG21 is required with the individual qualifier "FD1" (sent with the preceding PG19FD1 and PG20FD1 records).

For other processing codes, an optional PG21 with the individual qualifier "FD1" may be included with the preceding PG19FD1.

A conditional PG21 with the individual qualifier "FSV" may be transmitted with the preceding PG19FSV and PG20FSV.

FDA also highly encourages the transmission of PG21 with the individual qualifier "PK" which should be the point of contact for the filer/broker. "PK" may be sent in one of the following ways:

1) Under a PG19PK (transmitting PG19PK, PG20PK and PG21PK for the filer), the FDA preferred method, **OR**
2) As a secondary PG21 to FD1 using individual qualifier "PK" (transmitting PG19FD1, PG20FD1, PG21FD1, and PG21PK for the filer), **OR**
3) Under any other required PG19 entity as long as "PK" is the individual qualifier in PG21.

If provided, there should be only one PK per FDA line.
Although the PK (filer/broker contact information) is optional, transmitting this information will enable FDA to expeditiously contact the filer, instead of contacting the Importer of Record. If only the Importer of Record PG21 is transmitted and PK is not, FDA processing may be delayed.

Record Identifier PG21 (Point of Contact)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"21"	
Individual Qualifier	3AN	5-7	M	Identify the type of party or facility the Individual represents. Only "FD1", "PK" and "FSV" are allowed. PG21 with qualifier code "FSV" must follow PG19 with the qualifier code "FSV". Refer to the PG19 for details of FSV (Food Supplier Verification Program).	1
Individual Name	23X	8-30	C	Name of the Individual. Optional if the Individual Qualifier = "FSV" otherwise it is mandatory. If the name will not fit, continue in a PG60 record with Qualifier Code "INA".	
Telephone Number of the Individual	15X	31-45	C	Optional if the Individual Qualifier = "FSV" otherwise it is mandatory. For example, (713)555-8765 in US or (+65)9052-3529 in Singapore	
Email Address for the Individual	35X	46-80	M	Email Address of the individual. If the Email Address exceeds in length, continue in a PG60 record with Qualifier Code "EMA".	2

Table 10-17: Non-PN Food or PN Requirements Previously Met PG21

Note 1
Entity Role Codes and their descriptions can be found in CBP's ACE CATAIR Appendix PGA (PG19 – Entity Role Codes).

Data Element	Code	Description
Entity Role Codes	PK	Point of Contact (Filer/Broker contact information).

Table 10-18: Non-PN Food or PN Requirements Previously Met Entity Role Codes

Note 2
Only transmit one valid email address as you would in an email program. Do not include names, additional characters, etc.

Valid Example	first.last@company.com
Invalid Example	<first.last@company.com>
Invalid Example	FirstName LastName first.last@company.com
Invalid Example	FirstName LastName <first.last@company.com>
Invalid Example	first.last@company.com, first.last@company.com

10.11 Record Identifier PG23 (Affirmation of Compliance)

Conditional | Repeatable per PGA Line

This is a conditional PGA input record that provides data pertaining to FDA Affirmation of Compliance Criteria. This record is repeatable, but each affirmation of compliance code can only be transmitted once.

Record Identifier PG23 (Affirmation of Compliance)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"23"	
Affirmation of Compliance Code	5X	5-9	C	A code used to affirm compliance with FDA requirements. Refer to CBP's ACE CATAIR Appendix PGA (Food & Drug Affirmation of Compliance Codes) for valid codes.	1, 2
Affirmation of Compliance Qualifier	30X	10-39	C	Text describing the information required by the PGA. For 'indicator only' AoC codes, this field is left blank. When free text is allowed, Affirmation of Compliance Qualifiers cannot exceed 30X. All other qualifiers must follow the syntax instructions for each code as specified in CBP's ACE CATAIR Appendix PGA	1, 2
Filler	1X	80	C	Space fill	

Table 10-19: Non-PN Food or PN Requirements Previously Met PG23

Note 1
The FDA Affirmation of Compliance Codes and their descriptions are listed in the Appendix PGA (Food & Drug Affirmation of Compliance, FDA Affirmation of Compliance Codes) of ACE ABI CATAIR publication.

The list of AoC codes that are conditional to FDA Food Message Sets is noted below:

Data Element	**Code**	**Description**	**Syntax**	**Business Rules**	**Note**
Affirmation of Compliance Code	FCE	Food Canning Establishment Number	5N	If Government Agency Program Code = "FOO" and the product is either LACF or AF, then AoC Code FCE must be entered.	2
	SID	Schedule Identifier Number	11N	If Government Agency Program Code = "FOO" and the product is either LACF or AF, then AoC Code 'SID' must be entered. Format: CCYYMMDDnnn.	2
	VOL	LACF/AF Volume		If Government Agency Program Code = "FOO" and the product is LACF or AF, then AoC Code VOL or Container Dimensions (PG28 for details) must be entered.	2
	FSX	Product is exempt from FSVP requirements		Indicator only. This AoC is not required for industry codes 16 and 32.	
	RNE	Product is for R&E (Research and Evaluation) therefore is exempt from FSVP requirements		Indicator only.	

Table 10-20: Non-PN Food or PN Requirements Previously Met AoC Codes (Conditional)

The list of AoC codes that are optional to FDA Message Sets is noted below:

Data Element	Code	Description	Syntax	Business Rules	Note
Affirmation of Compliance Code	CCC	Chinese Ceramic Ware Factory Code	6AN	If Government Agency Program Code = “FOO” and Government Agency Processing Code = “CCW”, then CCC is allowed.	
	CIN	Color Identification Number	text	If Government Agency Program Code = “FOO” and Government Agency Processing Code = “ADD”, then CIN is allowed.	
	ERR	Entry Review Requested	Indicator only	ERR is just used as an indicator, no data will follow	
	FAP	Food Additive Petition Approval Number	6N	If Government Agency Program Code = “FOO” and Government Agency Processing Code = “ADD”, then FAP is allowed.	
	FCC	French Cheese Facility Certification Number	9X or 10X	If Government Agency Program Code = “FOO” and Government Agency Processing Code = “PRO”, then FCC is allowed. If length = 9, then the format should be ‘NN NNN NN’; if length = 10, then the format should be ‘NN NNN NNN’.	
	AIN	Food Additive Identification Number	6N or 8N or E+7N	If Government Agency Program Code = “FOO” and Government Agency Processing Code = “ADD”, then AIN is allowed.	
	VQI	Voluntary Qualified Importer	5N	Approved VQIP Application Number Syntax is 5N	
	JIF	Juice HACCP Importer Firm	1-10N	If Government Agency Program Code = FOO and the product is HACCP, then JIF is allowed.	
	SIF	Seafood HACCP Importer Firm	1-10N	If Government Agency Program Code = FOO and the product is HACCP, then SIF is allowed.	
	IBP	Indian Black Pepper Certificate	text	If Government Agency Program Code = “FOO” THEN IBP is allowed.	
	IFE	Import For Export	Indicator only		
	PKC	Package/Can Code		If Government Agency Program Code = “FOO”, then PKC is allowed.	
	REG	Animal Drug Establishment Registration Number	9N	If Government Agency Program Code = “FOO” and Government Agency Processing Code = “FEE”, then REG is allowed.	
	VFL	Medicated Feed Mill License (MFL)	7X	If Government Agency Program Code = “FOO” and Government Agency Processing Code = “FEE”, then VFL is allowed.	
	VFD	Veterinary Feed Directive	Indicator Only	If Government Agency Program Code = “FOO” and Government Agency Processing Code = “FEE”, then VFD is allowed.	

Table 10-21: Non-PN Food or PN Requirements Previously Met AoC Codes (Optional)

Note 2
Using the FDA Product Code in PG02, the following classifications are made where specific imported food/feed products require the submission of lot or code numbers or other identifier with prior notice. These include:
LACF and Acidified:
LACF: Industry Codes: 02-05, 07, 09, 12-18, 20-39, 41, 71, & 72 with PIC: **F** (Aseptic) and **E** (Commercially Sterile)
AF: Industry Codes: 02-05, 07, 09, 12-18, 20-39, 41, 71, & 72 with PIC: **I** (Acidified)
If the product is Low-Acid Canned Food (LACF) or Acidified Food (AF), both the FCE and SID must be provided; additionally, one of the following must be provided:

1. Container Measurements in PG28 **OR**
2. Container Volume AoC Code VOL

10.12 Record Identifier PG24 (Remarks)

Optional | Not Repeatable per PGA Line

This is an optional PGA input record that provides data pertaining to Remarks Type Code and Remarks Text.

PG24 cannot be repeated and only one PG24 is allowed for the same FDA line.

If entered, the Remarks Type Code should be GEN and must be under the PG02.

Currently, FDA processes PG24 record only at the Product-level (when under a PG02)

Record Identifier PG24 (Remarks)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"24"	
Remarks Type Code	3X	5-7	O	FDA uses only "GEN" as its valid value.	
Remarks Text	68X	13-80	O	Free form text relevant to the shipment or the commodity.	

Table 10-22: Non-PN Food or PN Requirements Previously Met PG24

10.13 Record Identifier PG25 (Product Condition)

Optional | Repeatable per PGA Line

For food filings not subject to PN regulations or PN requirements previously met, this is an optional PGA input record that provides data pertaining to Temperature Qualifier, Lot Number Qualifier, Lot Number, and PGA Line Value. This record is repeatable for Lot Numbers. If opting to transmit the line value, the PGA Line Value must be included on the first PG25 record.

Record Identifier PG25 (Product Condition)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"25"	
Temperature Qualifier	1A	5	O	Temperature Category being reported for quality control or preservation purposes. A=Ambient, F=Frozen, D=Dry Ice, R=Refrigerated/Chilled, H=Fresh, U=Uncontrolled, P=Flashpoint	
Lot Number Qualifier	1N	15	O	Code of the entity that assigned the Lot number. 1=Manufacturer and 3=Grower. IF Government Agency Program Code = "FOO" and Government Agency Processing Code = "NSF" THEN Lot Number Qualifier=3 ELSE Lot Number Qualifier=1 In the case of multiple PG25 records for a given FDA line, enter Lot Number Qualifier only in the first PG25 record.	
Lot Number	25X	16-40	O	The lot number that the manufacturer / Grower assigned to the product.	
PGA Line Value	12N	57-68	O	Although Line Value is optional, transmitting the value will assist in reviewing the product in a timely manner. Failure to transmit the value may result in delays associated with gathering missing information. If entered: • in the case of multiple PG25 records, enter value only in the first PG25 record • value should be in US Dollars, and enter whole dollars only • must be greater than zero and be right justified with preceding zeros	

Table 10-23: Non-PN Food or PN Requirements Previously Met PG25

10.14 Record Identifier PG26 (Product Packaging)

Optional | Repeatable per PGA Line

For food submissions, not subject to PN regulations or PN requirements previously met, this is an optional PGA input record that provides FDA with data pertaining to Packaging Qualifier, Quantity and Unit of Measure. If included, the following rules apply:

Although this is an optional record, if opting to transmit PG26 data, the Packaging Qualifier, Quantity, and Unit of Measure must all be transmitted in accordance with the following instructions:

This record can be repeated up to six (6) times, once for each unique packaging level. The first record is used to describe the largest (outermost) container and the number of containers at this packaging level. The second record is used to describe the contents of the next smallest container. If needed, qualifiers 2-6 are used in a similar manner (largest to smallest container). The final record must describe the actual amount of the product in the smallest container and must be selected from the list of base units below.

The appearance of any 'Packaging Qualifier' number level requires all levels under it to be represented. For instance, level 3 cannot be present unless levels 1 and 2 are present. The same unit of measure cannot be used multiple times on the same PGA line.

Record Identifier PG26 (Product Packaging)					
Data Element	**Length/Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"26"	
Packaging Qualifier	1N	5	C	This code identifies the level of packaging for the product. Outermost (largest=1) packages to the innermost (smallest=6) packages. There can be up to 6 levels of packaging. If reporting only one level, show the total quantity for the item and report that as level 1.	1, 4
Quantity	12N	6-17	C	Although quantity is optional, transmitting the quantity accurately and following the rules below will assist in reviewing the product in a timely manner. Failure to transmit the quantity records may result in delays associated with gathering missing information. If entered, this is the Quantity of the packaging level and two decimal places are implied. Must be greater than zero. Example: 000000000400 **Transmitting Quantity requires transmitting Packaging Qualifier and the Unit of Measure. Last unit transmitted must be a base unit and only one base unit is allowed.**	2, 4
Unit of Measure (Packaging Level)	5X	18-22	C	Type of packaging / packaging level. For example, BX. Cannot be repeated among the PG26 records.	3, 4

Table 10-24: Non-PN Food or PN Requirements Previously Met PG26

Note 1

This code identifies the level of packaging for the product. Valid values are 1, 2, 3, 4, 5 and 6: Outermost (largest=1) packages to the innermost (smallest=6) packages. There can be up to 6 levels of packaging.

Note 2
There are two implied decimal points when writing the quantity in Units of Measure for all packaging levels. In this example, 4 pieces are represented as 000000000400, with the nine leading zeroes as "fill" and two decimal places following the value.

Note 3
Valid FDA Food Units of Measure (UoM) for Packaging Containers are noted below:

Code	Description
AE	Aerosol
AM	Ampoule, Non-Protected
AP	Ampoule, Protected
AT	Atomizer
BA	Barrel (Container)
BB	Bobbin
BC	Bottle crate, Bottle rack
BE	Bundle
BF	Balloon, Non-Protected
BG	Bag
BH	Bunch
BI	Bin
BJ	Bucket
BK	Basket
BL	Bale, Compressed
BN	Bale, Non-Compressed
BO	Bottle, Non-Protected, Cyl
BP	Balloon, Protected
BQ	Bottle, Protected, Cylnd
BR	Bar
BS	Bottle, Non-Prot Bulbous
BU	Butt
BV	Bottle, Protected Bulbous
BX	Box
BZ	Bars in Bundle/Bunch/Trus
CA	Can, Rectangular
CAG	Cage
CB	Crate, Beer
CC	Churn
CE	Creel
CF	Coffer
CH	Chest
CI	Canister
CJ	Coffin
CK	Cask
CL	Coil

Code	Description
CO	Carboy, Non-Protected
CON	Container
CP	Carboy, Protected
CR	Crate
CS	Case
CT	Carton
CU	Cup
CV	Cover
CX	Can, Cylindrical
CY	Cylinder
CZ	Canvas
DJ	Demijohn, Non-Protected
DP	Demijohn, Protected
DR	Drum
EN	Envelope
FC	Crate, Fruit
FD	Crate, Framed
FI	Firkin
FL	Flask
FO	Footlocker
FR	Frame
GB	Bottle, Gas
HG	Hogshead
HR	Hamper
JC	Jerri can, Rectangular
JG	Jug
JR	Jar
JT	Jute bag
JY	Jerri can, Cylindrical
KEG	Keg
KIT	Kit
MB	Bag, Multi-ply
MC	Crate, Milk
MS	Sack, Multiwall
MT	Mat
NE	Unpacked or Unpackaged
NS	Nest
NT	Net
PA	Packet
PAL	Pallet
PC	Parcel

Code	Description
PH	Pitcher
PK	Package
PL	Pail
PO	Pouch
PT	Pot
PU	Tray or Tray Pack
PY	Plates in Bndl/Bnch/Truss
RG	Ring
RO	Roll
SA	Sack
SC	Crate, Shallow
SD	Spindle
SE	Sea-chest
SH	Sachet
SK	Case, Skeleton
SL	Slipsheet
SU	Suitcase
SW	Shrinkwrapped
SZ	Sheets in Bndl/Bnch/Truss
TB	Tub
TC	Tea-Chest
TD	Tube, Collapsible
TK	Tank, Rectangular
TN	Tin
TO	Ton
TR	Trunk
TS	Truss
TU	Tube
TY	Tank, Cylindrical
TZ	Tubes in Bndl/Bnch/Truss
VA	Vat
VG	Bulk Gas at 1031 MBAR
VI	Vial
VL	Bulk Liquid
VO	Bulk, Solid, Lg Particles
VP	Vacuum-packed
VQ	Bulk Liquefied Gas
VR	Bulk, Solid, Granular Parti

Code	Description
VY	Bulk, Solid, Fine Particle

Code	Description
WB	Wickerbottle

Table 10-25: Non-PN Food or PN Requirements Previously Met UoM for Packing Containers

Valid FDA Food Units of Measure for the Base Unit (Last Quantity Transmitted) are noted below:

Code	Description	Measure Type
BBL	Barrels (42 Gallons Ea)	Volume
BOL	Boluses	Dosage
CAR	Carats	Weight
CAP	Capsules	Dosage
CFT	Cubic Feet	Volume
CG	Centigrams	Weight
CM3	Cubic Centimeters	Volume
CYD	Cubic Yards	Volume
DOZ	Dozen	Count
DPC	Dozen Pieces	Count
DPR	Dozen Pairs	Count
FOZ	Ounces, fluid	Volume
G	Grams	Weight
GAL	Gallons (US)	Volume
GR	Gross	Count
KG	Kilograms	Weight
KM3	1,000 Cubic Meters	Volume
L	Liters	Volume
LB	Pounds (avdp)	Weight
M3	Cubic Meters	Volume
MCG	Micrograms	Weight
MG	Milligrams	Weight
ML	Milliliters	Volume
NO	Number	Count
OZ	Ounces, (avdp)	Weight
PCS	Pieces	Count
PRS	Pairs	Count
PTL	Pints, liquid (US)	Volume
QTL	Quarts, liquid (US)	Volume
STN	Short ton (2000 LB)	Weight
T	Metric Ton	Weight
TAB	Tablets	Dosage
TON	Long Ton (2240 LB)	Weight
TOZ	Ounces, Troy or Apoth	Weight

Table 10-26: Non-PN Food or PN Requirements Previously Met UoM for Base Unit

Note 4
Quantity Data provides additional information to FDA about the product and how it is packaged. The basic format for Quantity Data is in multiple pairs of data – quantity and unit of measure, i.e., 500 cases, 12 ounces, fluid, 1000 cartons, etc. Up to 6 data pairs may be submitted, beginning with the 1st pair for the outermost packaging when Packaging Qualifier = 1. The first pair may describe the largest container and the last pair must describe the amount of product in the smallest container. For example:
Product: 1000 cases of mineral water, 24/12 ounce bottles in each case

Units 1-Quantity	1000
Units 1-Measure	CS
Units 2-Quantity	24
Units 2-Measure	BO
Units 3-Quantity	12
Units 3-Measure	FOZ (Last level of packaging must be a base unit.)

10.15 Record Identifier PG27 (Shipping Container Information)

Optional | Repeatable per PGA Line

For food submissions, not subject to PN regulations or PN requirements previously met, this is an optional PGA input record that provides data pertaining to the shipping Container Number. This record may be repeated.

Record Identifier PG27 (Container Information)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"27"	
Container Number (Equipment ID)	20AN	5-24	O	The number of the shipping container as entered in the Bill based on the Mode of Transportation (MOT).	
Container Number (Equipment ID)	20AN	28-47	O	The number of the shipping container as entered in the Bill based on the Mode of Transportation (MOT).	
Container Number (Equipment ID)	20AN	51-70	O	The number of the shipping container as entered in the Bill based on the Mode of Transportation (MOT).	
Filler	7X	74-80	O	Space fill	

Table 10-27: Non-PN Food or PN Requirements Previously Met PG27

10.16 Record Identifier PG28 (Container Dimensions for AF and LACF)

Conditional | Not Repeatable per PGA Line

For Acidified (AF) and Low Acid Canned Food (LACF) this is a conditional PGA input record that provides data pertaining to reporting Container Dimensions for the Food and Drug Administration. Either the container dimensions or the container volume must be provided, and the measurement type should reflect what is filed in the scheduled process.

Record Identifier PG28 (Container Dimensions – Acidified and LACF)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"28"	
Container Dimensions #1	4N	5-8	C	The first dimension of the container. If the container is rectangle, the dimension is in width, height, and length order. If the container is cylindrical, the dimensions are in diameter and height order. Container dimension information is restricted to use with acidified and low acid canned foods. The first two spaces are inches. The second two positions are in 16ths.	1, 2
Container Dimensions #2	4N	9-12	C	The second dimension of the container. If the container is rectangle, the dimension is in width, height, and length order. If the container is cylindrical, the dimensions are in diameter and height order. The first two spaces are inches. The second two positions are in 16ths.	1, 2
Container Dimension #3	4N	13-16	C	The third dimension. If the container is rectangle, the dimension is in width, height, and length order. The first two spaces are inches. The second two positions are in 16ths.	1, 2

Table 10-28: Non-PN Food or PN Requirements Previously Met PG28

Note 1
IF Government Agency Program Code = "FOO" and
If the product is Low-Acid Canned Food (LACF) or Acidified Food (AF), one of the following must be provided (whichever measurement type is provided should reflect what is in the scheduled process on file with FDA).

1. Container Measurements in PG28 (either height and diameter or height/length, width and thickness OR
2. Container Volume (VOL) in PG23

Note 2
If the container is rectangular, the dimensions are in width, height & length order. Each dimension is expressed as a four-digit number. The first 2 digits give the number of whole inches. The next two digits give the additional fraction of the dimension expressed as sixteenths of an inch.

E.g. 1404 x 0800 x 0608 represents 14 4/16" width, 8" height and 6 8/16" length.

If the container is cylindrical the dimensions are in diameter & height order. Each dimension is expressed as a three-digit number. The first digit gives the number of whole inches. The next two digits give the additional fraction of the dimension expressed as sixteenths of an inch.

E.g. 300 x 108 represents 3" diameter & 1 8/16" height.

10.17 Record Identifier PG30 (Anticipated Arrival Information)

Mandatory | Repeatable per PGA Line

This is a mandatory PGA input record that provides data pertaining to the date, time and location of the anticipated arrival/entry information for all FDA products and the Foreign Trade Zone facility that the goods are being withdrawn from, if applicable.

For each line a PG30 record with an "A" (Anticipated arrival information) code, date, time and location of arrival is mandatory.

For entry type 21 coming from a Foreign Trade Zone, a PG30 record with an "F" (Foreign Trade Zone) code and FIRMS code for the FTZ location is required to exempt the shipment from prior notice because the requirements were previously met entering the Foreign Trade Zone.

Record Identifier PG30 (Anticipated Arrival Information)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"30"	
Anticipated Arrival Information	1A	5	M	A (Anticipated Arrival Information) If entry type = 21, then repeat PG30 and enter F (Foreign Trade Zone).	1, 2
Anticipated Arrival Date at Port of Entry	8N	6-13	C	A numeric date in MMDDCCYY (month, day, century, year) format. **Mandatory if Status = 'A'.**	1, 2
Anticipated Arrival Time at Port of Entry	4N	14-17	C	Military time HHMM in (hour, minute) format. (Example: 1015, this represents 10:15 a.m.). For midnight, use 2400 (0000 is invalid). **Mandatory if Status = 'A'.**	1, 2
Inspection or Arrival Location Code	4AN	18-21	C	Only a value of '4' (=FIRMS Codes) is allowed for entry type = 21. For entry type not = 21, this field is left blank.	
Inspection or Arrival Location	50X	22-71	C	Provide FIRMS Code here. For valid FIRMS Codes, Refer to ACS/ACE query https://www.cbp.gov/document/report/acs-public-firms-code-report	
Filler	8X	72-80	M	Space fill	

Table 10-29: Non-PN Food or PN Requirements Previously Met PG30

Note 1
A= Anticipated Arrival Date and Time at the Anticipated Port of Entry.

Port of Entry:
19 CFR 101.1.
Port and port of entry. The terms "port" and "port of entry" refer to any place designated by Executive Order of the President, by order of the Secretary of the Treasury, or by Act of Congress, at which a Customs officer is authorized to accept entries of merchandise to collect duties, and to enforce the various provisions of the Customs and navigation laws. The terms "port" and "port of entry" incorporate the geographical area under the jurisdiction of a port director. (The Customs ports in the Virgin Islands, although under the jurisdiction of the Secretary of the Treasury, have their own Customs laws (48 U.S.C. 1406(i)). These ports, therefore, are outside the Customs territory of the United States and the ports thereof are not "ports of entry" within the meaning of these regulations).

Note 2
Examples on how to submit PG30

For all Entry Types other than Entry Type 21 Warehouse for an FTZ Withdrawal	For Entry Type 21 Warehouse for an FTZ Withdrawal
PG30 Record • Anticipated Arrival Information status code = “A” (anticipated arrival information) is mandatory • Anticipated Arrival Date at Port of Entry is mandatory • Anticipated Arrival Time at Port of Entry is mandatory	PG30 Record • Anticipated Arrival Information status code = “A” (anticipated arrival information) is mandatory • Anticipated Arrival Date at Port of Entry is mandatory • Anticipated Arrival Time at Port of Entry is mandatory Additional PG30 Record • Anticipated Arrival Information status code = “F” (FTZ) is mandatory • Anticipated Arrival Date at Port of Entry is optional • Anticipated Arrival Time at Port of Entry is optional • Inspection or Arrival Location Code = “4” (FIRMS Code) is mandatory • FTZ Location is mandatory

10.18 Record Identifier PG55 (Additional Entity Roles)

This is an optional PGA input record used to provide additional roles performed by an entity or individual.

Not supported by FDA at this time

Currently, the PG55 record is not supported by FDA. Multiple PG19 records should be used to input more than one Entity-Role combination. Refer to the PG19 section for details.

Record Identifier PG55 (Additional Entity Roles)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"55"	
Entity Role Code	3AN	5-7	O	Additional role of the entity.	
Entity Role Code	3AN	8-10	O	Additional role of the entity.	
Entity Role Code	3AN	11-13	O	Additional role of the entity.	
Entity Role Code	3AN	14-16	O	Additional role of the entity.	
Entity Role Code	3AN	17-19	O	Additional role of the entity.	
Entity Role Code	3AN	20-22	O	Additional role of the entity.	
Entity Role Code	3AN	23-25	O	Additional role of the entity.	
Entity Role Code	3AN	26-28	O	Additional role of the entity.	
Entity Role Code	3AN	29-31	O	Additional role of the entity.	
Entity Role Code	3AN	32-34	O	Additional role of the entity.	
Filler	46X	35-80	M	Space fill	

Table 10-30: Non-PN Food or PN Requirements Previously Met PG55

10.19 Record Identifier PG60 (Additional Information)

Optional | Repeatable per PGA Line

This is an optional PGA input record used to provide additional information about data in the PG record that precedes it during the submission of a PGA record set.

This record can follow a PG07, PG19, PG20 or PG21 record, and can only be used to provide the additional information noted by the Additional Information Qualifier Code list.

This record may be repeated.

Record Identifier PG60 (Additional Information)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"60"	
Additional information qualifier code	3AN	5-7	C	Code indicating the type of additional information being provided	1
Additional Information	73X	8-80	C	Text of the additional information related to the additional reference qualifier code	

Table 10-31: Non-PN Food or PN Requirements Previously Met PG60

Note 1
Valid PG60 Additional Information Qualifier Codes applicable to FDA Message Set are noted below

Code	Description
ENA	Continuation of Entity Name for PG19
AD1	Continuation of Entity address Line 1 for PG19
AD2	Continuation of Entity address Line 2 for PG20
AD3	Entity address Line 3 for PG20
AD4	Entity address Line 4 for PG20
AD5	Entity address Line 5 for PG20
ECI	Continuation of Entity City for PG20
INA	Continuation of Individual Name for PG21
EMA	Continuation of Email Address for PG21
TBN	Continuation of Trade/Brand Name for PG07

Table 10-32: Non-PN Food or PN Requirements Previously Met PG60 Additional Information Qualifier Codes

PG60 record should follow immediately after its parent. For example, a PG60: ENA record should follow PG19 and a PG60: TBN record should follow PG07.

10.20 Record Identifier PG00 (Data Substitution)

This is an optional record used at the CBP entry (or entry summary) header, CBP entry (or entry summary) line and/or PGA message set levels to indicate data substitution.

PG00 Substitution Grouping
In situations where the trade finds it would be supplying identical information more than once within the PGA Message Set, a PG00 substitution grouping can be used, instead of repeating that information multiple times. Refer to the 'usage notes' in the ACE ABI CATAIR - Customs and Trade Automated Interface Requirements publication for detailed information.

Record Identifier PG00 (Data Substitution)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"00"	
Substitution Indicator	1X	5	O	Identifies either the start or end of the substitution group, or the location of where to place the substitute data within the PGA Message Set. The following codes are allowed: S=Start of the substitution group E=End of the substitution group R=Replace this record with the substitution group indicated by the Substitution Number	
Substitution Number	4AN	6-9	O	Sequential number assigned to, or referring to, a specific substitution group of data provided at the header level. This data element is mandatory when using the S or R substitution indicator.	
Filler	71X	10-80	M	Space fill	

Table 10-33: Non-PN Food or PN Requirements Previously Met PG00

11 Medical Devices Commodity Data Elements and Values

Medical Device commodities can be broken down into the following categories using the existing Government Agency data elements available in the PG01 message

PG01 - Government Agency Code	Commodity Type	PG01 - Government Agency Program Code	Commodity Sub-Type	PG01 - Government Agency Processing Code
FDA	Medical Devices	DEV	Radiation Emitting Devices§	RED
FDA	Medical Devices	DEV	Non-Radiation Emitting Devices	NED

Table 11-1: Medical Devices Commodity Hierarchy

§If the product is a medical device AND is a radiation emitting product, both the Medical Device and the Radiation Emitting Product Affirmations of Compliance will apply, and both sets of AoC codes should be transmitted under DEV/RED. Refer to PG23 in this chapter for details.

In submitting a Medical Device PGA Message Set to FDA, Importers are identifying themselves, the commodity, the intended use, the quantity of the commodity and valid FDA Affirmation of Compliance code values.

The following are the potential PGA records associated with submitting Medical Devices:

PG Record	Description
PG01	FDA program that regulates the product and the intended use code
PG02	Product Identifier; the Item Type and Product Code details.
PG06	Source Type(origin) other than the CBP country of origin
PG07	Trade/Brand Name
PG10	Product Description (Line level Item Common/Usual/Market Name Description)
PG19	Entity Role (manufacturer, FDA importer, shipper, etc.) Entity Identification, Entity Name, and Entity Address 1.
PG20	Additional address data on the entity in PG19
PG21	Individual Name, Telephone Number, and Email address
PG23	FDA's Affirmation of Compliance Criteria.
PG24	Remarks
PG25	Temperature Qualifier, Lot Number Qualifier, Lot Number, and PGA Line Value
PG26	Packaging qualifier and quantity of the shipment
PG27	Container Number
PG30	Date, time and location of anticipated arrival information
PG55	Identifies Entity from the previous PG19, PG20 and PG21 group as having additional roles.
PG60	Additional Information
PG00	Data substitution

Table 11-2: Medical Devices PG Records

11.1 Medical Devices Example

Medical Device Message Set Layout Sample below

Refer to the external file: **FDA SG Example PG Message Sets** **Tab: *Medical Devices***

PGA Records and Data Elements required are dependent on the agency program and processing code selected. For a more expansive set of examples of FDA PGA Message Sets, refer to the above document.

11.2 Record Identifier PG01 (PGA Identifier)

Mandatory | Not Repeatable per PGA Line

This is a mandatory PGA input record that provides data pertaining to the PGA Line Number, Government Agency Code, Government Agency Program Code, Government Agency Processing Code, Intended Use Code, Intended Use Description, and Disclaimer.

Record Identifier PG01 (PGA Identifier)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description/Required Value**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"01"	
PGA Line Number	3N	5-7	M	Begin with "001" and sequentially increment the line number on subsequent PG01 records, if applicable.	
Government Agency Code	3AN	8-10	M	"FDA"	
Government Agency Program Code	3X	11-13	C	"DEV"	1, 2
Government Agency Processing Code	3AN	14-16	C	Allowed values are 'RED' and 'NED'	1, 2
Intended Use Code	16X	42-57	C	Code identifying the intended use for the commodity after importation. For example, 081.001 (For Human Medical Use as a Medical Device).	3, 4, 5
Intended Use Description	21X	58-78	O	N/A for FDA lines.	
Correction Indicator	1X	79	O	For future use	
Disclaimer	1A	80	C	A code of A (= product is not regulated by this agency) indicating there is no agency declaration requirement. Leave it blank for no disclaimer. "F" indicating that the product is manufactured in any state of the US, the District of Columbia, or Puerto Rico and sourced directly to the warehouse without ever leaving the US. **May only be used for FDA on Entry Type 21**. No other codes are accepted	

Table 11-3: Medical Devices PG01

Note 1
Refer to Table 11-1 above for the commodity hierarchy for Medical Devices commodities.

Note 2
If the product is to be disclaimed, then these data elements should be populated with 'FDA'. Otherwise, the Government Agency Program Code, Government Agency Processing Code and Intended Use Code are mandatory.

Note 3
If IUC is 081.001, 081.002, or 081.004, then Manufacturer must be foreign; Manufacturer's country code in PG19/PG20 cannot be = US.

Note 4
Intended Use Code is mandatory unless disclaimed. CBP publication, Appendix R - Intended Use Codes for ACE, provides general descriptions of all Intended Use Codes for all Partner Government Agencies (PGAs). For FDA regulated products, use the IUC descriptions as specified per commodity throughout this document. See Appendix E for a mapping of FDA IUC descriptions to CBP Appendix R IUC descriptions.

For Medical Devices, only one of the following Intended Use Codes may be entered:

Intended Use Code	Intended Use Definition	Relevant Medical Device Import Scenarios
081.001	• Standard import of a foreign-manufactured device, accessories, or components regulated as a finished device • Import of refurbished device • Import of a reprocessed device	• Standard import of a medical device, accessories, or components regulated as a finished device • Import of refurbished device • Import of a reprocessed device
081.002	Import of a foreign-manufactured device for domestic refurbishing	
081.003	For Human Medical Use as Medical Device–domestically manufactured device that is part of a medical device convenience kit	
081.004	A foreign-manufactured device that is Part of a medical device convenience kit	
081.005	Importation of a device constituent part (finished device) for use in a medical product regulated under a drug (CDER) application type (e.g., for use in an NDA/ANDA/BLA drug-device combination product).	
081.006	Import of a medical device under enforcement discretion provisions per final guidance: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/medical-device-data-systems-medical-image-storage-devices-and-medical-image-communications-devices Import of a General Wellness Product per final guidance: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/general-wellness-policy-low-risk-devices	Applicable product codes: 80O - - UG; 86N - - FF 86N - - FG; 80N - - XQ 90L - - MB; 90L - - MD 80P- -WC for General Wellness Products
100.000	For Personal Use as a Non-Food Product – for personal use as a medical device	
110.000	For Public Exhibition or Display as a Non-Food Product	Includes import of device for trade show
140.000	For Charitable Organization Use as a Non-Food Product	
081.007	Component for further manufacturing into a finished medical device	
081.008	Importation of a device component for use in a medical product regulated under a drug (CDER) application type (e.g., for use in an NDA/ANDA/BLA drug-device combination product).	
170.000	For Repair of a Non-Food Product	Repair of medical device and re-exportation
180.010	For Research and Development as a Non-Food Product - For research and development as a medical device	Import of research or investigational use in vitro diagnostic device

Intended Use Code	Intended Use Definition	Relevant Medical Device Import Scenarios
180.014	For Research and Development as a Non-Food Product – for bench testing or nonclinical research use	• Import of a device for non-clinical use/bench testing • Import of device sample for customer evaluation
180.015	For Research and Development as a Non-Food Product – import of a medical device for clinical investigational use	
920.001	Import of a device that is US goods returned for refund/overstock (to manufacturer)	• Refund/overstock • Bench Testing • Corrective Action Prevention Action (CAPA) Plan Investigation • Recall
920.002	Import of a device that is US goods returned for sale to a third party	
940.000	Import of a Compassionate Use/Emergency Use Device	
950.001	Import of a single-use device for domestic reprocessing	
950.002	Import of a multi-use device for domestic reprocessing	
970.000	Import for Export	• Import of a medical device for further processing and re-exportation • Import of medical device or accessory for further manufacturing into an export only medical device
970.001	Import for Export	• Import of a medical device component for further manufacturing into an export only medical device

Table 11-4: Medical Devices Intended Use Codes

Note 5
If after consultation with the importer, who should know the intended use of the product, the filer still ***does not know*** the intended use of the product, “UNK” may be used in lieu of an IUC. In most cases, the line will be subject to manual review, and may result in a request for documentation and/or additional information about the product as the product offered for import will be treated as a standard import. Ensure the IUC (reason for importation) is transmitted to avoid delays. As per the ACE Rule, if “UNK” is submitted as the IUC for the article, the ACE filer is still responsible for submitting the other required data elements in this rule that are applicable to that article, at the time of entry. In the future, if those other data elements are not submitted in ACE at the time of entry, the entry may be transmitted by ACE to FDA for admissibility review, but FDA may reject the entry. If FDA rejects an entry filing, the ACE filer will need to resubmit the entry with complete and accurate information.

11.3 Record Identifier PG02 (Product Identifier)

Mandatory | Not Repeatable per PGA Line

This mandatory PGA input record is used to include information related to a product (P) by specifying the Item Type.

For Medical Device entries, the Product Code Number is provided within this record.

Record Identifier PG02 (Product Identifier)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"02"	
Item Type	1A	5	M	Code identifying the following records as pertaining to P=Product. No other values accepted. Only one "P" record is allowed for the same PGA Line # in PG01 record.	
Product Code Qualifier	4AN	6-9	M	"FDP".	1
Product Code Number	19X	10-28	M	FDA Product Code must be exactly 7 characters	

Table 11-5: Medical Devices PG02

Note 1
Product Code Qualifiers and their descriptions can be found in CBP's ACE CATAIR Appendix PGA (PG02 – Product Code Qualifiers). For FDA filings, the Product Code Qualifier is always "FDP".
Only one Product Code Number is allowed per line.

FDA Product Code Structure

Position	1-2	3	4	5	6-7
Name	Industry Code (N)	Class Code (AN)	Subclass Code (A or '-')	Process Indicator Code - PIC (A or '-')	Product (AN)

Legend - N: Numeric; A: Alphabetic; AN: Alphanumeric

Table 11-6: Medical Devices FDA Product Code Structure

IF Government Agency Program Code = "DEV"
THEN Industry Code is BETWEEN 73 and 92 (inclusive)

11.4 Record Identifier PG06 (Product Origin)

Mandatory | Repeatable per PGA Line

This is a mandatory PGA input record that provides data pertaining to Source Type (Origin) other than the CBP Country of Origin.

Record Identifier PG06 (Product Origin)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG".	
Record Type	2N	3-4	M	"06".	
Source Type Code	3AN	5-7	M	Mandatory value is 30 (Country of Source) for a component or 39 (Country of Production) for a finished product. Code 294 may be used to indicate a country has previously refused the line items.	1
Country Code	2X	8-9	M	Country of Production or Source is required for Medical Devices.	2

Table 11-7: Medical Devices PG06

Note 1
Source Type Codes and their descriptions can be found in CBP's ACE CATAIR Appendix PGA (PG06 – Source Type Codes).

Note 2
Any of the country codes from CBP's ACE CATAIR Appendix B (Section: Country and Currency Codes) can be entered.

11.5 Record Identifier PG07 (Product Trade Names)

Conditional | Not Repeatable per PGA Line

This is a conditional PGA input record that provides FDA with data pertaining to the Trade Name.

Record Identifier PG07 (Product Trade Names)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"07"	
Trade Name/Brand Name	35X	5-39	O	Trade/Brand Name of the Medical Device. For example, "ABC Reusable Tourniquet Cuff". Refer to Note 1 below. If Trade/Brand Name requires additional space, continue in a PG60 record with Qualifier Code "TBN".	1

Table 11-8: Medical Devices PG07

Note 1
DEV/NED: The Trade Name is optional. Encouraged, if provided on the invoice or otherwise available to the filer.
DEV/RED: The trade Name is conditional. If the Radiation Emitting Device is subject to a performance standard, and therefore requires Form 2877, then brand name is mandatory.

11.6 Record Identifier PG10 (Product Characteristics)

Mandatory | Not Repeatable per PGA Line

This is a mandatory PGA input record that allows for reporting the description of the product identified by the Product Code in PG02. For example, this record can be used to provide the model year of a product, which can be different from the year of manufacture provided in the PG07.

Record Identifier PG10 (Product Characteristics)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	“PG”	
Record Type	2N	3-4	M	”10”	
Commodity Characteristic Description	57X	24-80	M	Common, market, usual name; free form invoice description; not product code description. For examples, see Appendix A: Use of PG10 Record.	

Table 11-9: Medical Devices PG010

11.7 Record Identifier PG19 (Entity Data)

Mandatory | Repeatable per PGA Line

This is a mandatory PGA input record requiring Entity Role Code, Entity Name, and Entity Address 1.

Entity Identification Code [16 (DUNS #), 47 (FEI #)] and Entity number are optional data elements, but are listed as conditional because, if opting to transmit Entity Identification Code, then Entity Number must also be provided, and vice versa.

Record Identifier PG19 (Entity Data)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"19"	
Entity Role Code	3AN	5-7	M	Code identifying the role of the entity being provided. For example, MF. Each entity role code can only be transmitted once per PGA line.	1
Entity Identification Code	3AN	8-10	C	Code identifying the Entity Identification is entered. For example, 47 (FEI #). Mandatory, if Entity Number is entered.	2
Entity Number	15X	11-25	C	Identifying Number (DUNS or FEI) for the associated Entity Identification Code. Mandatory if Entity Identification Code is provided	2
Entity Name	32X	26-57	M	The name of the entity is required. If Entity Name requires additional space, continue in a PG60 record with Qualifier Code "ENA". Refer to the validation criteria below.	2
Entity Address 1	23X	58-80	M	The address of the entity is required. If Entity Address1 requires additional space, continue in a PG60 record with Qualifier Code "AD1". Refer to the validation criteria below.	2

Table 11-10: Medical Devices PG19

Note 1
List of Entity Role codes that are mandatory to FDA Message Sets are noted below:

Data Element	**Code**	**Description**
Entity Role Codes	MF	Manufacturer of goods
	DEQ	Shipper
	FD1	FDA Importer 1 (Importer of Record)
	DII	Device Initial Importer*****
	DP	Delivered-To Party

Table 11-11: Medical Devices Entity Role codes (Mandatory)

*****The Device Initial Importer (DII) must be in the US. When the DII is not required to register, the name and address of the US based firm receiving the goods is still required. Reference: 21 CFR 807.3(g): https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=807.3

List of Entity Role codes that are **optional** to FDA Message Sets are noted below:

Data Element	**Code**	**Description**
Entity Role Codes	PK	Point of Contact (Filer/Broker Contact Information)

Table 11-12: Medical Devices Entity Role codes (Optional)

Note 2

Entity Identification Codes and their descriptions can be found in CBP's ACE CATAIR Appendix PGA (PG19 – Entity Identification Codes). List of Entity Identification codes applicable to FDA Medical Device Message Sets is noted below:

Data Element	Code	Description	Length/ Class
Entity Identification Codes	16	D&B-assigned (DUNS number); must be 9 digits	9N
	47	FDA-assigned (FEI number); must be from 1 to 10 digits	1 -10N

Table 11-13: Medical Devices Entity Identification codes

FDA ENTITY IDENTIFICATION CODE AND ENTITY NUMBER SELECTION AND VALIDATION CRITERIA

FDA requires Entity Name and Entity Address. Additionally, FDA/CDRH prefers the transmission of FEI numbers, when available, for identifying the device Entities; an FEI will provide the best match with FDA systems. If FEI is unavailable, then the filer may provide the DUNS number.

Links to FEI numbers for medical device establishments can be found in the publicly available link https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm.

IF Entity Identification Code =16 (DUNS) THEN Entity Number must be Length = 9 and Type = N
ELSE IF Entity Identification Code =47 (FEI) THEN Entity Number must be Length from 1 to 10 and Type = N

11.8 Record Identifier PG20 (Entity Address)

Mandatory | Repeatable per PGA Line

This is a mandatory PGA input record that provides additional data pertaining to the Entity identified in the preceding PG19 record; such as Entity Address line 2, Apartment/Suite, City, State, and Zip/Postal Code. This record is used when there is additional address information for the entity.

Record Identifier PG20 (Entity Address)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"20"	
Entity Address 2	32X	5-36	C	Address Line 2 for the Entity. If Entity Address2 requires additional space, continue in a PG60 record with Qualifier Code "AD2".	1
Entity Apartment Number/Suite Number	5X	37-41	C	For example, 102 A.	
Entity City	21X	42-62	M	For example, SAN DIEGO. If Entity City requires additional space, continue in a PG60 record with Qualifier Code "ECI".	
Entity State/Province	3AN	63-65	C	Refer to CBP's ACE CATAIR Appendix B for valid codes.	2
Entity Country	2A	66-67	M	Refer to CBP's ACE CATAIR Appendix B for valid codes.	
Entity Zip/Postal Code	9X	68-76	C	For example, 92169.	2
Filler	4X	77-80	M	Space fill	

Table 11-14: Medical Devices PG20

Note 1
If the Entity requires more than 2 address lines, use the optional PG60 records with Qualifier Codes "AD3", "AD4" and "AD5" immediately under the PG20 record for the same Entity.

Note 2
Required for US or Canada based entities

11.9 Record Identifier PG21 (Point of Contact)

Mandatory | Repeatable per PGA Line

This is a mandatory PGA input record that provides point of contact information.

For each FDA line, at least one PG21 is required with the individual qualifier "FD1" (sent with the preceding PG19 and PG20 FD1 record).

FDA also highly encourages the transmission of PG21 with the individual qualifier "PK" which should be the point of contact for the filer/broker. "PK" may be sent in one of the following ways:

1) Under a PG19PK (transmitting PG19PK, PG20PK and PG21PK for the filer), the FDA preferred method, **OR**
2) As a secondary PG21 to FD1 using individual qualifier "PK" (transmitting PG19FD1, PG20FD1, PG21FD1, and PG21PK for the filer), **OR**
3) Under any other required PG19 entity as long as "PK" is the individual qualifier in PG21.

If provided, there should be only one PK per FDA line.

Although the PK (filer/broker contact information) is optional, transmitting this information will enable FDA to expeditiously contact the filer, instead of contacting the Importer of Record. If only the Importer of Record PG21 is transmitted and PK is not, FDA processing may be delayed.

Record Identifier PG21 (Point of Contact)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"21"	
Individual Qualifier	3AN	5-7	M	Identify the type of party or facility the Individual represents. Only "FD1" and "PK" are allowed.	
Individual Name	23X	8-30	M	Name of the Individual. If the name will not fit, continue in a PG60 record with Qualifier Code "INA".	
Telephone Number of the Individual	15X	31-45	M	For example, (713)555-8765 in US or (+65)9052-3529 in Singapore	
Email Address for the Individual	35X	46-80	M	Email Address of the individual. If the Email Address exceeds in length, continue in a PG60 record with Qualifier Code "EMA".	1

Table 11-15: Medical Devices PG21

Note 1
Only transmit the valid email address as you would in an email program. Do not include names, additional characters, etc.

Valid Example	first.last@company.com
Invalid Example	<first.last@company.com>
Invalid Example	FirstName LastName first.last@company.com
Invalid Example	FirstName LastName <first.last@company.com>
Invalid Example	first.last@company.com, first.last@company.com

11.10 Record Identifier PG23 (Affirmation of Compliance)

Conditional | Repeatable per PGA Line

This is a conditional PGA input record that provides data pertaining to FDA Affirmation of Compliance Criteria. This record is repeatable, but each affirmation of compliance code can only be transmitted once.

Record Identifier PG23 (Affirmation of Compliance)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"23"	
Affirmation of Compliance Code	5X	5-9	C	A code used to affirm compliance with FDA requirements. Refer to CBP's ACE CATAIR Appendix PGA (Food & Drug Affirmation of Compliance Codes) for valid codes.	1, 2
Affirmation of Compliance Qualifier	30X	10-39	C	Text describing the information required by the PGA. For 'indicator only' AoC codes, this field is left blank. All other qualifiers must follow the syntax instructions for each code. See table below and refer to CBP's ACE CATAIR Appendix PGA.	1, 2
Filler	1X	80	M	Space fill	

Table 11-16: Medical Devices PG23

Note 1
The list of Affirmation of Compliance codes for FDA-Medical Devices Message Sets is noted below, followed by the import scenarios/Intended Use Codes indicating when the AoCs should be provided N=Numeric digits; X=Alphanumeric.

Code	**Description**	**Syntax**
PM#	Device Premarket Number	Any of the following: P+6N; N+4N, 5N, or 6N; D+6N; H+6N; K+6N; DEN+6N; BP + 4-6N; BK + 6N; BH + 6N; BM + 6N; BR + 6N; DK + 6N; BD+6N
DDM	Device Domestic Manufacturer	1 - 10N
DEV	Device Foreign Manufacturer Registration Number	1 - 10N
DFE	Device Foreign Exporter Registration Number	1 - 10N
DI	Device Identifier	6-23X
CPT	Component Identifier	Indicator only
IFE	Import For Export	Indicator only
ERR	Entry Review Requested	Indicator only
IDE	Investigational Device Exemption Number	Any of the following: 4N; 5N; G+6N; OR "NSR"; when using G+6N, 'G000000' is not allowed; 0000 and 00000 are not allowed;
IRC	Device Impact Resistance Lens Certification	Indicator only
KIT	Device Imported Kit of Finished Device	Indicator only
LST	Device Listing Number	A+6N; B+6N; C+6N; D+6N; E+6N; L+6N; Q+6N; R+6N

Code	Description	Syntax
DA	New Drug Application Number or Abbreviated New Drug Application Number or Therapeutic Biologic Application Number	BA+4-6N or BN + 5-6 N or 6N
IND	Investigation New Drug Application Number	4-6N
LWC	Electrode Lead Wire or Patient Cable	Indicator Only

Table 11-17: Medical Devices Affirmation of Compliance codes

The table below shows which Affirmations of Compliance are Mandatory(M), Conditional(C)***** or Optional(O) based on the Intended Use Code/Import Scenario:

Intended Use[§] (Refer to PG01 for definitions)	Import Scenarios	Mandatory Affirmations	Conditional Affirmations*	Optional Affirmations
081.001[+]	• Standard import of a foreign-manufactured device, accessories, or components regulated as a finished device • Import of refurbished device • Import of a reprocessed device	DEV, DFE, LST	IRC, LWC, PM#	DI
081.002[+]******	Import of a foreign-manufactured device for domestic refurbishing	DEV, DFE, LST	IRC, LWC, PM#	DI
081.003	domestically manufactured device that is part of a medical device convenience kit	DDM, DFE, KIT, LST	IRC, LWC, PM#	DI
081.004[+]	A foreign-manufactured device that is Part of a medical device convenience kit	KIT, DEV, DFE, LST	PM#, LWC; IRC	DI
081.005	Device constituent part for drug-device combination product		DA, IND, DEV, DFE, LST	
140.000	Import of a device for charity	DEV, DFE, LST	IRC, LWC, PM#	DI
081.007	Component for further manufacturing into a finished medical device	CPT		LST, PM#
081.008	Device component for use in a drug-device combination product	CPT	DA, IND	
170.000	Repair of medical device and re-exportation		DFE, LST, IRC, LWC, PM#, DDM	DI
180.010	Import of research or investigational use in vitro diagnostic device			
180.014******	• Import of a device for non-clinical use/bench testing • Import of device sample for customer evaluation			
180.015******	Import of a medical device for clinical investigational use	IDE		
920.001	Import of a device that is US goods returned for refund/overstock (to manufacturer)	DDM, LST	DFE, IRC, LWC, PM#	DI
920.002	Import of device that is US goods returned for sale to a third party	DFE, DDM, LST	IRC, LWC, PM#	DI
950.001******	Import of a single-use device for domestic reprocessing	DDM, LST	DFE, IRC, LWC, PM#	DI

Intended Use[§] (Refer to PG01 for definitions)	Import Scenarios	Mandatory Affirmations	Conditional Affirmations*	Optional Affirmations
950.002**	Import of a multi-use device for domestic reprocessing		DDM, DFE, IRC, LST, LWC, PM#	DI
970.000	Import for Export: • Import of a medical device for further processing and re-exportation • Importation of a medical device or accessory for further manufacturing into an export-only medical device	DEV, DFE, IFE, LST		
970.001	Import for Export: • Importation of a medical device component for further manufacturing into an export-only medical device	IFE, CPT, DDM, LST		
100.000**	Device for Personal Use			
110.000**	Public Exhibition / Trade Show			
940.000**	Compassionate Use / Emergency Device			
081.006	Import under enforcement discretion provisions per final guidance			

Table 11-18: Medical Devices Affirmations of Compliance based on the Intended Use Codes

[+]If IUC is 081.001, 081.002, or 081.004, then Manufacturer must be foreign; Manufacturer's country code in PG20 cannot be US.

[*]Conditional Affirmations are required if applicable to the product being declared. For example, if the product requires premarket clearance (510(k)), then PM# must be provided.

**Annotates that additional information may be needed at time of entry for FDA to make a final admissibility decision.

§ If after consultation with the importer, who should know the intended use of the product, the filer still ***does not know*** the intended use of the product, "UNK" may be used in lieu of an IUC. In most cases, the line will be subject to manual review, and may result in a request for documentation and/or additional information about the product as the product offered for import will be treated as a standard import. Ensure the IUC (reason for importation) is transmitted to avoid delays. As per the ACE Rule, if "UNK" is submitted as the IUC for the article, the ACE filer is still responsible for submitting the other required data elements in this rule that are applicable to that article, at the time of entry. In the future, if those other data elements are not submitted in ACE at the time of entry, the entry may be transmitted by ACE to FDA for admissibility review, but FDA may reject the entry. If FDA rejects an entry filing, the ACE filer will need to resubmit the entry with complete and accurate information.

List of **OPTIONAL** Affirmation of Compliance codes for FDA-Medical Device Message Sets are noted below:

Code	Description	Syntax
DI	Device Identifier (part of the Unique Device Identifier, UDI)	6-23X
ERR	Entry Review Requested	Indicator only

Table 11-19: Medical Device Affirmations of Compliance Codes

Note 2

If the product is a medical device and is a radiation emitting product, both the Medical Device and the Radiation Emitting Product Affirmations of Compliance will apply, and both sets of AoC codes should be transmitted under DEV/RED.

List of **CONDITIONAL** Affirmation of Compliance codes for Medical Devices that are radiation emitting products are provided below in Table 11-20.

If 2877 is required: The chart below contains Affirmations of Compliance that are based on the applicability of a performance standard to your product and the conditions under which it is being imported. The Affirmations of Compliance codes below replicate the required information on the FDA-2877 form. The Affirmation of Compliance Codes RA1-RA7 refer to Declaration A, RB1 and RB2 refer to Declaration B, RC1 and RC2 refer to Declaration C, and RD1-RD3 refer to Declaration D on the form.

List of **CONDITIONAL** Affirmation of Compliance codes for FDA-Medical Device Message Sets are noted below:

Affirmation	Qualifier	Examples and Additional Information	Additional Affirmations Required	Text on 2877
RA1	date	format MM/YYYY		1. Was manufactured prior to the effective date of any applicable standard. Date of Manufacture.
RA2	text	text is reason for exclusion. Example: DOD exemption		2. Are excluded by the applicability clause or definition in the standard or by FDA written guidance. Specify reason for exclusion.
RA3	none			3. Are personal household goods of an individual entering the U.S. or being returned to a U.S. resident (Limit: 3 of each product type)
RA4	none			4. Are property of a party residing outside the U.S. and will be returned to the owner after repair or servicing.
RA5	text	text is description of the end-product. Example: Laser Diode		5. Are components or subassemblies to be used in manufacturing or as replacement parts
RA6	none			6. Are prototypes intended for ongoing product development by the importing firms, are labeled “FOR TEST/EVALUATION ONLY” and will be exported, destroyed, or held for future testing – there is a quantity limit for this option-stated on the back of the 2877 (page 2)
RA7	text	text is description of the end-product		7. Are being reprocessed in accordance with P.L. 104-134 or other FDA guidance, are labeled “FOR EXPORT ONLY” and will not be sold, distributed or transferred without FDA approval.
RB1	none		If RB1 is entered, then either ACC or ANC is required.	B1. Comply with the performance standards-1. *Last annual report or Product/Initial Report*
RB2	text	text is reason the product complies		B2. Comply with the performance standards-2. *Unknown manufacturer/report number. State reason:*
RC1±	none			C1. Do not comply with performance standards; are being held under a temporary import bond; will not be introduced into commerce, will be used under a radiation protection plan, and will be destroyed or exported under U.S. Customs Supervision when the mission is complete – 1. *Research, Investigations/Studies, or Training (Attach Form FDA 766)*

Affirmation	Qualifier	Examples and Additional Information	Additional Affirmations Required	Text on 2877
RC2	text	text is dates and use restriction	-	C2. Do not comply with performance standards; are being held under a temporary import bond; will not be introduced into commerce, will be used under a radiation protection plan, and will be destroyed or exported under U.S. Customs Supervision when the mission is complete – 1. *Trade Show/Demonstration; List dates and use restrictions*
RD1±	none			D1. Do not comply with performance standards; are held and will remain under bond; and will not be introduced into commerce until notification is received from FDA that products have been brought into compliance in accordance with an FDA approved petition. (Refer to the Form FDA 766) -1. *Approved Petition is attached.*
RD2±	none			D2. Do not comply with performance standards; are held and will remain under bond; and will not be introduced into commerce until notification is received from FDA that products have been brought into compliance in accordance with an FDA approved petition. (Refer to the Form FDA 766) – *2. Petition request is attached.*
RD3	date	date is the date form 766 will be provided, due within 60 days of submission.	-	D3. Do not comply with performance standards; are held and will remain under bond; and will not be introduced into commerce until notification is received from FDA that products have been brought into compliance in accordance with an FDA approved petition. (Refer to the Form FDA 766) – *3. Request will be submitted within 60 days.*
ACC	Product Report accession number	Syntax: 7 or 11 characters long Format: nnXnnnn-nnn where n is a 1-digit number and X is either a letter or a 1-digit number; '-nnn' is the optional Supplement Number.	If ACC is entered, then RB1 is required	
ANC	Annual Report accession number	Syntax: 7 or 11 characters long Format: nnXnnnn-nnn where n is a 1-digit number and X is either a letter or a 1-digit number; '-nnn' is the optional Supplement Number.	If ANC is entered, then RB1 is required	

Table 11-20: Medical Device Affirmations of Compliance codes (Conditional)

± Annotates that additional information may be needed at time of entry for FDA to make a final admissibility decision.

List of **OPTIONAL** Affirmation of Compliance codes for Medical Devices that are Radiation Emitting products are below:

Affirmation	Qualifier	Examples and Additional Information	Additional Affirmations Required	Remarks
MDL	Text	Model Number of the Product		
ERR	Text	Entry Review Requested		Indicator Only. No data will follow.
IFE	Text	Import For Export		Indicator only. No data will follow
CCM	Text	Name of the Certified Component Manufacturer		EPRC Certified Component Manufacturer - in the diagnostic x-ray systems and their major components performance standard, manufacturers of major components are required to certify such components, which can be assembled by others into the finished x-ray system. In cases where the certifying component manufacturer is different from the manufacturer who is shipping the entire system to the U.S., this Affirmation of Compliance may be used to provide additional identifying information about that component manufacturer.

Table 11-21: Medical Device Affirmation of Compliance Codes (Optional)

11.11 Record Identifier PG24 (Remarks)

Optional | Not Repeatable per PGA Line

This is an optional PGA input record that provides data pertaining to Remarks Type Code and Remarks Text.

PG24 cannot be repeated; only one PG24 is allowed for the same FDA line.

If entered, the 'Remarks Type Code' should be GEN and must be under the PG02.

Currently, FDA processes PG24 record only at the Product-level (when under a PG02)

Record Identifier PG24 (Remarks)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"24"	
Remarks Type Code	3X	5-7	O	FDA uses only "GEN" as its valid value.	
Remarks Text	68X	13-80	O	Free form text relevant to the shipment or the commodity.	

Table 11-22: Medical Device PG24

11.12 Record Identifier PG25 (Product Condition)

Optional | Repeatable per PGA Line

This is an optional PGA input record that provides data pertaining to Temperature Qualifier, Lot Number Qualifier, Lot Number, and PGA Line Value. This record is repeatable for multiple Lot Numbers. If opting to transmit the line value, the PGA Line Value must be included on the first PG25 record.

Record Identifier PG25 (Product Condition)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"25"	
Temperature Qualifier	1A	5	O	Temperature Category being reported for quality control or preservation purposes. A=Ambient, F=Frozen, D=Dry Ice, R=Refrigerated/Chilled, H=Fresh, U=Uncontrolled, P=Flashpoint	
Lot Number Qualifier	1N	15	O	Code of the entity that assigned the Lot number. 1=Manufacturer In the case of multiple PG25 records for a given FDA line, enter Lot Number Qualifier only in the first PG25 record.	
Lot Number	25X	16-40	O	The lot number that the manufacturer assigned to the product.	
PGA Line Value	12N	57-68	O	Although Line Value is optional, transmitting the value will assist in reviewing the product in a timely manner. Failure to transmit the value may result in delays associated with gathering missing information. If entered: • in the case of multiple PG25 records, enter value only in the first PG25 record • value should be in US Dollars, and enter whole dollars only • must be greater than zero and be right justified with preceding zeros	

Table 11-23: Medical Device PG25

11.13 Record Identifier PG26 (Product Packaging)

Conditional | Repeatable per PGA Line

This is a conditional PGA input record that provides FDA with data pertaining to Packaging Qualifier, Quantity and Unit of Measure. Quantity is optional for processing code "NED" and mandatory for processing code "RED" if the product requires a 2877. If opting to transmit quantity then Packaging Qualifier, Quantity, and Unit of Measure must be provided. Quantity should be transmitted as per the following instructions:

This record can be repeated up to six (6) times, once for each unique packaging level. The first record is used to describe the largest (outermost) container and the number of containers at this packaging level. The second record is used to describe the contents of the next smallest container. If needed, qualifiers 2-6 are used in a similar manner (largest to smallest container). The final record must describe the actual amount of the product in the smallest container.

The appearance of any 'Packaging Qualifier' number level requires all levels under it to be represented. For instance, level 3 cannot be present unless levels 1 and 2 are present.

Record Identifier PG26 (Product Packaging)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"26"	
Packaging Qualifier	1N	5	C	This code identifies the level of packaging for the product. Outermost (largest=1) packages to the innermost (smallest=6) packages. There can be up to 6 levels of packaging. If reporting only one level, show the total quantity for the item and report that as level 1.	1,4
Quantity	12N	6-17	C	Although quantity is optional for DEV/NED, transmitting the quantity accurately and following the rules below will assist in reviewing the product in a timely manner. Failure to transmit the quantity records may result in delays associated with gathering missing information. Quantity is conditional for DEV/RED. Refer to the Radiation Emitting Products chapter (PG26) for further discussions on this topic. When entered: This is the Quantity of the packaging level, For example, 000000000400. Two decimal places are implied. Must be greater than zero. **Transmitting Quantity requires transmitting Packaging Qualifier and the Unit of Measure. Last unit transmitted must be a base unit and only one base unit is allowed.**	2,4
Unit of Measure (Packaging Level)	5X	18-22	C	Type of packaging / packaging level. For example, BX. At least, 'Pieces' must be selected. Cannot be repeated among the PG26 records.	3,4

Table 11-24: Medical Devices PG26

Note 1
This code identifies the level of packaging for the product. Valid values are 1, 2, 3, 4, 5 and 6: Outermost (largest=1) packages to the innermost (smallest=6) packages. There can be up to 6 levels of packaging.

Note 2
There are two implied decimal points when writing the quantity in Units of Measure for all packaging levels. In this example, 4 pieces are represented as 000000000400, with the nine leading zeroes as "fill" and two decimal places following the value.

Note 3
List of Unit of Measure (UoM) codes applicable to FDA-Medical Device Message Sets and valid FDA Units of Measure for **Packaging Containers** are noted below:

Code	Description
CS	Case
CT	Carton
BX	Box
PK	Package

Table 11-25: Medical Devices UoM for Packaging Containers

Valid FDA Units of Measure for the **Base Unit** (Last Quantity Transmitted) are noted below:

Code	Description	Measure Type
PCS	Pieces	Count

Table 11-26: Medical Devices UoM for Base Unit

Note 4
Quantity Data provides additional information to FDA about the product and how it is packaged. The basic format for Quantity Data is in multiple pairs of data – quantity and unit of measure, i.e., 200 cartons, 6 boxes, 8 pieces, etc. Up to 6 data pairs may be submitted, beginning with the 1st pair for the outermost packaging when Packaging Qualifier = 1. The first pair may describe the largest container and the last pair must describe the amount of product in the smallest container. For example:

200 Cartons of 6 boxes of PEDIATRIC TOURNIQUET CUFF SET in each carton
8 pieces per box

Units 1-Quantity 200
Units 1-Measure CT

Units 2-Quantity 6
Units 2-Measure BX

Units 3-Quantity 8
Units 3-Measure PCS

The lowest unit of measure must be PCS (Pieces – Count).

11.14 Record Identifier PG27 (Shipping Container Information)

Optional | Repeatable per PGA Line

This is an optional PGA input record that provides data pertaining to the shipping Container Number. This record may be repeated.

Record Identifier PG27 (Container Information)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"27"	
Container Number (Equipment ID)	20AN	5-24	O	The number of the shipping container.	
Container Number (Equipment ID)	20AN	28-47	O	The number of the shipping container.	
Container Number (Equipment ID)	20AN	51-70	O	The number of the shipping container.	

Table 11-27: Medical Devices PG27

11.15 Record Identifier PG30 (Anticipated Arrival Information)

Mandatory | Repeatable per PGA Line

This is a mandatory PGA input record that provides data pertaining to the date, time and location of the anticipated arrival/entry information for all FDA products.

For each line a PG30 record with an "A" (Anticipated arrival information) status code, date and time of arrival is mandatory. For entry type 21 coming from a Foreign Trade Zone, a PG30 record with an "F" (Foreign Trade Zone) code and FIRMS code for the FTZ location is required.

Record Identifier PG30 (Anticipated Arrival Information)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"30"	
Anticipated Arrival Information	1A	5	M	A (Anticipated Arrival Information). If entry type = 21, then repeat PG30 and enter F (Foreign Trade Zone).	1, 2
Anticipated Arrival Date at Port of Entry	8N	6-13	C	A numeric date in MMDDCCYY (month, day, century, year) format. **Mandatory if Status = 'A'.**	1, 2
Anticipated Arrival Time at Port of Entry	4N	14-17	C	Military time HHMM in (hour, minute) format. (Example: 1015, this represents 10:15 a.m.). For midnight, use 2400 (0000 is invalid). **Mandatory if Status = 'A'.**	1, 2
Inspection or Arrival Location Code	4AN	18-21	C	Only a value of '4' (=FIRMS Code) is allowed for entry type = 21. For entry type not = 21, this field is left blank.	
Inspection or Arrival Location	50X	22-71	C	Provide FIRMS Code here.For valid FIRMS codes, refer to ACS/ACE query. https://www.cbp.gov/document/report/acs-public-firms-code-report	
Filler	8X	72-80	M	Space fill	

Table 11-28: Medical Devices PG30

Note 1
A= Anticipated Arrival Date and Time at the Anticipated Port of Entry.

Port of Entry:
19 CFR 101.1.
Port and port of entry. The terms "port" and "port of entry" refer to any place designated by Executive Order of the President, by order of the Secretary of the Treasury, or by Act of Congress, at which a Customs officer is authorized to accept entries of merchandise to collect duties, and to enforce the various provisions of the Customs and navigation laws. The terms "port" and "port of entry" incorporate the geographical area under the jurisdiction of a port director. (The Customs ports in the Virgin Islands, although under the jurisdiction of the Secretary of the Treasury, have their own Customs laws (48 U.S.C. 1406(i)). These ports, therefore, are outside the Customs territory of the United States and the ports thereof are not "ports of entry" within the meaning of these regulations).

Note 2
Examples on how to submit PG30

For all Entry Types other than Entry Type 21 Warehouse for an FTZ Withdrawal	For Entry Type 21 Warehouse for an FTZ Withdrawal
PG30 Record • Anticipated Arrival Information status code = “A” (anticipated arrival information) is mandatory • Anticipated Arrival Date at Port of Entry is mandatory • Anticipated Arrival Time at Port of Entry is mandatory	PG30 Record • Anticipated Arrival Information status code = “A” (anticipated arrival information) is mandatory • Anticipated Arrival Date at Port of Entry is mandatory • Anticipated Arrival Time at Port of Entry is mandatory Additional PG30 Record • Anticipated Arrival Information status code = “F” (FTZ) is mandatory • Anticipated Arrival Date at Port of Entry is optional • Anticipated Arrival Time at Port of Entry is optional • Inspection or Arrival Location Code = “4” (FIRMS Code) is mandatory • FTZ Location is mandatory

11.16 Record Identifier PG55 (Additional Entity Roles)

This is an optional PGA input record used to provide additional roles performed by an entity or individual.

Not supported by FDA at this time

Currently, the PG55 record is not supported by FDA. Multiple PG19 records should be used to input more than one Entity-Role combination. Refer to the PG19 section for details.

Record Identifier PG55 (Additional Entity Roles)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"55"	
Entity Role Code	3AN	5-7	O	Additional role of the entity.	
Entity Role Code	3AN	8-10	O	Additional role of the entity.	
Entity Role Code	3AN	11-13	O	Additional role of the entity.	
Entity Role Code	3AN	14-16	O	Additional role of the entity.	
Entity Role Code	3AN	17-19	O	Additional role of the entity.	
Entity Role Code	3AN	20-22	O	Additional role of the entity.	
Entity Role Code	3AN	23-25	O	Additional role of the entity.	
Entity Role Code	3AN	26-28	O	Additional role of the entity.	
Entity Role Code	3AN	29-31	O	Additional role of the entity.	
Entity Role Code	3AN	32-34	O	Additional role of the entity.	
Filler	8X	72-80	M	Space fill	

Table 11-29: Medical Devices PG55

11.17 Record Identifier PG60 (Additional Information)

Optional | Repeatable per PGA Line

This is an optional PGA input record used to provide additional information about data in the PG record that precedes it during the submission of a PGA record set.

This record can follow a PG07, PG19, PG20 or PG21 record, and can only be used to provide the additional information noted by the Additional Information Qualifier Code list.

This record may be repeated.

Record Identifier PG60 (Additional Information)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"60"	
Additional information qualifier code	3AN	5-7	C	Code indicating the type of additional information being provided	1
Additional Information	73X	8-80	C	Text of the additional information related to the additional reference qualifier code	

Table 11-30 Medical Devices PG60

Note 1
Valid PG60 Additional Information Qualifier Codes applicable to FDA Message Set are noted below:

Code	Description
ENA	Continuation of Entity Name for PG19
AD1	Continuation of Entity address Line 1 for PG19
AD2	Continuation of Entity address Line 2 for PG20
AD3	Entity address Line 3 for PG20
AD4	Entity address Line 4 for PG20
AD5	Entity address Line 5 for PG20
ECI	Continuation of Entity City for PG20
INA	Continuation of Individual Name for PG21
EMA	Continuation of Email Address for PG21
TBN	Continuation of Trade/Brand Name for PG07

Table 11-31: Medical Devices PG60 Additional Information Qualifier Codes

PG60 record should follow immediately after its parent. For example, a PG60: ENA record should follow PG19 and a PG60: TBN record should follow PG07.

11.18 Record Identifier PG00 (Data Substitution)

This is an optional record used at the CBP entry (or entry summary) header, CBP entry (or entry summary) line and/or PGA message set levels to indicate data substitution.

PG00 Substitution Grouping
In situations where the trade finds it would be supplying identical information more than once within the PGA Message Set, a PG00 substitution grouping can be used, instead of repeating that information multiple times. Refer to the 'usage notes' in the ACE ABI CATAIR - Customs and Trade Automated Interface Requirements publication for detailed information.

Record Identifier PG00 (Data Substitution)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"00"	
Substitution Indicator	1X	5	O	Identifies either the start or end of the substitution group, or the location of where to place the substitute data within the PGA Message Set. The following codes are allowed: S=Start of the substitution group E=End of the substitution group R=Replace this record with the substitution group indicated by the Substitution Number	
Substitution Number	4AN	6-9	O	Sequential number assigned to, or referring to, a specific substitution group of data provided at the header level. This data element is mandatory when using the S or R substitution indicator.	
Filler	71X	10-80	M	Space fill	

Table 11-32: Medical Devices PG00

12 Tobacco Commodity Data Elements and Values

Tobacco commodities can be broken down into the following categories using the existing Government Agency data elements available in the PG01 message

PG01 - Government Agency Code	Commodity Type	PG01 - Government Agency Program Code	Commodity Sub-Type	PG01 - Government Agency Processing Code±
FDA	Tobacco	TOB	Consumer Use	CSU
FDA	Tobacco	TOB	For Further Manufacturing	FFM
FDA	Tobacco	TOB	Investigational	INV

Table 12-1: Tobacco Commodity Hierarchy

± Required to identify a tobacco product as “for further manufacturing (FFM)”, for “consumer use” (CSU), or for “investigational use” (INV). This information is needed to determine the marketing status of the product. Ref: Sections 905, 910, and 911 of the FD&C Act.

The following are the potential PGA records associated with submitting Tobacco Products:

PG Record	Description
PG01	FDA program office that regulates the product, and the intended use code.
PG02	Item type and Product Code details
PG06	Source Type(origin) other than the CBP country of origin
PG07	Trade/Brand Name
PG10	Product Description (Line level Item Common/Usual/Market Name Description)
PG19	Entity (manufacturer, consignee, shipper, etc.) of Record’s identification information
PG20	Additional address data on the entity in PG19
PG21	Entity (manufacturer, consignee, shipper, etc.) of Record’s individual point of contact, phone number and email address.
PG23	FDA’s Affirmation of Compliance Criteria.
PG24	Remarks
PG25	Temperature qualifier, Lot Number Qualifier, Lot Number, and PGA Line Value
PG26	Packaging qualifier and quantity of the shipment
PG30	Date, time and location of anticipated arrival information
PG55	Additional roles performed by entity or individual
PG60	Additional Information
PG00	Data Substitution

Table 12-2: Tobacco PGA Records

12.1 Tobacco Example

Tobacco Message Set Layout for Sample

Refer to the external file: **FDA SG Example PG Message Sets** **Tab: *Tobacco***

PGA Records and Data Elements required are dependent on the agency program and processing code selected. For a more expansive set of examples of FDA PGA Message Sets, refer to the above document.

12.2 Record Identifier PG01 (PGA Identifier)

Mandatory | Not Repeatable per PGA Line

This is a mandatory PGA input record that provides data pertaining to the PGA Line Number, Government Agency Code, Government Agency Program Code, Government Agency Processing Code, Intended Use Code, Intended Use Description, and Disclaimer.

Record Identifier PG01 (PGA Identifier)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description/Required Value**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"01"	
PGA Line Number	3N	5-7	M	Begin with "001" and sequentially increment the line number on subsequent PG01 records, if applicable	
Government Agency Code	3AN	8-10	M	"FDA"	
Government Agency Program Code	3X	11-13	C	"TOB"	1, 2
Government Agency Processing Code	3AN	14-16	C	Allowed values: CSU, FFM, INV	1, 2
Intended Use Code	16X	42-57	C		3,4, 5
Intended Use Description	21X	58-78	O	N/A for FDA lines.	
Correction Indicator	1X	79	O	For future use	
Disclaimer	1A	80	C	A code of A (= product is not regulated by this agency) indicating there is no agency declaration requirement. Leave it blank for no disclaimer. "F" indicating that the product is manufactured in any state of the US, the District of Columbia, or Puerto Rico and sourced directly to the warehouse without ever leaving the US. **May only be used for FDA on Entry Type 21**. No other codes are accepted	

Table 12-3: Tobacco PG01

Note 1
Refer to the Table 12-1 above for the commodity hierarchy for Tobacco commodities.

Note 2
If the product is Disclaimed, then these data elements should both be populated with 'FDA'. Otherwise the Government Agency Program Code and Government Agency Processing Code are mandatory.

Note 3
If the Disclaimer is 'A' then the Intended Use Code is left blank; otherwise the Intended Use Code is conditional. If Government Agency Program Code = "TOB" and Government Agency Processing Code = "INV" then one of the 180 Base Code Intended Use Codes must be supplied.

Note 4

CBP publication, Appendix R - Intended Use Codes for ACE, provides general descriptions of all Intended Use Codes for all Partner Government Agencies (PGAs). For FDA regulated products, use the IUC descriptions as specified per commodity throughout this document. See Appendix E for a mapping of FDA IUC descriptions to CBP Appendix R IUC descriptions. Applicable Intended Use Codes for Program Code TOB are noted below:

Intended Use Code	Intended Use Description
150.000	For commercial process as non-food
155.000	For Commercial Assembly as a Non-Food Product to be consumed
180.001	For Research and Development as a non-Food Product - Animal or plant for biomedical research
180.000	For Research and Development as a non-Food Product – All other Uses
110.000	For Public Exhibition or Display as a Non-Food Product
130.000	For Consumer Use as a Non- Food Product
140.000	For Charitable Organization Use as Non-Food Product
130.037	For re-packaging and re-labelling**

Table 12-4: Tobacco Intended Use Codes

****Although the registration and listing provisions of Section 905 of the FD&C Act currently only apply to domestic manufacturers, it's important for enforcement purposes to know when products are being imported for repackaging or relabeling because the re-packagers / re-labelers will need to register with FDA. Under Section 905, the term "manufacture, preparation, compounding, or processing" includes repackaging or otherwise changing the container, wrapper, or labeling of any tobacco product package in furtherance of the distribution of the tobacco product from the original place of manufacture to the person who makes final delivery or sale to the ultimate consumer or user. Ref: 701(b); Section 905 of the FD&C Act (21 U.S.C. §387e)

Note 5
If after consultation with the importer, who should know the intended use of the product, the filer still ***does not know*** the intended use of the product, "UNK" may be used in lieu of an IUC. In most cases, the line will be subject to manual review, and may result in a request for documentation and/or additional information about the product as the product offered for import will be treated as a standard import. Ensure the IUC (reason for importation) is transmitted to avoid delays. As per the ACE Rule, if "UNK" is submitted as the IUC for the article, the ACE filer is still responsible for submitting the other required data elements in this rule that are applicable to that article, at the time of entry. In the future, if those other data elements are not submitted in ACE at the time of entry, the entry may be transmitted by ACE to FDA for admissibility review, but FDA may reject the entry. If FDA rejects an entry filing, the ACE filer will need to resubmit the entry with complete and accurate information.

12.3 Record Identifier PG02 (Product Identifier)

Mandatory | Not Repeatable per PGA Line

This mandatory PGA input record is used to include information related to a product (P).

Record Identifier PG02 (Product Identifier)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"02"	
Item Type	1A	5	M	Code identifying the following records as pertaining to P=Product. No other values accepted. Only one "P" record is allowed for the same PGA Line # in PG01 record.	
Product Code Qualifier	4AN	6-9	M	"FDP"	1
Product Code Number	19X	10-28	M	FDA Product Code must be exactly 7 characters	

Table 12-5: Tobacco PG02

Note 1
Product Code Qualifiers and their descriptions can be found in CBP's ACE CATAIR Appendix PGA (PG02 – Product Code Qualifiers). For FDA filings, the Product Code Qualifier is always "FDP".
Only one FDA Product Code Number is allowed per line.

FDA Product Code Structure

Position	1-2	3	4	5	6-7
Name	Industry Code (N)	Class Code (AN)	Subclass Code (A or '-')	Process Indicator Code - PIC (A or '-')	Product (AN)

Legend - N: Numeric; A: Alphabetic; AN: Alphanumeric

Table 12-6: Tobacco FDA Product Code Structure

IF Government Agency Program Code = "TOB"
THEN Industry Code = 98

12.4 Record Identifier PG06 (Product Origin)

Mandatory | Not Repeatable per PGA Line

This is a mandatory PGA input record that provides data pertaining to Source Type (Origin) other than the CBP Country of Origin.

Record Identifier PG06 (Product Origin)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"06"	
Source Type Code	3AN	5-7	M	For Tobacco, Source Type Code 39 (Country of Production) is required. Other Source Type Codes, 262 (Place of Growth) or HRV (Harvested) or 30 (Country of Source) may be entered, if available. Code 294 may be used to indicate a country has previously refused the line items.	1
Country Code	2X	8-9	M	Country of Production or Source is required for Tobacco.	2

Table 12-7: Tobacco PG06

Note 1
Source Type Codes and their descriptions can be found in CBP's ACE CATAIR Appendix PGA (PG06 – Source Type Codes).

Note 2
Any of the country codes from CBP's ACE CATAIR Appendix B (Section: Country and Currency Codes) can be entered.

12.5 Record Identifier PG07 (Product Trade Names)

Conditional | Not Repeatable per PGA Line

This is a conditional PGA input record that provides data pertaining to Trade or Brand Name. Brand name is required to help identify if the product meets FDA's pre-market authorization requirements under Section 910 of the FD&C Act.

Record Identifier PG07 (Product Trade Names)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"07"	
Trade Name/Brand Name	35X	5-39	C	When submitted, Trade and/or Brand Name includes the product Brand and Sub-brand name If Government Agency Processing Code is CSU (Consumer Use) then trade or brand name is mandatory. If Government Agency Processing Code is FFM (For Further Manufacturing) or INV (Investigational), then trade name/brand name is optional. If Trade/Brand Name requires additional space, continue in a PG60 record with Qualifier Code "TBN".	1

Table 12-8: Tobacco PG07

Note 1
Trade Name/Brand Name is only required for products intended for consumer use, not for products intended for further manufacturing and for investigational use.

12.6 Record Identifier PG10 (Product Characteristics)

Mandatory | Not Repeatable per PGA Line

This is a mandatory PGA input record that allows for reporting the description of the product identified by the Product Code in PG02.

Record Identifier PG10 (Product Characteristics)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"10"	
Commodity Characteristic Description	57X	24-80	M	Common, market, usual name; free form invoice description; not product code description. For examples, see Appendix A: Use of PG10 Record. Transmit information such as length, color, and pack count, flavor, and strength of nicotine as applicable.	

Table 12-9: Tobacco PG10

12.7 Record Identifier PG19 (Entity Data)

Mandatory | Repeatable per PGA Line

This is a mandatory PGA input record that provides FDA with data pertaining to Entity Role, Entity Name and Entity Address 1. Entity Identification Code [16 (DUNS #), 47 (FEI #)] is a conditional data element.

Record Identifier PG19 (Entity Data)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"19"	
Entity Role Code	3AN	5-7	M	Code identifying the role of the entity being provided. For example: MF, DP. Each entity role code can only be transmitted once per PGA line.	1
Entity Identification Code	3AN	8-10	C	Code identifying the Entity Identification is entered. For example: 16 (DUNS #), 47 (FEI #). Mandatory, if Entity Number is entered.	2
Entity Number	15X	11-25	C	Identifying Number (DUNS or FEI) for the associated Entity Identification Code. Mandatory if Entity Identification Code is provided	2
Entity Name	32X	26-57	M	The name of the entity is required. If Entity Name requires additional space, continue in a PG60 record with Qualifier Code "ENA". Refer to the validation criteria below.	2
Entity Address 1	23X	58-80	M	The address of the entity is required. If Entity Address1 requires additional space, continue in a PG60 record with Qualifier Code "AD1".	2

Table 12-10: Tobacco PG19

Note 1
List of Entity Role codes that are mandatory to FDA Message Sets is noted below:

Data Element	**Code**	**Description**
Entity Role Codes	MF	Manufacturer of goods
	DEQ	Shipper
	FD1	FDA Importer (Importer of Record)
	DP	Delivered-to Party

Table 12-11: Tobacco Entity Role Codes (Mandatory)

List of Entity Role codes **conditional** to FDA Tobacco Message Sets are noted below:
(If Government Agency Processing Code is INV then either ITL or LAB is mandatory.

Data Element	**Code**	**Description**
Entity Identification Codes	ITL	Independent Third Party Laboratory
	LAB	Laboratory or Clinical Site

Table 12-12: Tobacco Entity Role Codes (Conditional)

List of Entity Role codes that are **optional** to FDA Tobacco Message Set are noted below:

Data Element	**Code**	**Description**
Entity Role Codes	RD	Retailer/Distributor
	TB	Submitter
	PK	Point of Contact (Filer/Broker Contact Information)

Table 12-13: Tobacco Entity Role Codes (Optional)

Note 2

Entity Identification Codes and their descriptions can be found in CBP's ACE CATAIR Appendix PGA (PG19 – Entity Identification Codes). List of Entity Identification codes applicable to FDA Tobacco Message Sets is noted below:

Data Element	Code	Description	Length/ Class
Entity Identification Codes	16	D&B-assigned (DUNS number); must be 9 digits	9N
	47	FDA-assigned (FEI number); must be from 1 to 10 digits	1 -10N

Table 12-14: Tobacco Entity Identification Codes

FDA ENTITY IDENTIFICATION CODE AND ENTITY NUMBER SELECTION AND VALIDATION CRITERIA

FDA/CTP requires Entity Name and Entity Address. Additionally, an FEI number is preferred, when available.

IF Entity Identification Code =16 (DUNS) THEN Entity Number must be Length = 9 and Type = N
ELSE IF Entity Identification Code =47 (FEI) THEN Entity Number must be Length from 1 to 10 and Type = N

.

12.8 Record Identifier PG20 (Entity Address)

Mandatory | Repeatable per PGA Line

This is a mandatory PGA input record that provides additional data pertaining to the Entity identified in the preceding PG19 record; such as Entity Address line 2, Apartment/Suite, City, State, and Zip/Postal Code. This record is used when there is additional address information for the entity.

Record Identifier PG20 (Entity Address)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"20"	
Entity Address 2	32X	5-36	C	Address Line 2 for the Entity. If Entity Address2 requires additional space, continue in a PG60 record with Qualifier Code "AD2".	1
Entity Apartment Number/Suite Number	5X	37-41	C	For example, 102 A.	
Entity City	21X	42-62	M	For example, SUGARLAND. If Entity City requires additional space, continue in a PG60 record with Qualifier Code "ECI".	
Entity State/Province	3AN	63-65	C	Refer to CBP's ACE CATAIR Appendix B for valid codes.	2
Entity Country	2A	66-67	M	Refer to CBP's ACE CATAIR Appendix B for valid codes.	
Entity Zip/Postal Code	9X	68-76	C	For example, 77004.	2
Filler	4X	77-80	C	Space fill	

Table 12-15: Tobacco PG20

Note 1
If the Entity requires more than 2 address lines, use the optional PG60 records with Qualifier Codes "AD3", "AD4" and "AD5" immediately under the PG20 record for the same Entity.

Note 2
Required for US or Canada based entities

12.9 Record Identifier PG21 (Point of Contact)

Mandatory | Repeatable per PGA Line

This is a mandatory PGA input record that provides FDA with data about an Individual Point of Contact (POC) related to the Entity (the party) in the preceding PG19 record. Included in this record are the Individual Name, Telephone Number and Email address. A typical example is a POC for the Filer.

For each FDA line, at least one PG21 is required with the individual qualifier "FD1" (sent with the preceding PG19 and PG20 FD1 record).

FDA also highly encourages the transmission of PG21 with the individual qualifier "PK" which should be the point of contact for the filer/broker. "PK" may be sent in one of the following ways:

1) Under a PG19PK (transmitting PG19PK, PG20PK and PG21PK for the filer), the FDA preferred method, **OR**
2) As a secondary PG21 to FD1 using individual qualifier "PK" (transmitting PG19FD1, PG20FD1, PG21FD1, and PG21PK for the filer), **OR**
3) Under any other required PG19 entity as long as "PK" is the individual qualifier in PG21.

If provided, there should be only one PK per FDA line.

Although the PK (filer contact information) is optional, transmitting this information will enable FDA to expeditiously contact the filer, instead of contacting the Importer of Record to obtain the contact information for the filer. If only the Importer of Record PG21 is transmitted and PK is not, FDA processing may be delayed.

Record Identifier PG21 (Point of Contact)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"21"	
Individual Qualifier	3AN	5-7	M	Identify the type of party or facility the Individual represents. Only "FD1" and "PK" are allowed.	1
Individual Name	23X	8-30	M	Name of the Individual. If the name will not fit, continue in a PG60 record with Qualifier Code "INA".	
Telephone Number of the Individual	15X	31-45	M	For example, (713)555-8765 in US or (+65)9052-3529 in Singapore	
Email Address for the Individual	35X	46-80	M	Email Address of the individual. If the Email Address exceeds in length, continue in a PG60 record with Qualifier Code "EMA".	2

Table 12-16: Tobacco PG21

Note 1
Entity Role Codes and their descriptions can be found in CBP's ACE CATAIR Appendix PGA (PG19 – Entity Role Codes).

Note 2
Only transmit the valid email address as you would in an email program. Do not include names, additional characters, etc.

Valid Example	first.last@company.com
Invalid Example	<first.last@company.com>
Invalid Example	FirstName LastName first.last@company.com
Invalid Example	FirstName LastName <first.last@company.com>
Invalid Example	first.last@company.com, first.last@company.com

12.10 Record Identifier PG23 (Affirmation of Compliance)

Optional | Repeatable per PGA Line

For Tobacco, this is an optional PGA input record that provides data pertaining to FDA Affirmation of Compliance Criteria. This record is repeatable, but each affirmation of compliance code can only be transmitted once.

Record Identifier PG23 (Affirmation of Compliance)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"23"	
Affirmation of Compliance Code	5X	5-9	O	A code used to affirm compliance with FDA requirements. Refer to CBP's ACE CATAIR Appendix PGA (Food & Drug Affirmation of Compliance Codes) for valid codes.	1
Affirmation of Compliance Qualifier	30X	10-39	C	Text, describing the information allowed by the PGA. For 'indicator only' AoC codes, this field is left blank. All other qualifiers must follow the syntax instructions for each code as specified in CBP's ACE CATAIR Appendix PGA.	
Filler	1X	80	M	Space fill	

Table 12-17: Tobacco PG23

Note 1
The FDA Affirmation of Compliance Codes and their descriptions are listed in the Appendix PGA (Food & Drug Affirmation of Compliance, FDA Affirmation of Compliance Codes) of ACE ABI CATAIR publication. The list of AoC codes that are optional to FDA Message Sets is noted below:

Data Element	**Code**	**Description**	**Syntax**	**Business Rules**
Affirmation of Compliance Code	ILS	Confirmation of **Ingredient Listings Submission** to FDA: Manufacturers and importers of tobacco products to the U.S. must provide a list of ingredients to FDA. Code of "ILS" affirms Ingredients Listings was previously submitted.	Indicator only	If Government Agency Processing Code is "CSU", then "ILS" may be entered.
	HPC	**Harmful or Potentially Harmful Constituents (HPHC)** Report: All manufacturers and importers of tobacco products to the U.S. must provide HPHC information to FDA. Code of "HPC" confirms HPHC information was previously submitted.	Indicator only	If Government Agency Processing Code is "CSU", then "HPC" may be entered.
	CMT	**Commercially Marketed Tobacco.** Code of "CMT" **indicates that the product was** commercially marketed in the U.S. as of February 15, 2007. CMT products are also frequently referred to as "grandfathered" tobacco products. If Tobacco Submission Tracking (TST) number is available from a	Indicator only	If Government Agency Processing Code is "CSU" and the product was commercially marketed in the U.S. as of February 15, 2007, then "CMT" may be entered.

Data Element	Code	Description	Syntax	Business Rules
		Stand-alone Grandfathered Determination, it may be submitted		
Affirmation of Compliance Code	SE -or- PMT -or- EXE	If the product was not commercially marketed in the U.S. as of February 15, 2007, then one of the following may be affirmed: SE = Substantially Equivalent Indicate SE if the product has a submitted Substantial Equivalence application with FDA PMT= Premarket Tobacco Application Indicate PMT if the product has a submitted Premarket Tobacco application with FDA EXE= Exemption from Substantial Equivalence Indicate EXE if the product has a submitted exemption from substantial equivalence with FDA	Indicator only	If Government Agency Processing Code is "CSU" and the product was not commercially marketed in the U.S. as of February 15, 2007 (CMT was not declared) then, one of SE, PMT, or EXE may be entered.
	TST**	Tobacco Submission Tracking Number	7X or 7X-24X	If Government Agency Processing Code is "CSU" and affirmations "SE", "PMT", or "EXE" were declared, then "TST" is entered. If declaring CMT, then TST is optional.
	ERR	Entry Review Requested	Indicator only	ERR is just used as an indicator, no data will follow

Table 12-18: Tobacco Affirmation of Compliance Codes

****Tobacco Submission Tracking (TST) Number is issued by FDA/CTP for the tobacco product identified in the FDA line. The submission tracking number is the Substantially Equivalent (SE), Premarket Tobacco Application (PMT), or Exemption from Substantial Equivalence (EX) number. This affirmation is mandatory if the tobacco product was not commercially marketed in the U.S. as of February 15, 2007. For example: TST PM1234567, TST EX1234567, TST SE1234567

12.11 Record Identifier PG24 (Remarks)

Optional | Not Repeatable per PGA Line

This is an optional PGA input record that provides data pertaining to Remarks Type Code and Remarks Text.

PG24 cannot be repeated and only one PG24 is allowed for the same FDA line.

If entered, the Remarks Type Code should be GEN and must be under the PG02.

Currently, FDA processes PG24 record only at the Product-level (when under a PG02)

Record Identifier PG24 (Remarks)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"24"	
Remarks Type Code	3X	5-7	O	FDA uses only "GEN" as its valid value.	
Remarks Text	68X	13-80	O	Free form text relevant to the shipment or the commodity.	

Table 12-19: Tobacco PG24

12.12 Record Identifier PG25 (Product Condition)

Optional | Repeatable per PGA Line

This is an optional PGA input record that provides data pertaining to Temperature Qualifier, Degree Type, Actual Temperature, Lot Number, Production Date, Range of the Lot, PGA Line Value, and PGA Unit Value. This record is repeatable for multiple Lot Numbers. If opting to transmit the line value, the PGA Line Value must be included on the first PG25 record.

Record Identifier PG25 (Product Condition)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"25"	
Temperature Qualifier	1A	5	O	Temperature Category being reported for quality control or preservation purposes. A=Ambient, F=Frozen, D=Dry Ice, R=Refrigerated/Chilled, H=Fresh, U=Uncontrolled, P=Flashpoint	
Lot Number Qualifier**	1N	15	O	Includes Lots and/or Batches If Government Agency Program Code = "TOB", then Lot Number Qualifier=3 In the case of multiple PG25 records for a given FDA line, enter Lot Number Qualifier only in the first PG25 record.	
Lot Number	25X	16-40	O	The lot number that the manufacturer assigned to the product.	1
PGA Line Value	12N	57-68	O	Although Line Value is optional, transmitting the value will assist in reviewing the product in a timely manner. Failure to transmit the value may result in delays associated with gathering missing information. If entered: • in the case of multiple PG25 records, enter value only in the first PG25 record • must be greater than zero and be right justified with preceding zeros • value should be entered in US Dollars, and whole dollars only	

Table 12-20: Tobacco PG25

Note 1
Lot Number is not currently required for importing tobacco products but may be required in future CTP regulations. Ref: 21 CFR 7; 701(b)

12.13 Record Identifier PG26 (Product Packaging)

Optional | Repeatable per PGA Line

This is an optional PGA input record that provides FDA with data pertaining to Packaging Qualifier, Quantity and Unit of Measure. If included, the following rules apply:

This record can be repeated up to six (6) times, once for each unique packaging level. The first record is used to describe the largest (outermost) container and the number of containers at this packaging level. The second record is used to describe the contents of the next smallest container. If needed, qualifiers 2-6 are used in a similar manner (largest to smallest container). The final record must describe the actual amount of the product in the smallest container and be a code from the table of base units listed below.

The appearance of any 'Packaging Qualifier' number level requires all levels under it to be represented. For instance, level 3 cannot be present unless levels 1 and 2 are present. The same unit of measure cannot be used multiple times on the same PGA line.

Record Identifier PG26 (Product Packaging)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"26"	
Packaging Qualifier	1N	5	C	Used to determine the quantity of tobacco products being imported, such as the number of cigarettes, cartons, cartons per pack, etc. Under 21 1140.16(b), cigarette packages are required to contain a minimum of 20 cigarettes. This code identifies the level of packaging for the product. Outermost (largest=1) packages to the innermost (smallest=6) packages. There can be up to 6 levels of packaging. If reporting only one level, show the total quantity for the item and report that as level 1.	1, 4
Quantity	12N	6-17	C	Although quantity is optional, transmitting the quantity accurately and following the rules below will assist in reviewing the product in a timely manner. Failure to transmit the quantity records may result in delays associated with gathering missing information. If entered, this is the total quantity for the packaging level. Must be greater than zero. Two decimal places are implied. The base quantity must always be the last quantity transmitted. **Transmitting Quantity requires transmitting Packaging Qualifier and the Unit of Measure. Last unit transmitted must be a base unit and only one base unit is allowed.**	2, 4
Unit of Measure (Packaging Level)	5X	18-22	C	Type of packaging / packaging level. For example, BX. Cannot be repeated among the PG26 records.	3, 4

Table 12-21: Tobacco PG26

Note 1

This code identifies the level of packaging for the product. Valid values are 1, 2, 3, 4, 5 and 6: Outermost (largest=1) packages to the innermost (smallest=6) packages. There can be up to 6 levels of packaging.

Note 2
There are two implied decimal points when writing the quantity in Units of Measure for all packaging levels. In this example, 4 pieces are represented as 000000000400, with the nine leading zeroes as "fill" and two decimal places following the value.

Note 3
List of Unit of Measure codes applicable to FDA-Tobacco Message Sets
For a full list of applicable Unit of Measure codes, refer to Appendix D: FDA Unit of Measurement Codes in this document or to the CBP's ACE CATAIR Appendix PGA (PG26: Unit of Measure - Valid FDA Units of Measure for Packaging ContainersPG26: Unit of Measure -Valid FDA Units of Measure for the Base Unit (Last Quantity Transmitted)).

Valid FDA Units of Measure (UoM) for **Packaging Containers** are noted below:

Code	Description
AT	Atomizer
BL	Bale, Compressed
BN	Bale, Non-Compressed
BX	Box
CON	Container
CS	Case
CT	Carton
CTR	Cartridge
DR	Drum
KIT	Kit
PK	Package
VI	Vial
VL	Bulk Liquid

Table 12-22: Tobacco UoM for Packaging Containers

Valid FDA Units of Measure for the Base Unit (Last Quantity Transmitted) are noted below:

Code	Description	Measure Type
BBL	Barrels (42 Gallons Ea)	Volume
DOZ	Dozen	Count
DPC	Dozen Pieces	Count
FOZ	Ounces, fluid	Volume
GAL	Gallons (US)	Volume
L	Liters	Volume
ML	Milliliters	Volume
NO	Number	Count
PCS	Pieces	Count
PTL	Pints, liquid (US)	Volume
QTL	Quarts, liquid (US)	Volume
G	Grams	Weight
KG	Kilograms	Weight
LB	Pounds (avdp)	Weight

Table 12-23: Tobacco UoM Base Units

Note 4
Quantity Data provides additional information to FDA about the product and how it is packaged. The basic format for Quantity Data is in multiple pairs of data – quantity and unit of measure, i.e., 500 cases, 12 ounces, fluid, 1000 cartons, etc. Up to 6 data pairs may be submitted, beginning with the 1st pair for the outermost packaging when Packaging Qualifier = 1. The first pair may describe the largest container and the last pair must describe the amount of product in the smallest container. For example:

For example:
Product: 1000 cartons of cigarettes, 10 packs in each carton, 20 cigarettes in each pack
Units 1-Quantity= 1000

Units 1-Measure =CT
Units 2-Quantity=10
Units 2-Measure=PK
Units 3-Quantity=20
Units 3-Measure=PCS

12.14 Record Identifier PG30 (Anticipated Arrival Information)

Mandatory | Repeatable per PGA Line

This is a mandatory PGA input record that provides data pertaining to the date, time and location of the anticipated arrival/entry information for all FDA products.

For each line a PG30 record with an "A" (Anticipated arrival information) status code, date and time of arrival is mandatory. For entry type 21 coming from a Foreign Trade Zone, a PG30 record with an "F" (Foreign Trade Zone) code and FIRMS code for the FTZ location is required.

Record Identifier PG30 (Anticipated Arrival Information)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"30"	
Anticipated Arrival Information	1A	5	M	A (Anticipated Arrival Information). If entry type = 21, then repeat PG30 and enter F (Foreign Trade Zone).	1, 2
Anticipated Arrival Date at Port of Entry	8N	6-13	C	A numeric date in MMDDCCYY (month, day, century, year) format. Mandatory if Status = 'A'.	1, 2
Anticipated Arrival Time at Port of Entry	4N	14-17	C	Military time HHMM in (hour, minute) format. (Example: 1015, this represents 10:15 a.m.). For midnight, use 2400 (0000 is invalid). Mandatory if Status = 'A'.	1, 2
Inspection or Arrival Location Code	4AN	18-21	C	Only a value of '4' (=FIRMS Code) is allowed for entry type = 21. For entry type not = 21, this field is left blank.	
Inspection or Arrival Location	50X	22-71	C	Provide FIRMS Code here. For valid FIRMS codes, refer to ACS/ACE query. https://www.cbp.gov/document/report/acs-public-firms-code-report	
Filler	8X	72-80	M	Space fill	

Table 12-24: Tobacco PG30

Note 1
A= Anticipated Arrival Date and Time at the Anticipated Port of Entry.

Port of Entry:
19 CFR 101.1.
Port and port of entry. The terms "port" and "port of entry" refer to any place designated by Executive Order of the President, by order of the Secretary of the Treasury, or by Act of Congress, at which a Customs officer is authorized to accept entries of merchandise to collect duties, and to enforce the various provisions of the Customs and navigation laws. The terms "port" and "port of entry" incorporate the geographical area under the jurisdiction of a port director. (The Customs ports in the Virgin Islands, although under the jurisdiction of the Secretary of the Treasury, have their own Customs laws (48 U.S.C. 1406(i)). These ports, therefore, are outside the Customs territory of the United States and the ports thereof are not "ports of entry" within the meaning of these regulations).

Note 2
Examples on how to submit PG30

For all Entry Types other than Entry Type 21 Warehouse for an FTZ Withdrawal	For Entry Type 21 Warehouse for an FTZ Withdrawal
PG30 Record • Anticipated Arrival Information status code = “A” (anticipated arrival information) is mandatory • Anticipated Arrival Date at Port of Entry is mandatory • Anticipated Arrival Time at Port of Entry is mandatory	PG30 Record • Anticipated Arrival Information status code = “A” (anticipated arrival information) is mandatory • Anticipated Arrival Date at Port of Entry is mandatory • Anticipated Arrival Time at Port of Entry is mandatory Additional PG30 Record • Anticipated Arrival Information status code = “F” (FTZ) is mandatory • Anticipated Arrival Date at Port of Entry is optional • Anticipated Arrival Time at Port of Entry is optional • Inspection or Arrival Location Code = “4” (FIRMS Code) is mandatory • FTZ Location is mandatory

12.15 Record Identifier PG55 (Additional Entity Roles)

This is an optional PGA input record used to provide additional roles performed by an entity or individual.

Not supported by FDA at this time

Currently, the PG55 record is not supported by FDA. Multiple PG19 records should be used to input more than one Entity-Role combination. Refer to the PG19 section for details.

Record Identifier PG55 (Additional Entity Roles)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"55"	
Entity Role Code	3AN	5-7	O	Additional role of the entity.	
Entity Role Code	3AN	8-10	O	Additional role of the entity.	
Entity Role Code	3AN	11-13	O	Additional role of the entity.	
Entity Role Code	3AN	14-16	O	Additional role of the entity.	
Entity Role Code	3AN	17-19	O	Additional role of the entity.	
Entity Role Code	3AN	20-22	O	Additional role of the entity.	
Entity Role Code	3AN	23-25	O	Additional role of the entity.	
Entity Role Code	3AN	26-28	O	Additional role of the entity.	
Entity Role Code	3AN	29-31	O	Additional role of the entity.	
Entity Role Code	3AN	32-34	O	Additional role of the entity.	
Filler	46X	35-80	M	Space fill	

Table 12-25: Tobacco PG55

12.16 Record Identifier PG60 (Additional Information)

Optional | Repeatable per PGA Line

This is an optional PGA input record used to provide additional information about data in the PG record that precedes it during the submission of a PGA record set.

This record can follow a PG07, PG19, PG20 or PG21 record, and can only be used to provide the additional information noted by the Additional Information Qualifier Code list.

This record may be repeated.

Record Identifier PG60 (Additional Information)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"60"	
Additional information qualifier code	3AN	5-7	C	Code indicating the type of additional information being provided	1
Additional Information	73X	8-80	C	Text of the additional information related to the additional reference qualifier code	

Table 12-26: Tobacco PG60

Note 1
Valid PG60 Additional Information Qualifier Codes applicable to FDA Message Set are:

Code	Description
ENA	Continuation of Entity Name for PG19
AD1	Continuation of Entity address Line 1 for PG19
AD2	Continuation of Entity address Line 2 for PG20
AD3	Entity address Line 3 for PG20
AD4	Entity address Line 4 for PG20
AD5	Entity address Line 5 for PG20
ECI	Continuation of Entity City for PG20
INA	Continuation of Individual Name for PG21
EMA	Continuation of Email Address for PG21
TBN	Continuation of Trade/Brand Name for PG07

Table 12-27: Tobacco Additional Qualifier Codes

PG60 record should follow immediately after its parent. For example, a PG60: ENA record should follow PG19 and a PG60: TBN record should follow PG07.

12.17 Record Identifier PG00 (Data Substitution)

This is an optional record used at the CBP entry (or entry summary) header, CBP entry (or entry summary) line and/or PGA message set levels to indicate data substitution.

PG00 Substitution Grouping
In situations where the trade finds it would be supplying identical information more than once within the PGA Message Set, a PG00 substitution grouping can be used, instead of repeating that information multiple times. Refer to the 'usage notes' in the ACE ABI CATAIR - Customs and Trade Automated Interface Requirements publication for detailed information.

Record Identifier PG00 (Data Substitution)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"00"	
Substitution Indicator	1X	5	O	Identifies either the start or end of the substitution group, or the location of where to place the substitute data within the PGA Message Set. The following codes are allowed: S=Start of the substitution group E=End of the substitution group R=Replace this record with the substitution group indicated by the Substitution Number	
Substitution Number	4AN	6-9	O	Sequential number assigned to, or referring to, a specific substitution group of data provided at the header level. This data element is mandatory when using the S or R substitution indicator.	
Filler	71X	10-80	M	Space fill	

Table 12-28: Tobacco PG00

13 Radiation Emitting Products Commodity Data Elements and Values

Radiation Emitting Product commodities can be broken down into the following categories using the existing Government Agency data elements available in the PG01 message.

PG01 - Government Agency Code	Commodity Type	PG01 - Government Agency Program Code	Commodity Sub-Type	PG01 - Government Agency Processing Code
FDA	Radiation Emitting Products	RAD	Non-Medical Radiation Emitting Products	REP

Table 13-1: Radiation Emitting Products Commodity Hierarchy

The following table describes the Radiation Emitting Product Categories when a Performance Standard applies, i.e. the product requires a 2877. This table also indicates if certain Radiation Emitting Product Categories are also classified as Medical Devices. The Radiation Emitting Product Classification website, http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD_RH/classification.cfm, provides information on Radiation Emitting Products.

Radiation Emitting Product Category	2877 Required	Medical Device[§]
Diagnostic Ultrasound Devices	N	Y
Sonic Medical Products	N	Y
Sonic Non-Medical Products	N	N
Therapeutic Ultrasonic Devices	Y	Y
Ultrasonic Medical Devices (Miscellaneous)	N	Y
Ultrasound Non-Medical Devices	N	N
Veterinary Diagnostic Ultrasonic Products	N	N
Veterinary Therapy Ultrasonic Products	N	N
Analytical X-Ray Systems, Non-Medical	N	N
Cabinet X-Ray Systems, Medical	Y	Y
Cabinet X-Ray Systems, Non-Medical	Y	N
Cargo Non-Intrusive Security Systems	N	N
Cathode Ray Tube (without Electronics Chassis)	N	N
Cold-Cathode Gas Discharge Tubes	Y	N
Dental Diagnostic X-Ray Equipment	Y	Y
Diagnostic Nuclear Medicine Devices	N	Y
Diagnostic X-Ray Equipment (Non-Certified)	N	N
High Voltage Vacuum Switches	N	N
High Voltage Vacuum Tubes	N	N
Industrial Particle Beam Systems	N	N
Industrial X-Ray Systems (Excluding Cabinet)	N	N
Medical Accelerators	N	Y
Medical Diagnostic X-Ray Equipment	N	Y, except product codes RCA, RCB, RBZ, RCD
Non-Medical Accelerators	N	N
Personnel Security Systems	N	N
Radioisotope Therapy Devices	N	Y
Therapeutic X-Ray Systems	N	Y
TV Receivers & Products Containing Same	Y	ONLY the following product codes are medical devices: FET, FWB, FWC, FWD, FWE, FWF, FWG, HJG, and ODA. All other product codes in this category are not medical devices.
Veterinary X-Ray Systems	N	N
X-Ray Bone Densitometers	N	Y

Radiation Emitting Product Category	2877 Required	Medical Device§
X-Ray Film and Film Processing Materials	N	ONLY the following product codes are medical devices: LQA and JAC. All other product codes in this category are not medical devices.
Household ELF Products	N	N
Industrial Dielectric Heaters	N	N
Microwave Communication, Data Transmit, and Measurement Products	N	N
Microwave Diathermy Machines	N	Y
Microwave Heating and Drying Products	N	N
Microwave Hyperthermia Therapy Devices	N	Y
Microwave Identification, Safety, Security, and Surveillance Products	N	N
Microwave Medical Products	N	Y, except product code RDG
Microwave Ovens (Food Prep)	Y	N
Nuclear Magnetic Resonance Devices	N	Y
Other Microwave Products	N	N
Data Measurement, Transmit, Control Laser Products	Y	N
General Optical Products, Medical, Non-Laser	N	Y, except product code RGV, RGU
General Optical Products, Non-Medical, Non-Laser	N	N
In Vitro and Other Medical Laser Products	Y	Y, except product code RGB
Laser Light Show/Display Products	Y	N
Laser Products (Pre-Standard)	N	N
Material Processing Laser Products	Y	N
Medical Laser Products	Y	Y, except product code RGC
Mercury Vapor Lamps	Y	N
Other Demonstration Laser Products	Y	N
Other Laser Products	Y	N
Positioning Medical Laser Products	Y	Y, except product code RGC
Research, Scientific, Laboratory Laser Products	Y	N
Safety, Security, Surveillance Laser Products	Y	N
Sunlamp Products (Certified)	Y	Y
Sunlamp Products (Pre-Standard)	N	N
Surveying, Leveling, Alignment Laser Products	Y	N
Toy, Novelty, Play Laser Products	Y	N
Ultraviolet Commercial/Consumer Products, Non-Laser	N	N
Ultraviolet Hygiene Products, Non-Laser	N	ONLY the following product codes are medical devices: LYL, MCF, NOB. All other product codes in this category are not medical devices.
Ultraviolet Medical Products, Non-Laser	N	Y
Ultraviolet Surveillance & Detection Products, Non-Laser	N	N
Utility/Peripheral Laser Products	Y	

Table 13-2: Radiation Emitting Product Categories

***** If the radiation emitting product is a medical device, it will be filed under the Government Agency Program Code 'DEV' – go to the Medical Devices Commodity Data Elements and Values earlier in this document. If not, use this chapter and file under the Government Agency Program Code 'RAD'.

The following are the potential PGA records associated with submitting Radiation-Emitting Products.

PG Record	Description
PG01	FDA program office that regulates the product and the intended use
PG02	Product Identifier; the item type and Product Code details
PG06	Source Type(origin) other than the CBP country of origin
PG07	Trade/Brand Name
PG10	Product Description (Line level Item Common/Usual/Market Name Description)
PG19	Entity Role (manufacturer, consignee, shipper, etc.) Entity Identification, Entity Name, and Entity Address 1
PG20	Additional address data on the entity in PG19
PG21	Individual Name, Telephone Number, and Email address
PG23	FDA's Affirmation of Compliance Criteria
PG24	Remarks
PG25	Temperature qualifier, Lot Number Qualifier, Lot Number and PGA Line Value
PG26	Packaging qualifier and quantity of the shipment
PG27	Container Number
PG30	Date, time and location of anticipated arrival information
PG55	Identifies Entity from the previous PG19, PG20, and PG21 group as having additional roles.
PG60	Additional Information
PG00	Data substitution

Table 13-3: Radiation Emitting Products PGA Records

13.1 Radiation Emitting Products Example

Radiation Emitting Products Message Set Layout for Sample

Refer to the external file: **FDA SG Example PG Message Sets** **Tab:** ***Radiation Emitting Products***

PGA Records and Data Elements required are dependent on the agency program and processing code selected. For a more expansive set of examples of FDA PGA Message Sets, refer to the above document.

13.2 Record Identifier PG01 (PGA Identifier)

Mandatory | Not Repeatable per PGA Line

This is a mandatory PGA input record that provides data pertaining to the PGA Line Number, Government Agency Code, Government Agency Program Code, Government Agency Processing Code, Intended Use Code, Intended Use Description, and Disclaimer.

Record Identifier PG01 (PGA Identifier)					
Data Element	**Length/Class**	**Position**	**Status**	**Description/Required Value**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"01"	
PGA Line Number	3N	5-7	M	Begin with "001" and sequentially increment the line number on subsequent PG01 records, if applicable	
Government Agency Code	3AN	8-10	M	"FDA"	
Government Agency Program Code	3X	11-13	C	"RAD"	1, 2
Government Agency Processing Code	3AN	14-16	C	"REP"	1, 2
Intended Use Code	16X	42-57	C	Code identifying the intended use for the commodity after importation.	2, 3, 4, 5
Intended Use Description	21X	58-78	O	N/A for FDA lines	
Correction Indicator	1X	79	O	For future use	
Disclaimer	1A	80	C	A code of A (= product is not regulated by this agency) indicating there is no agency declaration requirement. Leave it blank for no disclaimer. "F" indicating that the product is manufactured in any state of the US, the District of Columbia, or Puerto Rico and sourced directly to the warehouse without ever leaving the US. **May only be used for FDA on Entry Type 21**. No other codes are accepted	2

Table 13-4: Radiation Emitting Products PG01

Note 1
Refer to the Table 13-1 above for the commodity hierarchy for Radiation Emitting Products commodities.

Note 2
If the product is Disclaimed, then these data elements should both be populated with 'FDA'. Otherwise the Government Agency Program Code, Government Agency Processing Code and Intended Use Code are mandatory.

Note 3
CBP publication, Appendix R - Intended Use Codes for ACE, provides general descriptions of all Intended Use Codes for all Partner Government Agencies (PGAs). For FDA regulated products, use the IUC descriptions as specified per commodity throughout this document. See Appendix E for a mapping of FDA IUC descriptions to CBP Appendix R IUC descriptions. For Radiation-Emitting Products, only one of the following Intended Use Codes may be entered:

Intended Use Code	Intended Use Description
085.000	For Veterinary Medical Use as a Non-Food Product under Controlled Distribution
090.000	For Military Use as a Non- Food Product
100.000	For Personal Use as a Non- Food Product
110.000	For Public Exhibition or Display as a Non-Food Product
120.000	For Public Safety Use as a Non-Food Product
130.000	For Consumer Use as a Non- Food Product
140.000	For Charitable Organization Use as Non-Food Product
150.000	For Commercial Processing as a Non-Food Product
155.000	For Commercial Assembly as a Non-Food Product
170.000	For Repair of a Non-Food Product
180.000	For Research and Development as a Non-Food Product
970.000	For Import for Export
980.000	For Other Use

Table 13-5: Radiation Emitting Products Intended Use Codes

Note 4
If the Intended Use Code used is 980.000, use PG10 Commodity Characteristic Description field to describe the Intended Use such as ‘Sample devices’, ‘Return shipment’, etc.

Note 5:
If after consultation with the importer, who should know the intended use of the product, the filer still ***does not know*** the intended use of the product, “UNK” may be used in lieu of an IUC. In most cases, the line will be subject to manual review, and may result in a request for documentation and/or additional information about the product as the product offered for import will be treated as a standard import. Ensure the IUC (reason for importation) is transmitted to avoid delays. As per the ACE Rule, if “UNK” is submitted as the IUC for the article, the ACE filer is still responsible for submitting the other required data elements in this rule that are applicable to that article, at the time of entry. In the future, if those other data elements are not submitted in ACE at the time of entry, the entry may be transmitted by ACE to FDA for admissibility review, but FDA may reject the entry. If FDA rejects an entry filing, the ACE filer will need to resubmit the entry with complete and accurate information.
.

.

13.3 Record Identifier PG02 (Product Identifier)

Mandatory | Not Repeatable per PGA Line

This mandatory PGA input record is used to include information related to a product (P).

For Radiation-Emitting Product entries, the Product Code Number is provided within this record.

Record Identifier PG02 (Product Identifier)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"02"	
Item Type	1A	5	M	Code identifying the following records as pertaining to P=Product. Only one "P" record is allowed for the same PGA Line # in PG01	
Product Code Qualifier	4AN	6-9	M	"FDP".	1
Product Code Number	19X	10-28	M	FDA Product Code must be exactly 7 characters	

Table 13-6: Radiation Emitting Products PG02

Note 1
Product Code Qualifiers and their descriptions can be found in CBP's ACE CATAIR Appendix PGA (PG02 – Product Code Qualifiers). For FDA filings, the Product Code Qualifier is always "FDP".
Only one FDA Product Code Number is allowed per line.

FDA Product Code Structure

Position	1-2	3	4	5	6-7
Name	Industry Code (N)	Class Code (AN)	Subclass Code (A or '-')	Process Indicator Code - PIC (A or '-')	Product (AN)

Legend - N: Numeric; A: Alphabetic; AN: Alphanumeric

Table 13-7: Radiation Emitting Products FDA Product Code Structure

IF Government Agency Program Code = "RAD"
THEN Industry Code is between 94 and 97 (inclusive)

13.4 Record Identifier PG06 (Product Origin)

Mandatory | Repeatable per PGA Line

This is a mandatory PGA input record that provides data pertaining to Source Type (Origin) other than the CBP Country of Origin.

Record Identifier PG06 (Product Origin)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	”PG”	
Record Type	2N	3-4	M	”06”	
Source Type Code	3AN	5-7	M	Mandatory value is 30 (Country of Source) for a component or 39 (Country of Production) for a finished product. Code 294 may be used to indicate a country has previously refused the line items.	1
Country Code	2X	8-9	M	A two-letter code that identifies the country from where the product was produced packed or shipped. Valid Country and Currency Code codes are in Appendix B in the ACS ABI CATAIR.	2

Table 13-8: Radiation Emitting Products PG06

Note 1
Source Type Codes and their descriptions can be found in CBP’s ACE CATAIR Appendix PGA (PG06 – Source Type Codes).

Note 2
Any of the country codes from CBP’s ACE CATAIR Appendix B (Section: Country and Currency Codes) can be entered.

13.5 Record Identifier PG07 (Product Trade Names)

Conditional | Not Repeatable per PGA Line

This is a conditional PGA input record that provides FDA with data pertaining to Name, Model, Manufacture Year, and Item Identity Number.

Record Identifier PG07 (Product Trade Names)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"07"	
Trade Name/Brand Name	35X	5-39	C	Trade/Brand Name of the Radiation-Emitting Device. For example, Sony Laser scanner RM2. Refer to Note 1 below. If Trade/Brand Name requires additional space, continue in a PG60 record with Qualifier Code "TBN".	1

Table 13-9: Radiation Emitting Products PG07

Note 1
If product requires 2877, then brand name is mandatory.

13.6 Record Identifier PG10 (Product Characteristics)

Mandatory | Not Repeatable per PGA Line

This is a mandatory PGA input record that allows for reporting the description of the product identified by the Product Code in PG02. For example, this record can be used to provide the model year of a product, which can be different from the year of manufacture provided in the PG07.

Record Identifier PG10 (Product Characteristics)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"10"	
Commodity Characteristic Description	57X	24-80	M	Common, market, usual name; free form invoice description; not product code description. For examples, see Appendix A: Use of PG10 Record.	

Table 13-10: Radiation Emitting Products PG10

13.7 Record Identifier PG19 (Entity Data)

Mandatory | Repeatable per PGA Line

For Radiation Emitting Products, this is a mandatory PGA input record requiring Entity Role, Entity Name, and Entity Address 1.

Entity Identification Code [16 (DUNS #), 47 (FEI #)] and Entity number are optional data elements, but they are listed as conditional because If opting to transmit Entity Identification Code, then Entity Number must also be provided, and vice versa.

Record Identifier PG19 (Entity Data)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"19"	
Entity Role Code	3AN	5-7	M	Code identifying the role of the entity being provided. For example, MF. Each entity role code can only be transmitted once per PGA line.	1
Entity Identification Code	3AN	8-10	C	Code identifying the Entity Identification is entered. For example, 16 (DUNS #) or 47 (FEI #). Mandatory, if Entity Number is entered.	2
Entity Number	15X	11-25	C	Identifying Number (DUNS or FEI) for the associated Entity Identification Code. Mandatory if Entity Identification Code is provided.	2
Entity Name	32X	26-57	M	The name of the entity is required. If Entity Name requires additional space, continue in a PG60 record with Qualifier Code "ENA". Refer to the validation criteria below.	2
Entity Address 1	23X	58-80	M	The address of the entity is required. If Entity Address1 requires additional space, continue in a PG60 record with Qualifier Code "AD1".	

Table 13-11: Radiation Emitting Products PG19

Note 1
List of Entity Role codes that mandatory to FDA Radiation-Emitting Products Message Sets is noted below:

Data Element	**Code**	**Description**
Entity Role Codes	MF	Manufacturer of goods
	DEQ	Shipper
	FD1	FDA Importer (Importer of Record)
	DP	Delivered-To Party

Table 13-12: Radiation Emitting Products Entity Role Codes (Mandatory)

List of Entity Role codes that are optional to FDA Message Sets is noted below:

Data Element	**Code**	**Description**
Entity Role Codes	PK	Point of Contact (Filer/Broker contact information)

Table 13-13: Radiation Emitting Products Entity Role Codes (Optional)

Note 2
Entity Identification Codes and their descriptions can be found in CBP's ACE CATAIR Appendix PGA (PG19 – Entity Identification Codes). List of Entity Identification codes applicable to FDA Medical Device Message Sets is noted below:

Data Element	Code	Description	Length/ Class
Entity Identification Codes	16	D&B-assigned (DUNS number); must be 9 digits	9N
	47	FDA-assigned (FEI number); must be from 1 to 10 digits	1 -10N

Table 13-14: Radiation Emitting Products Entity Identification Codes

FDA ENTITY IDENTIFICATION CODE AND ENTITY NUMBER SELECTION AND VALIDATION CRITERIA

FDA requires Entity Name and Entity Address. Additionally, FDA prefers to use DUNS numbers for identifying the Entity; If DUNS is unavailable then FEI may be provided.

IF Entity Identification Code =16 (DUNS) THEN Entity Number must be Length = 9 and Type = N
ELSE IF Entity Identification Code =47 (FEI) THEN Entity Number must be Length from 1 to 10 and Type = N

13.8 Record Identifier PG20 (Entity Address)

Mandatory | Repeatable per PGA Line

This is a mandatory PGA input record that provides additional data pertaining to the Entity identified in the preceding PG19 record; such as Entity Address line 2, Apartment/Suite, City, State, and Zip/Postal Code. This record is used when there is additional address information for the entity.

Record Identifier PG20 (Entity Address)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"20"	
Entity Address 2	32X	5-36	C	Address Line 2 for the Entity. If Entity Address2 requires additional space, continue in a PG60 record with Qualifier Code "AD2".	1
Entity Apartment Number/Suite Number	5X	37-41	C	For example, 102 A.	
Entity City	21X	42-62	M	For example, SAN DIEGO. If Entity City requires additional space, continue in a PG60 record with Qualifier Code "ECI".	
Entity State/Province	3AN	63-65	C	Refer to CBP's ACE CATAIR Appendix B for valid codes.	2
Entity Country	2A	66-67	M	Refer to CBP's ACE CATAIR Appendix B for valid codes.	
Entity Zip/Postal Code	9X	68-76	C	For example, 92169.	2
Filler	4X	77-80	M	Space fill	

Table 13-15: Radiation Emitting Products PG20

Note 1
If the Entity requires more than 2 address lines, use the optional PG60 records with Qualifier Codes "AD3", "AD4" and "AD5" immediately under the PG20 record for the same Entity.

Note 2
Required for US or Canada based entities

13.9 Record Identifier PG21 (Point of Contact)

Mandatory | Repeatable per PGA Line

This is a mandatory PGA input record that provides FDA with data about an Individual Point of Contact (POC) related to the Entity (the party) in the preceding PG19 record. Included in this record are the Individual Name, Telephone Number and Email address. A typical example is a POC for the Filer.

For each FDA line, at least one PG21 is required with the individual qualifier "FD1" (sent with the preceding PG19 and PG20 FD1 record).

FDA also highly encourages the transmission of PG21 with the individual qualifier "PK" which should be the point of contact for the filer/broker. "PK" may be sent in one of the following ways:

1) Under a PG19PK (transmitting PG19PK, PG20PK and PG21PK for the filer), the FDA preferred method, **OR**
2) As a secondary PG21 to FD1 using individual qualifier "PK" (transmitting PG19FD1, PG20FD1, PG21FD1, and PG21PK for the filer), **OR**
3) Under any other required PG19 entity as long as "PK" is the individual qualifier in PG21.

If provided, there should be only one PK per FDA line.

Although the PK (filer contact information) is optional, transmitting this information will enable FDA to expeditiously contact the filer, instead of contacting the Importer of Record to obtain the contact information for the filer. If only the Importer of Record PG21 is transmitted and PK is not, FDA processing may be delayed.

Record Identifier PG21 (Point of Contact)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"21"	
Individual Qualifier	3AN	5-7	M	Identify the type of party or facility the Individual represents. Only "FD1" and "PK" are allowed.	1
Individual Name	23X	8-30	M	Name of the Individual. If the name will not fit, continue in a PG60 record with Qualifier Code "INA".	
Telephone Number of the Individual	15X	31-45	M	For example, (713)555-8765 in US or (+65)9052-3529 in Singapore	
Email Address for the Individual	35X	46-80	M	Email address of the individual. If the Email Address exceeds in length, continue in a PG60 record with Qualifier Code "EMA".	2

Table 13-16: Radiation Emitting Products PG21

Note 1
Entity Role Codes and their descriptions can be found in CBP's ACE CATAIR Appendix PGA (PG19 – Entity Role Codes).

Note 2
Only transmit the valid email address as you would in an email program. Do not include names, additional characters, etc.

Valid Example	first.last@company.com
Invalid Example	<first.last@company.com>
Invalid Example	FirstName LastName first.last@company.com
Invalid Example	FirstName LastName <first.last@company.com>
Invalid Example	first.last@company.com, first.last@company.com

13.10 Record Identifier PG23 (Affirmation of Compliance)

Conditional | Repeatable per PGA Line

This is a conditional PGA input record that provides data pertaining to FDA Affirmation of Compliance Criteria. This record is repeatable, but each affirmation of compliance code can only be transmitted once.

For Radiation Emitting Products, that are also Medical Devices, the devices will be filed under Government Agency Program Code "DEV" and Government Agency Processing Code "RED". If the product is a medical device and is a radiation emitting product, both the Medical Device and the Radiation Emitting Product Affirmations of Compliance will apply, and both sets of AoC codes should be transmitted under DEV/RED. Refer to the Medical Devices chapter earlier in this document.

Record Identifier PG23 (Affirmation of Compliance)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"23"	
Affirmation of Compliance Code	5X	5-9	C	A code used to affirm compliance with FDA requirements. Refer to CBP's ACE CATAIR Appendix PGA (Food & Drug Affirmation of Compliance Codes) for valid codes.	1
Affirmation of Compliance Qualifier	30X	10-39	C	Text describing the information required by the PGA. For 'indicator only' AoC codes, this field is left blank. When free text is allowed, Affirmation of Compliance Qualifiers cannot exceed 30X. All other qualifiers must follow the syntax instructions for each code. See table below and refer to CBP's ACE CATAIR Appendix PGA.	1
Filler	1X	80	C	Space fill	

Table 13-17: Radiation Emitting Products PG23

Note 1
List of Affirmation of Compliance codes that are **conditional** to FDA Radiation Emitting Product Message Sets

If 2877 is required: The chart below contains Affirmations of Compliance that are based on the applicability of a performance standard to the product and the conditions under which it is being imported. The Affirmations of Compliance codes below replicate the required information on the FDA-2877 form.

Affirmation	**Qualifier**	**Examples and Additional Information**	**Additional Affirmations Required**	**Text on 2877**
RA1	date	format MM/YYYY	-	1. Was manufactured prior to the effective date of any applicable standard. Date of Manufacture.
RA2	text	text is reason for exclusion. Example: DOD exemption	-	2. Are excluded by the applicability clause or definition in the standard or by FDA written guidance. Specify reason for exclusion.
RA3	none			3. Are personal household goods of an individual entering the U.S. or being returned to a U.S. resident (Limit: 3 of each product type)

Affirmation	Qualifier	Examples and Additional Information	Additional Affirmations Required	Text on 2877
RA4	none			4. Are property of a party residing outside the U.S. and will be returned to the owner after repair or servicing.
RA5	text	text is description of the end-product. Example: Laser Diode		5. Are components or subassemblies to be used in manufacturing or as replacement parts
RA6	none			6. Are prototypes intended for ongoing product development by the importing firms, are labeled "FOR TEST/EVALUATION ONLY" and will be exported, destroyed, or held for future testing - there is a quantity limit for this option-stated on the back of the 2877 (page 2)
RA7	text	text is description of the end-product		7. Are being reprocessed in accordance with P.L. 104-134 or other FDA guidance, are labeled "FOR EXPORT ONLY" and will not be sold, distributed or transferred without FDA approval.
RB1	none		If RB1 is entered, then either ACC or ANC is required.	B1. Comply with the performance standards-1. *Last annual report or Product/Initial Report*
RB2	text	text is reason the product complies		B2. Comply with the performance standards-2. *Unknown manufacturer/report number. State reason:*
RC1±	none			C1. Do not comply with performance standards; are being held under a temporary import bond; will not be introduced into commerce, will be used under a radiation protection plan, and will be destroyed or exported under U.S. Customs Supervision when the mission is complete - 1. *Research, Investigations/Studies, or Training (Attach Form FDA 766)*
RC2	text	text is dates and use restriction	-	C2. Do not comply with performance standards; are being held under a temporary import bond; will not be introduced into commerce, will be used under a radiation protection plan, and will be destroyed or exported under U.S. Customs Supervision when the mission is complete - 1. *Trade Show/Demonstration; List dates and use restrictions*
RD1±	none			D1. Do not comply with performance standards; are held and will remain under bond; and will not be introduced into commerce until notification is received from FDA that products have been brought into compliance in accordance with an FDA approved petition. (Refer to the Form FDA 766) -1. *Approved Petition is attached.*

Affirmation	Qualifier	Examples and Additional Information	Additional Affirmations Required	Text on 2877
RD2±	none			D2. Do not comply with performance standards; are held and will remain under bond; and will not be introduced into commerce until notification is received from FDA that products have been brought into compliance in accordance with an FDA approved petition. (Refer to the Form FDA 766) -*2. Petition request is attached.*
RD3	date	date is the date form 766 will be provided, due within 60 days of submission.	-	D3. Do not comply with performance standards; are held and will remain under bond; and will not be introduced into commerce until notification is received from FDA that products have been brought into compliance in accordance with an FDA approved petition. (Refer to the Form FDA 766) -*3. Request will be submitted within 60 days.*
ACC	Product Report accession number	Syntax: 7 or 11 characters long Format: nnXnnnn-nnn where n is a 1-digit number and X is either a letter or a 1-digit number; '-nnn' is the optional Supplement Number	If ACC is entered, then RB1 is required	
ANC	Annual Report accession number	Syntax: 7 or 11 characters long Format: nnXnnnn-nnn where n is a 1-digit number and X is either a letter or a 1-digit number; '-nnn' is the optional Supplement Number.	If ANC is entered, then RB1 is required	

Table 13-18: Radiation Emitting Products Affirmation of Compliance Codes (Conditional)

± Annotates that additional information may be needed at time of entry for FDA to make a final admissibility decision.

List of Affirmation of Compliance codes that are **optional** to FDA Radiation Emitting Product Message Set is noted below:

Affirmation	Qualifier	Examples and Additional Information	Additional Affirmations Required	Remarks
MDL	Text	Model Number of the Product		
ERR	Text	Entry Review Requested		Indicator Only. No data will follow.
IFE	Text	Import For Export		Indicator only. No data will follow.
CCM	Text	Name of the Certified Component Manufacturer		EPRC Certified Component Manufacturer - in the diagnostic x-ray systems and their major components performance standard, manufacturers of major components are required to certify such components, which can be assembled by others into the finished x-ray system. In cases where the certifying component manufacturer is different from the manufacturer who is shipping the entire system to the U.S., this Affirmation of Compliance may be used to provide additional identifying information about that component manufacturer.

Table 13-19: Radiation Emitting Products Affirmation of Compliance Codes (Optional)

13.11 Record Identifier PG24 (Remarks)

Optional | Not Repeatable per PGA Line

This is an optional PGA input record that provides data pertaining to Remarks Type Code and Remarks Text.

PG24 cannot be repeated and only one PG24 is allowed for the same FDA line.

If entered, the Remarks Type Code should be GEN and must be under the PG02.

Currently, FDA processes PG24 record only at the Product-level (when under a PG02)

Record Identifier PG24 (Remarks)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"24"	
Remarks Type Code	3X	5-7	O	FDA uses only "GEN" as its valid value.	
Remarks Text	68X	13-80	O	Free form text relevant to the shipment or the commodity.	

Table 13-20: Radiation Emitting Products PG24

13.12 Record Identifier PG25 (Product Condition)

Optional | Repeatable per PGA Line

This is an optional PGA input record that provides data pertaining to Temperature Qualifier, Lot Number Qualifier, Lot Number, and PGA Line Value. This record is repeatable for multiple and Lot Numbers. If opting to transmit line value, the PGA Line Value must be included on the first PG25 record.

Record Identifier PG25 (Product Condition)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"25"	
Temperature Qualifier	1A	5	O	Temperature Category being reported for quality control or preservation purposes. A=Ambient, F=Frozen, D=Dry Ice, R=Refrigerated/Chilled, H=Fresh, U=Uncontrolled, P=Flashpoint	
Lot Number Qualifier	1N	15	O	Code of the entity that assigned the Lot number. 1=Manufacturer In the case of multiple PG25 records for a given FDA line, enter Lot Number Qualifier only in the first PG25 record.	
Lot Number	25X	16-40	O	The lot number that the manufacturer assigned to the product.	
PGA Line Value	12N	57-68	O	Although Line Value is optional, transmitting the value will assist in reviewing the product in a timely manner. Failure to transmit the value may result in delays associated with gathering missing information. If entered: • in the case of multiple PG25 records, enter value only in the first PG25 record • value should be in US Dollars, and enter whole dollars only • must be greater than zero and be right justified with preceding zeros	

Table 13-21: Radiation Emitting Products PG25

13.13 Record Identifier PG26 (Product Packaging)

Conditional | Repeatable per PGA Line

This is a conditional PGA input record that provides FDA with data pertaining to Packaging Qualifier, Quantity and Unit of Measure. Applies only for products subject to 2877 otherwise it is optional. If opting to transmit PG26, Packaging Qualifier, Unit of Measure, and Quantity must all be transmitted in accordance with the following instructions:

This record can be repeated up to six (6) times, once for each unique packaging level. The first record is used to describe the largest (outermost) container and the number of containers at this packaging level. The second record is used to describe the contents of the next smallest container. If needed, qualifiers 2-6 are used in a similar manner (largest to smallest container). The final record must describe the actual amount of the product in the smallest container and be a code from the table of base units listed below.

The appearance of any 'Packaging Qualifier' number level requires all levels under it to be represented. For instance, level 3 cannot be present unless levels 1 and 2 are present. The same unit of measure cannot be used multiple times on the same PGA line.

Record Identifier PG26 (Product Packaging)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"26"	
Packaging Qualifier	1N	5	C	This code identifies the level of packaging for the product. Outermost (largest=1) packages to the innermost (smallest=6) packages. There can be up to 6 levels of packaging. If reporting only one level, show the total quantity for the item and report that as level 1.	1,4
Quantity	12N	6-17	C	Although quantity is optional for non-2877 products, transmitting the quantity accurately and following the rules below will assist in reviewing the product in a timely manner. Failure to transmit the quantity records may result in delays associated with gathering missing information. Quantity is conditional for 2877 products. If entered, this is the total quantity for the packaging level. Must be greater than zero. Two decimal places are implied. The base quantity must always be the last quantity transmitted. **Transmitting Quantity requires transmitting Packaging Qualifier and the Unit of Measure. Last unit transmitted must be a base unit and only one base unit is allowed.**	2,4
Unit of Measure (Packaging Level)	5X	18-22	C	Type of packaging / packaging level. For example, BX. At least, 'Pieces' must be selected. Cannot be repeated among the PG26 records.	3,4

Table 13-22: Radiation Emitting Products PG26

Note 1

This code identifies the level of packaging for the product. Valid values are 1, 2, 3, 4, 5 and 6: Outermost (largest=1) packages to the innermost (smallest=6) packages. There can be up to 6 levels of packaging.

Note 2
There are two implied decimal points when writing the quantity in Units of Measure for all packaging levels. In this example, 4 pieces are represented as 000000000400, with the nine leading zeroes as "fill" and two decimal places following the value.

Note 3
List of Unit of Measure codes applicable to FDA-Radiation-Emitting Products Message Sets:

Valid FDA Units of Measure (UoM) for Packaging Containers are noted below:

Code	Description
CS	Case
CT	Carton
BX	Box
PK	Package

Table 13-23: Radiation Emitting Products UoM for Packaging Containers

Valid FDA Units of Measure for the Base Unit (Last Quantity Transmitted) are noted below:

Code	Description	Measure Type
PCS	Pieces	Count

Table 13-24: Radiation Emitting Products UoM for Base Units

Note 4
Quantity Data provides additional information to FDA about the product and how it is packaged. The basic format for Quantity Data is in multiple pairs of data – quantity and unit of measure, i.e., 500 cases, 12 ounces, fluid, 1000 cartons, etc. Up to 6 data pairs may be submitted, beginning with the 1st pair for the outermost packaging when Packaging Qualifier = 1. The first pair may describe the largest container and the last pair must describe the amount of product in the smallest container.

For example:

950	Microwave Ovens	
	Units 1-Quantity	950
	Units 1-Measure	PCS

13.14 Record Identifier PG27 (Shipping Container Information)

Optional | Repeatable per PGA Line

This is an optionalPGA input record that provides data pertaining to the shipping Container Number. This record may be repeated.

Record Identifier PG27 (Container Information)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"27"	
Container Number (Equipment ID)	20AN	5-24	O	The number of the shipping container.	
Container Number (Equipment ID)	20AN	28-47	O	The number of the shipping container.	
Container Number (Equipment ID)	20AN	51-70	O	The number of the shipping container.	

Table 13-25: Radiation Emitting Products PG27

13.15 Record Identifier PG30 (Anticipated Arrival Information)

Mandatory | Repeatable per PGA Line

This is a mandatory PGA input record that provides data pertaining to the date, time and location of the anticipated arrival/entry information for all FDA products.

For each line a PG30 record with an "A" (Anticipated arrival information) status code, date and time of arrival is mandatory. For entry type 21 coming from a Foreign Trade Zone, a PG30 record with an "F" (Foreign Trade Zone) code and FIRMS code for the FTZ location is required.

Record Identifier PG30 (Anticipated Arrival Information)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"30"	
Anticipated Arrival Information	1A	5	M	A (Anticipated Arrival Information). If entry type = 21, then repeat PG30 and enter F (Foreign Trade Zone).	1, 2
Anticipated Arrival Date at Port of Entry	8N	6-13	C	A numeric date in MMDDCCYY (month, day, century, year) format. **Mandatory if Status = 'A'**	1, 2
Anticipated Arrival Time at Port of Entry	4N	14-17	C	Military time HHMM in (hour, minute) format. (Example: 1015, this represents 10:15 a.m.). For midnight, use 2400 (0000 is invalid). **Mandatory if Status = 'A'**	1, 2
Inspection or Arrival Location Code	4AN	18-21	C	Only a value of '4' (=FIRMS Code) is allowed for entry type = 21. For entry type not = 21, this field is left blank.	
Inspection or Arrival Location	50X	22-71	C	Provide FIRMS Code here.For valid FIRMS codes, refer to ACS/ACE query. https://www.cbp.gov/document/report/acs-public-firms-code-report	
Filler	8X	72-80	M	Space fill	

Table 13-26: Radiation Emitting Products PG30

Note 1
A= Anticipated Arrival Date and Time at the Anticipated Port of Entry.

Port of Entry:
19 CFR 101.1.
Port and port of entry. The terms "port" and "port of entry" refer to any place designated by Executive Order of the President, by order of the Secretary of the Treasury, or by Act of Congress, at which a Customs officer is authorized to accept entries of merchandise to collect duties, and to enforce the various provisions of the Customs and navigation laws. The terms "port" and "port of entry" incorporate the geographical area under the jurisdiction of a port director. (The Customs ports in the Virgin Islands, although under the jurisdiction of the Secretary of the Treasury, have their own Customs laws (48 U.S.C. 1406(i)). These ports, therefore, are outside the Customs territory of the United States and the ports thereof are not "ports of entry" within the meaning of these regulations).

Note 2
Examples on how to submit PG30

For all Entry Types other than Entry Type 21 Warehouse for an FTZ Withdrawal	For Entry Type 21 Warehouse for an FTZ Withdrawal
PG30 Record • Anticipated Arrival Information status code = “A” (anticipated arrival information) is mandatory • Anticipated Arrival Date at Port of Entry is mandatory • Anticipated Arrival Time at Port of Entry is mandatory	PG30 Record • Anticipated Arrival Information status code = “A” (anticipated arrival information) is mandatory • Anticipated Arrival Date at Port of Entry is mandatory • Anticipated Arrival Time at Port of Entry is mandatory Additional PG30 Record • Anticipated Arrival Information status code = “F” (FTZ) is mandatory • Anticipated Arrival Date at Port of Entry is optional • Anticipated Arrival Time at Port of Entry is optional • Inspection or Arrival Location Code = “4” (FIRMS Code) is mandatory • FTZ Location is mandatory

13.16 Record Identifier PG55 (Additional Entity Roles)

This is an optional PGA input record used to provide additional roles performed by an entity or individual.

Not supported by FDA at this time

Currently. the PG55 record is not supported by FDA. Multiple PG19 records should be used to input more than one Entity-Role combination. Refer to the PG19 section for details.

Record Identifier PG55 (Additional Entity Roles)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"55"	
Entity Role Code	3AN	5-7	O	Additional role of the entity.	
Entity Role Code	3AN	8-10	O	Additional role of the entity.	
Entity Role Code	3AN	11-13	O	Additional role of the entity.	
Entity Role Code	3AN	14-16	O	Additional role of the entity.	
Entity Role Code	3AN	17-19	O	Additional role of the entity.	
Entity Role Code	3AN	20-22	O	Additional role of the entity.	
Entity Role Code	3AN	23-25	O	Additional role of the entity.	
Entity Role Code	3AN	26-28	O	Additional role of the entity.	
Entity Role Code	3AN	29-31	O	Additional role of the entity.	
Entity Role Code	3AN	32-34	O	Additional role of the entity.	
Filler	8X	72-80	M	Space fill	

Table 13-27: Radiation Emitting Products PG55

13.17 Record Identifier PG60 (Additional Information)

Optional | Repeatable per PGA Line

This is an optional PGA input record used to provide additional information about data in the PG record that precedes it during the submission of a PGA record set.

This record can follow a PG07, PG19, PG20 or PG21 record, and can only be used to provide the additional information noted by the Additional Information Qualifier Code list.

This record may be repeated.

Record Identifier PG60 (Additional Information)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"60"	
Additional information qualifier code	3AN	5-7	C	Code indicating the type of additional information being provided	1
Additional Information	73X	8-80	C	Text of the additional information related to the additional reference qualifier code	

Table 13-28: Radiation Emitting Products PG60

Note 1
Valid PG60 Additional Information Qualifier Codes applicable to FDA Message Set are:

Code	**Description**
ENA	Continuation of Entity Name for PG19
AD1	Continuation of Entity address Line 1 for PG19
AD2	Continuation of Entity address Line 2 for PG20
AD3	Entity address Line 3 for PG20
AD4	Entity address Line 4 for PG20
AD5	Entity address Line 5 for PG20
ECI	Continuation of Entity City for PG20
INA	Continuation of Individual Name for PG21
EMA	Continuation of Email Address for PG21
TBN	Continuation of Trade/Brand Name for PG07

Table 13-29: Radiation Emitting Products PG60 Additional Information Qualifier Codes

PG60 record should follow immediately after its parent. For example, a PG60: ENA record should follow PG19 and a PG60: TBN record should follow PG07.

13.18 Record Identifier PG00 (Data Substitution)

This is an optional record used at the CBP entry (or entry summary) header, CBP entry (or entry summary) line and/or PGA message set levels to indicate data substitution.

PG00 Substitution Grouping
In situations where the trade finds it would be supplying identical information more than once within the PGA Message Set, a PG00 substitution grouping can be used, instead of repeating that information multiple times. Refer to the 'usage notes' in the ACE ABI CATAIR - Customs and Trade Automated Interface Requirements publication for detailed information.

Record Identifier PG00 (Data Substitution)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"00"	
Substitution Indicator	1X	5	O	Identifies either the start or end of the substitution group, or the location of where to place the substitute data within the PGA Message Set. The following codes are allowed: S=Start of the substitution group E=End of the substitution group R=Replace this record with the substitution group indicated by the Substitution Number	
Substitution Number	4AN	6-9	O	Sequential number assigned to, or referring to, a specific substitution group of data provided at the header level. This data element is mandatory when using the S or R substitution indicator.	
Filler	71X	10-80	M	Space fill	

Table 13-30: Radiation Emitting Products PG00

14 Animal Drugs and Devices Commodity Data Elements and Values

Animal Drugs and Devices commodities can be broken down into the following categories using the existing Government Agency data elements available in the PG01 message.

PG01 - Government Agency Code	Commodity Type	PG01 - Government Agency Program Code	Commodity Sub-Type	PG01 - Government Agency Processing Code
FDA	Animal Drugs and Devices	VME	Animal Drugs	ADR
FDA	Animal Drugs and Devices	VME	Animal Devices	ADE

Table 14-1: Animal Drugs and Devices Commodity Hierarchy

The following are the potential PGA records associated with submitting Animal Drugs and Devices:

PG Record	Description
PG01	FDA program office within FDA and the intended use code
PG02	Product Identifier; the item type and Product Code details
PG04	Product Constituent Active Ingredient
PG06	Product Source information
PG07	The Trade/Brand Name
PG10	Product Description (Line level Item Common/Usual/Market Name Description)
PG19	Entity Role (manufacturer, consignee, shipper, etc.) Entity Identification, Entity Name, and Entity Address 1
PG20	Additional Entity Identification (Address line 2, Apartment/Suite, City, State, and Zip/Postal Code).
PG21	Additional Entity Role
PG23	FDA's Affirmation of Compliance Criteria
PG24	Remarks
PG25	Temperature qualifier, Lot Number Qualifier, Lot Number and PGA Line Value
PG26	Packaging qualifier and quantity of the shipment
PG30	Date, time and location of anticipated arrival information
PG55	Additional roles performed by an entity or individual
PG60	Additional Information
PG00	Data Substitution

Table 14-2: Animal Drugs and Devices PGA Records

14.1 Animal Drugs and Devices Example

Animal Drugs and Devices Message Set Layout for Sample

Refer to the external file: **FDA SG Example PG Message Sets** **Tab:** ***Animal Drugs & Devices***

PGA Records and Data Elements required are dependent on the agency program and processing code selected. For a more expansive set of examples of FDA PGA Message Sets, refer to the above document.

14.2 Record Identifier PG01 (PGA Identifier)

Mandatory | Not Repeatable per PGA Line

This is a mandatory PGA input record that provides data pertaining to the PGA Line Number, Government Agency Code, Government Agency Program Code, Government Agency Processing Code, Intended Use Code, Intended Use Description, and Disclaimer.

Record Identifier PG01 (PGA Identifier)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description/Required Value**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"01"	
PGA Line Number	3N	5-7	M	Begin with "001" and sequentially increment the line number on subsequent PG01 records, if applicable.	
Government Agency Code	3AN	8-10	M	"FDA"	
Government Agency Program Code	3X	11-13	C	"VME"	1, 2
Government Agency Processing Code	3AN	14-16	C	Codes allowed: ADR, ADE	1, 2
Intended Use Code	16X	42-57	C	Refer to the below list of Intended Use Codes.	3, 4
Intended Use Description	21X	58-78	O	N/A for FDA lines.	
Correction Indicator	1X	79	O	For future use	
Disclaimer	1A	80	C	A code of A (= product is not regulated by this agency) indicating there is no agency declaration requirement. Leave it blank for no disclaimer. "F" indicating that the product is manufactured in any state of the US, the District of Columbia, or Puerto Rico and sourced directly to the warehouse without ever leaving the US. **May only be used for FDA on Entry Type 21**. No other codes are accepted	

Table 14-3: Animal Drugs and Devices PG01

Note 1
Refer to Table 14-1 above for commodity type and sub-type for Animal Drugs and Devices.

Note 2
If the product is to be disclaimed, then these data elements should both be populated with 'FDA'. Otherwise the Government Agency Program Code and Government Agency Processing Code are mandatory.

Note 3
CBP publication, Appendix R - Intended Use Codes for ACE, provides general descriptions of all Intended Use Codes for all Partner Government Agencies (PGAs). For FDA regulated products, use the IUC descriptions as specified per commodity throughout this document. See Appendix E for a mapping of FDA IUC descriptions to CBP Appendix R IUC descriptions. The acceptable codes are listed below

Intended Use Code	Intended Use Description
085.003	Drug subject of a new animal drug application, conditionally approved application, or Index listing
100.000	Importation for Personal Use
150.013	Active Pharmaceutical Ingredient / Bulk Drug Substance to be used for Pharmacy Compounding
150.020	Active Pharmaceutical Ingredient / Bulk Drug Substance used to be further manufactured into a finished drug subject of a new animal drug application, conditionally approved application, or Index listing
180.009	For research and development in a pharmaceutical product – clinical investigations in animals (INAD or JINAD)
180.018	For research and development in a pharmaceutical product – for tests in-vitro or in laboratory research animals.
920.000	US Goods Returned
970.000	Import for Export
980.000	For Other Use: (APIs or Finished Drugs not elsewhere classified)

Table 14-4: Animal Drugs Intended Use Codes

Intended Use Code	FDA Import Scenario
085.000	For Veterinary Medical Use as a Non-Food Product

Table 14-5: Animal Devices Intended Use Codes

Note 4:
If after consultation with the importer, who should know the intended use of the product, the filer still ***does not know*** the intended use of the product, “UNK” may be used in lieu of an IUC. In most cases, the line will be subject to manual review, and may result in a request for documentation and/or additional information about the product as the product offered for import will be treated as a standard import. Ensure the IUC (reason for importation) is transmitted to avoid delays. As per the ACE Rule, if “UNK” is submitted as the IUC for the article, the ACE filer is still responsible for submitting the other required data elements in this rule that are applicable to that article, at the time of entry. In the future, if those other data elements are not submitted in ACE at the time of entry, the entry may be transmitted by ACE to FDA for admissibility review, but FDA may reject the entry. If FDA rejects an entry filing, the ACE filer will need to resubmit the entry with complete and accurate information.

14.3 Record Identifier PG02 (Product Identifier)

Mandatory | Not Repeatable per PGA Line

This mandatory PGA input record is used to include information related to a product (P).

Record Identifier PG02 (Product Identifier)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1 2	M	"PG"	
Record Type	2N	3-4	M	"02"	
Item Type	1A	5	M	Code identifying the following records as pertaining to P=Product. No other values accepted. Only one "P" record is allowed for the same PGA Line # in PG01 record.	
Product Code Qualifier	4AN	6-9	M	"FDP".	
Product Code Number	19X	10-28	M	FDA Product Code must be exactly 7 characters	

Table 14-5: Animal Drugs and Devices PG02

Product Code Qualifiers and their descriptions can be found in CBP's ACE CATAIR Appendix PGA (PG02 – Product Code Qualifiers). For FDA filings, the Product Code Qualifier is always "FDP".
Only one FDA Product Code is allowed per line.

FDA Product Code Structure

Position	1-2	3	4	5	6-7
Name	Industry Code (N)	Class Code (AN)	Subclass Code (A or '-')	Process Indicator Code - PIC (A or '-')	Product (AN)

Legend - N: Numeric; A: Alphabetic; AN: Alphanumeric

Table 14-6: Animal Drugs and Devices FDA Product Code Structure

*** Edit to limit Industry Codes, dependent upon the Government Agency Program/Processing Codes ***

IF Government Agency Program Code = "VME" and Government Agency Processing Code = "ADE"
THEN Industry Code should be 68.

IF Government Agency Program Code = "VME" and Government Agency Processing Code = "ADR"
THEN Industry Code should be 54, 56, 58, 60, 61, 62, 63, 64, 65, 66 or 67.

IF Government Agency Program Code = "VME" and Government Agency Processing Code = "ADR"
AND IF Industry Code = '54'
THEN Subclass Code should be ('N', and 'R').

14.4 Record Identifier PG04 (Product Constituent Element)

Optional | Repeatable per PGA Line

This is an optional PGA input record that provides data pertaining to Constituent Active Ingredient Qualifier, Name of the Constituent Element, Quantity of Constituent Element, Unit of Measure, and Percent of Constituent Element for the product identified by Product Code Number in PG02. This record can be repeated.

The PG04 record is optional for Government Agency Processing Codes "ADE" or "ADR". If opting to transmit this record, Name of the Constituent Element, Quantity, and either Unit of Measure or Percent are required. i.e., the record must be sent with complete information.

Using a Drug example, Appendix C: Sample use of PG04 – Product Constituent Element shows how PG04 can be used at the Product-level for multiple Constituent Elements.
Currently, FDA processes PG06-PG07-PG10 records only at the Product-level (when under a PG02).

Record Identifier PG04 (Product Constituent Element)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"04"	
Constituent Active Ingredient Qualifier	1A	5	O	Active ingredient = "*Y*" if yes, blank if no.	1
Name of the Constituent Element	51X	6-56	O		1
Quantity of Constituent Element	12N	57-68	O	2 decimal places are implied	1
Unit of Measure (Constituent Element)	5AN	69-73	O		1
Percent of Constituent Element	7N	74-80	O	4 decimal places are implied	1, 2

Table 14-7: Animal Drugs and Devices PG04

Note 1
IF Government Agency Program Code = "VME" AND Government Agency Processing Code = "ADR"
THEN Constituent Active Ingredient Qualifier and Name of the Constituent Element are entered.
Either the quantity and Unit of Measure are entered **OR** the Percent Constituent Element is entered.

May repeat PG04 for EACH Active Pharmaceutical Ingredient
Example1: Ibuprofen, 200mg tablets
Name of the Constituent Element = Ibuprofen
Quantity of Constituent Element = 200 and
Unit of Measure (Constituent Element) = milligrams

Example2: Aluminum zirconium tetrachlorohydrex
Name of the Constituent Element = aluminum zirconium tetrachlorohydrex
Percent of Constituent Element 18.2% (entered as 0182000)

Note 2

Examples of Percentages:

1000000	=	100%
0990000	=	99%
0090000	=	9%
0009000	=	.9%
0000900	=	.09%
0000090	=	.009%
0000009	=	.0009%

14.5 Record Identifier PG06 (Product Origin)

Mandatory | Repeatable per PGA Line

This is a mandatory PGA input record that provides data pertaining to Source Type (Origin) - other than the CBP Country of Origin - for the product identified by Product Code Number in PG02.

Using a Drug example, Appendix C: Sample use of PG04 – Product Constituent Element shows how PG04 can be used at the Product-level for multiple Constituent Elements. **Currently, FDA processes PG06-PG07-PG10 records only at the Product-level (when under a PG02)**.

Record Identifier PG06 (Product Origin)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1 2	M	"PG"	
Record Type	2N	3-4	M	"06"	
Source Type Code	3AN	5-7	M	Mandatory value is 30 (Country of Source) or 39 (Country of Production). Code 294 may be used to indicate a country has previously refused the line items.	1
Country Code	2X	8-9	M	Country of Production or Source is required for Animal Drugs.	2

Table 14-8: Animal Drugs and Devices PG06

Note 1
Source Type Codes and their descriptions can be found in CBP's ACE CATAIR Appendix PGA (PG06 – Source Type Codes).

Note 2
Any of the country codes from CBP's ACE CATAIR Appendix B (Section: Country and Currency Codes) can be entered.

14.6 Record Identifier PG07 (Product Trade Names)

Optional | Not Repeatable per PGA Line

This is an optional PGA input record that provides FDA with data pertaining to Trade Name for the product identified by Product Code Number in PG02.

Using a Drug example, Appendix C: Sample use of PG04 – Product Constituent Element shows how PG04 can be used at the Product-level for multiple Constituent Elements. **Currently, FDA processes PG06-PG07-PG10 records only at the Product-level (when under a PG02)**.

Record Identifier PG07 (Product Trade Names)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1 2	M	"PG"	
Record Type	2N	3-4	M	"07"	
Trade Name/Brand Name	35X	5-39	O	Trade, or Brand Name that describes the animal drug or device at each line level. If Trade/Brand Name requires additional space, continue in a PG60 record with Qualifier Code "TBN".	

Table 14-9: Animal Drugs and Devices PG07

14.7 Record Identifier PG10 (Product Characteristics)

Mandatory | Not Repeatable per PGA Line

This is a mandatory PGA input record that allows for reporting the description of the product identified by the Product Code in PG02.

Using a Drug example, Appendix C: Sample use of PG04 – Product Constituent Element shows how PG04 can be used at the Product-level for multiple Constituent Elements. **Currently, FDA processes PG06-PG07-PG10 records only at the Product-level (when under a PG02).**

Record Identifier PG10 (Product Characteristics)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"10"	
Commodity Characteristic Description	57X	24-80	M	Common, market, usual name; free form invoice description; not product code description. For examples, see Appendix A: Use of PG10 Record.	

Table 14-10: Animal Drugs and Devices PG10

14.8 Record Identifier PG19 (Entity Data)

Mandatory | Repeatable per PGA Line

This is a mandatory PGA input record requiring Entity Role, Entity Name, and Entity Address 1.

Entity Identification Code [16 (DUNS #), 47 (FEI #)] and Entity number are optional data elements, but they are listed as conditional because If opting to transmit Entity Identification Code, then Entity Number must also be provided, and vice versa.

Record Identifier PG19 (Entity Data)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"19"	
Entity Role Code	3AN	5-7	M	Code identifying the role of the entity being provided. For example, MF. Each entity role code can only be transmitted once per PGA line.	1
Entity Identification Code	3AN	8-10	C	Code identifying the Entity Identification is entered. For example, 16 (DUNS #) or 47 (FEI #). Mandatory, if Entity Number is entered.	2
Entity Number	15X	11-25	C	Identifying Number (DUNS or FEI) for the associated Entity Identification Code. Mandatory if Entity Identification Code is provided	2
Entity Name	32X	26-57	M	The name of the entity is required. If Entity Name requires additional space, continue in a PG60 record with Qualifier Code "ENA". Refer to the validation criteria below.	2
Entity Address 1	23X	58-80	M	The address of the entity is required. If Entity Address1 requires additional space, continue in a PG60 record with Qualifier Code "AD1".	2

Table 14-11: Animal Drugs and Devices PG19

Note 1
List of Entity Role codes that are mandatory to FDA Animal Drug and Device Message Sets are noted below:

Data Element	**Code**	**Description**
Entity Role Codes	MF	Manufacturer of goods (Final producer for the final drug product). If the product is a bulk API, use "MF" as the Entity Role Code (rather than "GD – Producer of API); If the product is in finished form, provide MF of final product.
	DEQ	Shipper
	FD1	FDA Importer (Importer of Record)
	DP	Delivered-To Party

Table 14-12: Animal Drugs and Devices Entity Role Codes (Mandatory)

List of Entity Role codes that are optional to FDA Animal Drug and Device Message Sets are noted below:

Data Element	Code	Description
Entity Role Codes	GD	Producer (Producer of the Active Pharmaceutical Ingredient (API)
	PK	Point of Contact (Filer/Broker Contact Information)

Table 14-13: Animal Drugs and Devices Entity Role Codes (Optional)

REPEAT GD for EACH Active Pharmaceutical Ingredient in the dosage form.

Note 2
Entity Identification Codes and their descriptions can be found in CBP's ACE CATAIR Appendix PGA (PG19 – Entity Identification Codes). List of Entity Identification codes applicable to FDA Animal Drug and Device Message Sets are noted below:

Data Element	Code	Description	Length/ Class
Entity Identification Codes	16	D&B-assigned (DUNS number); must be 9 digits	9N
	47	FDA-assigned (FEI number); must be from 1 to 10 digits	1 -10N

Table 14-14: Animal Drugs and Devices Entity Identification Codes

FDA ENTITY IDENTIFICATION CODE AND ENTITY NUMBER SELECTION AND VALIDATION CRITERIA

FDA requires Entity Name and Entity Address.

IF Entity Identification Code =16 (DUNS) THEN Entity Number must be Length = 9 and Type = N
ELSE IF Entity Identification Code =47 (FEI) THEN Entity Number must be Length from 1 to 10 and Type = N

14.9 Record Identifier PG20 (Entity Address)

Mandatory | Repeatable per PGA Line

This is a mandatory PGA input record that provides additional data pertaining to Entity identification such as Entity Address line 2, Apartment/Suite, City, State, and Zip/Postal Code. This record is used when there is additional address information for the entity.

Record Identifier PG20 (Entity Address)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"20"	
Entity Address 2	32X	5-36	C	Address Line 2 for the Entity. If Entity Address2 requires additional space, continue in a PG60 record with Qualifier Code "AD2".	1
Entity Apartment Number/Suite Number	5X	37-41	C	Apartment/Suite number of the entity.	
Entity City	21X	42-62	M	City of the entity. If Entity City requires additional space, continue in a PG60 record with Qualifier Code "ECI".	
Entity State/Province	3AN	63-65	C	Refer to CBP's ACE CATAIR Appendix B for valid codes.	2
Entity Country	2A	66-67	M	Refer to CBP's ACE CATAIR Appendix B for valid codes.	
Entity Zip/Postal Code	9X	68-76	C	Zip/Postal Code of the entity.	2
Filler	4X	77-80	C	Space fill	

Table 14-15: Animal Drugs and Devices PG20

Note 1
If the Entity requires more than 2 address lines, use the optional PG60 records with Qualifier Codes "AD3", "AD4" and "AD5" immediately under the PG20 record for the same Entity.

Note 2
Required for US or Canada based entities

14.10 Record Identifier PG21 (Point of Contact)

Mandatory | Repeatable per PGA Line

This is a mandatory PGA input record that provides point of contact information.

For each FDA line, at least one PG21 is required with the individual qualifier "FD1" (sent with the preceding PG19 and PG20 FD1 record).

FDA also highly encourages the transmission of PG21 with the individual qualifier "PK" which should be the point of contact for the filer/broker. "PK" may be sent in one of the following ways:

1) Under a PG19PK (transmitting PG19PK, PG20PK and PG21PK for the filer), the FDA preferred method, **OR**
2) As a secondary PG21 to FD1 using individual qualifier "PK" (transmitting PG19FD1, PG20FD1, PG21FD1, and PG21PK for the filer), **OR**
3) Under any other required PG19 entity as long as "PK" is the individual qualifier in PG21.

If provided, there should be only one PK per FDA line.

Although the PK (filer/broker contact information) is optional, transmitting this information will enable FDA to expeditiously contact the filer, instead of contacting the Importer of Record. If only the Importer of Record PG21 is transmitted and PK is not, FDA processing may be delayed.

Record Identifier PG21 (Point of Contact)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"21"	
Individual Qualifier	3AN	5-7	M	Identify the type of party or facility the Individual represents. Only "FD1" and "PK" are allowed.	
Individual Name	23X	8-30	M	Name of the Individual. If the name will not fit, continue in a PG60 record with Qualifier Code "INA".	
Telephone Number of the Individual	15X	31-45	M	Telephone number of the Individual. For example, (713)555-8765 in US or (+65)9052-3529 in Singapore	
Email Address for the Individual	35X	46-80	M	Email Address of the individual. If the Email Address exceeds in length, continue in a PG60 record with Qualifier Code "EMA".	1

Table 14-16: Animal Drugs and Devices PG21

Note 1
Only transmit the valid email address as you would in an email program. Do not include names, additional characters, etc.

Valid Example	first.last@company.com
Invalid Example	<first.last@company.com>
Invalid Example	FirstName LastName first.last@company.com
Invalid Example	FirstName LastName <first.last@company.com>
Invalid Example	first.last@company.com, first.last@company.com

14.11 Record Identifier PG23 (Affirmation of Compliance)

Conditional | Repeatable per PGA Line

This is a conditional PGA input record that provides data pertaining to FDA Affirmation of Compliance Criteria. This record is repeatable, but each affirmation of compliance code can only be transmitted once.

Record Identifier PG23 (Affirmation of Compliance)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"23"	
Affirmation of Compliance Code	5X	5-9	C	A code used to affirm compliance with FDA requirements. There must be at least one PG23 record with the AoC code of REG when filing animal drug. Refer to CBP's ACE CATAIR Appendix PGA (Food & Drug Affirmation of Compliance Codes) for valid codes.	1
Affirmation of Compliance Qualifier	30X	10-39	C	Text describing the information required by the PGA. For 'indicator only' AoC codes, this field is left blank. All other qualifiers must follow the syntax instructions for each code as specified in CBP's ACE CATAIR Appendix PGA	
Filler	1X	80	M	Space fill	

Table 14-17: Animal Drugs and Devices PG23

Note 1
The FDA Affirmation of Compliance Codes and their descriptions are listed in CBP's ACE CATAIR Appendix PGA (Food & Drug Affirmation of Compliance Codes)

Affirmation of Compliance Codes are **OPTIONAL** for Animal Devices.

The list of AoC codes that are conditional to the FDA Animal Drug Message Sets, with Program Code = VME and Processing Code = ADR are noted below:

Data Element	**Code**	**Description**	**Syntax**	**Business Rules**
	REG	Animal Drug Establishment Registration Number	9N	If Intended Use Code = 085.003, 150.020, 150.013, or 980.000, then REG is mandatory.
	VAN	Abbreviated New Animal Drug Application Number (ANADA)	6N	If Intended Use Code = 085.003 or 150.020, then either VNA or VAN is mandatory. If Intended Use Code = 980.000, then either VAN, VNA is optional.
	VIN	Investigational New Animal Drug Number (INAD and JINAD)	6N	If Intended Use Code = 180.009, then VIN is mandatory. If Intended Use Code = 180.018, then VIN is optional.
	VNA	New Animal Drug Application Number (NADA) [also includes conditionally approved animal drugs (CNADA), Type A	6N	If Intended Use Code = 085.003 or 150.020, then either VNA or VAN is mandatory.

Data Element	Code	Description	Syntax	Business Rules
		Medicated Articles, Legally Marketed Unapproved New Animal Indexed Drugs for Minor Species (MIF)]		If Intended Use Code = 980.000, then either VAN, VNA is optional.
	NDC	National Drug Code	10N	If Intended Use Code = 085.003, 150.020, 150.013, OR 980.000, then NDC is mandatory.

Table 14-18: Animal Drugs Affirmation of Compliance Codes (Conditional)

The list of AoC codes that are optional to the FDA Animal Drug Message Sets are noted below:

Data Element	Code	Description	Syntax	Business Rules
	ERR	Entry Review Requested	Indicator only	ERR is just used as an indicator, no data will follow
	VFL	Medicated Feed Mill License (MFL)	7X	If Government Agency Program Code = "VME" and Government Agency Processing Code = "ADR" and Intended Use Code = 085.003 or 980.000, then VFL is optional.
	VFD	Veterinary Feed Directive	Indicator Only	If Government Agency Program Code = "VME" and Government Agency Processing Code = "ADR" and Intended Use Code = 085.003 or 980.000, then VFD is optional.

Table 14-19: Animal Drugs Affirmation of Compliance Codes (Optional)

The table below shows which Affirmations of Compliance are Mandatory (M), Conditional (C), or Optional (O) based on the Intended Use Code/Import Scenario:

Intended Use[§] (Refer to PG01 for definitions)	Import Scenarios	Mandatory AoC	Conditional AoC	Optional AoC
085.003	Drug subject of a new animal drug application, conditionally approved application, or Index listing	REG, NDC, and either VAN, or VNA		VFL, VFD
100.000	Importation for Personal Use			
150.013	Active Pharmaceutical Ingredient / Bulk Drug Substance to be used for Pharmacy Compounding	REG, NDC		
150.020	Active Pharmaceutical Ingredient / Bulk Drug Substance used to be further manufactured into a finished drug subject of a new animal drug application, conditionally approved application, or Index listing	REG, NDC, and either VAN, or VNA		
180.009	For research and development in a pharmaceutical product – clinical investigations in animals (INAD or JINAD)	VIN		
180.018	For research and development in a pharmaceutical product – for tests in-vitro or in laboratory research animals.			VIN
920.000	US Goods Returned			
970.000	Import for Export			
980.000	For Other Use: (APIs or Finished Drugs not elsewhere classified)	REG, NDC		VAN, VNA, VFL, VFD

Table 14-20: Animal Drugs IUC and AoC Codes Mapping

Intended Use[§] (Refer to PG01 for definitions)	FDA Import Scenario	Mandatory AoC	Conditional AoC	Optional AoC
085.000	For Veterinary Medical Use as a Non-Food Product			

Table 14-21: Animal Devices IUC and AoC Codes Mapping

[§] If after consultation with the importer, who should know the intended use of the product, the filer still ***does not know*** the intended use of the product, "UNK" may be used in lieu of an IUC. In most cases, the line will be subject to manual review, and may result in a request for documentation and/or additional information about the product as the product offered for import will be treated as a standard import. Ensure the IUC (reason for importation) is transmitted to avoid delays. As per the ACE Rule, if "UNK" is submitted as the IUC for the article, the ACE filer is still responsible for submitting the other required data elements in this rule that are applicable to that article, at the time of entry. In the future, if those other data elements are not submitted in ACE at the time of entry, the entry may be transmitted by ACE to FDA for admissibility review, but FDA may reject the entry. If FDA rejects an entry filing, the ACE filer will need to resubmit the entry with complete and accurate information.

14.12 Record Identifier PG24 (Remarks)

Optional | Not Repeatable per PGA Line

This is an optional PGA input record that provides data pertaining to Remarks Type Code and Remarks Text.

PG24 cannot be repeated and only one PG24 is allowed for the same FDA line.

If entered, the Remarks Type Code should be GEN and must be under the PG02.

Currently, FDA processes PG24 record only at the Product-level (when under a PG02).

Record Identifier PG24 (Remarks)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"24"	
Remarks Type Code	3X	5-7	O	FDA uses only "GEN" as its valid value.	
Remarks Text	68X	13-80	O	Free form text relevant to the shipment or the commodity.	

Table 14-22: Animal Drugs and Devices PG24

14.13 Record Identifier PG25 (Product Condition)

Optional | Repeatable per PGA Line

This is an optional PGA input record that provides data pertaining to Temperature Qualifier, Lot Number Qualifier, Lot Number, and PGA Line Value. This record is repeatable for multiple Lot Numbers. If opting to transmit line value, the PGA Line Value must be included on the first PG25 record.

Record Identifier PG25 (Product Condition)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"25"	
Temperature Qualifier	1A	5	O	Temperature Category being reported for quality control or preservation purposes. A=Ambient, F=Frozen R=Refrigerated/Chilled, D=Dry Ice H=Fresh, U=Uncontrolled P=Flashpoint	
Lot Number Qualifier	1N	15	O	Code of the entity that assigned the Lot number. For Animal Drugs the only valid value is: 1=Manufacturer In the case of multiple PG25 records for a given FDA line, enter Lot Number Qualifier only in the first PG25 record.	
Lot Number	25X	16-40	O	The lot number that the manufacturer/ producer/grower assigned to the product.	
PGA Line Value	12N	57-68	O	Although Line Value is optional, transmitting the value will assist in reviewing the product in a timely manner. Failure to transmit the value may result in delays associated with gathering missing information. If entered: • in the case of multiple PG25 records, enter value only in the first PG25 record • value should be in US Dollars, and enter whole dollars only • must be greater than zero and be right justified with preceding zeros.	

Table 14-23: Animal Drugs and Devices PG25

14.14 Record Identifier PG26 (Product Packaging)

Optional | Repeatable per PGA Line

This is an optional PGA input record that provides FDA with data pertaining to Packaging Qualifier, Quantity and Unit of Measure. If included, the following rules apply:

This record can be repeated up to six (6) times, once for each unique packaging level. The first record is used to describe the largest (outermost) container and the number of containers at this packaging level. The second record is used to describe the contents of the next smallest container. If needed, qualifiers 2-6 are used in a similar manner (largest to smallest container). The final record must describe the actual amount of the product in the smallest container and be a code from the table of base units listed below.

The appearance of any 'Packaging Qualifier' number level requires all levels under it to be represented. For instance, level 3 cannot be present unless levels 1 and 2 are present. The same unit of measure cannot be used multiple times on the same PGA line.

Record Identifier PG26 (Product Packaging)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"26"	
Packaging Qualifier	1N	5	C	This code identifies the level of packaging for the product. Outermost (largest=1) packages to the innermost (smallest=6) packages. There can be up to 6 levels of packaging. If reporting only one level, show the total quantity for the item and report that as level 1.	1,4
Quantity	12N	6-17	C	Although quantity is optional, transmitting the quantity accurately and following the rules below will assist in reviewing the product in a timely manner. Failure to transmit the quantity records may result in delays associated with gathering missing information. If entered, this is the total quantity for the packaging level. Must be greater than zero. Two decimal places are implied. The base quantity must always be the last quantity transmitted. **Transmitting Quantity requires transmitting Packaging Qualifier and the Unit of Measure. Last unit transmitted must be a base unit and only one base unit is allowed.**	2,4
Unit of Measure (Packaging Level)	5X	18-22	C	Type of packaging / packaging level. For example, BX. Cannot be repeated among the PG26 records.	3,4

Table 14 23: Table 14 23: Animal Drugs and Devices PG26

Note 1
This code identifies the level of packaging for the product. Valid values are 1, 2, 3, 4, 5 and 6: Outermost (largest=1) packages to the innermost (smallest=6) packages. There can be up to 6 levels of packaging

Note 2

There are two implied decimal points when writing the quantity in Units of Measure for all packaging levels. In this example, 4 pieces are represented as 000000000400, with the nine leading zeroes as “fill” and two decimal places following the value.

Note 3
List of Unit of Measure codes applicable to FDA- Animal Drugs and Devices Message Sets. For a full list of applicable Unit of Measure codes for Packaging Containers and Base Unit Codes, refer to Appendix D: FDA Unit of Measurement Codes in this document.

Note 4
Quantity Data provides additional information to FDA about the product and how it is packaged. The basic format for Quantity Data is in multiple pairs of data – quantity and unit of measure, i.e., 500 cases, 12 ounces, fluid, 1000 cartons, etc. Up to 6 data pairs may be submitted, beginning with the 1st pair for the outermost packaging when Packaging Qualifier = 1. The first pairs may describe the largest container and the last pair must describe the amount of product in the smallest container.
For example:
100 Cartons, 24 Aspirin 100 tablets 325 mg

Units 1-Quantity	100
Units 1-Measure	CT
Units 2-Quantity	24
Units 2-Measure	BO
Units 3-Quantity	100
Units 3-Measure	TAB

In this case, the invoice description contains the strength of the aspirin tablets. The product quantity is listed using the "Tablets" quantity unit code.

14.15 Record Identifier PG30 (Anticipated Arrival Information)

Mandatory | Repeatable per PGA Line

This is a mandatory PGA input record that provides data pertaining to the date, time and location of the anticipated arrival/entry information for all FDA products.

For each line a PG30 record with an "A" (Anticipated arrival information) status code, date and time of arrival is mandatory. For entry type 21 coming from a Foreign Trade Zone, a PG30 record with an "F" (Foreign Trade Zone) code and FIRMS code for the FTZ location is required.

Record Identifier PG30 (Anticipated Arrival Information and)					
Data Element	**Length/Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"30"	
Anticipated Arrival Information	1A	5	M	A (Anticipated Arrival Information). If entry type = 21, then repeat PG30 and enter F (Foreign Trade Zone).	1, 2
Anticipated Arrival Date at Port of Entry	8N	6-13	C	A numeric date in MMDDCCYY (month, day, century, year) format. Mandatory if Status = 'A'.	1, 2
Anticipated Arrival Time at Port of Entry	4N	14-17	C	Military time HHMM in (hour, minute) format. (Example: 1015, this represents 10:15 a.m.). For midnight, use 2400 (0000 is invalid). Mandatory if Status = 'A'.	1, 2
Inspection or Arrival Location Code	4AN	18-21	C	Only a value of '4' (=FIRMS Code) is allowed for entry type = 21. For entry type not = 21, this field is left blank.	
Inspection or Arrival Location	50X	22-71	C	Provide FIRMS Code. For valid FIRMS codes, refer to ACS/ACE query. https://www.cbp.gov/document/report/acs-public-firms-code-report	
Filler	8X	72-80	M	Space fill	

Table 14-24: Animal Drugs and Devices PG30

Note 1
A= Anticipated Arrival Date and Time at the Anticipated Port of Entry.
Port of Entry:
19 CFR 101.1.
Port and port of entry. The terms "port" and "port of entry" refer to any place designated by Executive Order of the President, by order of the Secretary of the Treasury, or by Act of Congress, at which a Customs officer is authorized to accept entries of merchandise to collect duties, and to enforce the various provisions of the Customs and navigation laws. The terms "port" and "port of entry" incorporate the geographical area under the jurisdiction of a port director. (The Customs ports in the Virgin Islands, although under the jurisdiction of the Secretary of the Treasury, have their own Customs laws (48 U.S.C. 1406(i)). These ports, therefore, are outside the Customs territory of the United States and the ports thereof are not "ports of entry" within the meaning of these regulations).

Note 2
Examples on how to submit PG30

For all Entry Types other than Entry Type 21 Warehouse for an FTZ Withdrawal	For Entry Type 21 Warehouse for an FTZ Withdrawal
PG30 Record • Anticipated Arrival Information status code = “A” (anticipated arrival information) is mandatory • Anticipated Arrival Date at Port of Entry is mandatory • Anticipated Arrival Time at Port of Entry is mandatory	PG30 Record • Anticipated Arrival Information status code = “A” (anticipated arrival information) is mandatory • Anticipated Arrival Date at Port of Entry is mandatory • Anticipated Arrival Time at Port of Entry is mandatory Additional PG30 Record • Anticipated Arrival Information status code = “F” (FTZ) is mandatory • Anticipated Arrival Date at Port of Entry is optional • Anticipated Arrival Time at Port of Entry is optional • Inspection or Arrival Location Code = “4” (FIRMS Code) is mandatory • FTZ Location is mandatory

14.16 Record Identifier PG55 (Additional Entity Roles)

This is an optional PGA input record used to provide additional roles performed by an entity or individual.

Not supported by FDA at this time

Currently, the PG55 record is not supported by FDA. Multiple PG19 records should be used to input more than one Entity-Role combination. Refer to the PG19 section for details.

Record Identifier PG55 (Additional Entity Roles)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"55"	
Entity Role Code	3AN	5-7	O	Additional role of the entity.	
Entity Role Code	3AN	8-10	O	Additional role of the entity.	
Entity Role Code	3AN	11-13	O	Additional role of the entity.	
Entity Role Code	3AN	14-16	O	Additional role of the entity.	
Entity Role Code	3AN	17-19	O	Additional role of the entity.	
Entity Role Code	3AN	20-22	O	Additional role of the entity.	
Entity Role Code	3AN	23-25	O	Additional role of the entity.	
Entity Role Code	3AN	26-28	O	Additional role of the entity.	
Entity Role Code	3AN	29-31	O	Additional role of the entity.	
Entity Role Code	3AN	32-34	O	Additional role of the entity.	
Filler	8X	72-80	M	Space fill	

Table 14-25: Animal Drugs and Devices PG55

14.17 Record Identifier PG60 (Additional Information)

Optional | Repeatable per PGA Line

This is an optional PGA input record used to provide additional information about data in the PG record that precedes it during the submission of a PGA record set.

This record can follow a PG07, PG19, PG20 or PG21 record, and can only be used to provide the additional information noted by the Additional Information Qualifier Code list.

This record may be repeated.

Record Identifier PG60 (Additional Information)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"60"	
Additional information qualifier code	3AN	5-7	C	Code indicating the type of additional information being provided	1
Additional Information	73X	8-80	C	Text of the additional information related to the additional reference qualifier code	

Table 14-26: Animal Drugs and Devices PG60

Note 1
Valid PG60 Additional Information Qualifier Codes applicable to FDA Message Set are noted below:

Code	**Description**
ENA	Continuation of Entity Name for PG19
AD1	Continuation of Entity address Line 1 for PG19
AD2	Continuation of Entity address Line 2 for PG20
AD3	Entity address Line 3 for PG20
AD4	Entity address Line 4 for PG20
AD5	Entity address Line 5 for PG20
ECI	Continuation of Entity City for PG20
INA	Continuation of Individual Name for PG21
EMA	Continuation of Email Address for PG21
TBN	Continuation of Trade/Brand Name for PG07

Table 14-27: Animal Drugs and Devices PG60 Additional Information Qualifier Codes

PG60 record should follow immediately after its parent. For example, a PG60: ENA record should follow PG19 and a PG60: TBN record should follow PG07.

14.18 Record Identifier PG00 (Data Substitution)

This is an optional record used at the CBP entry (or entry summary) header, CBP entry (or entry summary) line and/or PGA message set levels to indicate data substitution.

PG00 Substitution Grouping
In situations where the trade finds it would be supplying identical information more than once within the PGA Message Set, a PG00 substitution grouping can be used, instead of repeating that information multiple times. Refer to the 'usage notes' in the ACE ABI CATAIR - Customs and Trade Automated Interface Requirements publication for detailed information.

Record Identifier PG00 (Data Substitution)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"00"	
Substitution Indicator	1X	5	O	Identifies either the start or end of the substitution group, or the location of where to place the substitute data within the PGA Message Set. The following codes are allowed: S=Start of the substitution group E=End of the substitution group R=Replace this record with the substitution group indicated by the Substitution Number	
Substitution Number	4AN	6-9	O	Sequential number assigned to, or referring to, a specific substitution group of data provided at the header level. This data element is mandatory when using the S or R substitution indicator.	
Filler	71X	10-80	M	Space fill	

Table 14-28: Animal Drugs and Devices PG00

Appendix A: Use of PG10 Record

Below is an example of how the PG10 record is used to capture the information currently collected in multiple OI records. A group of PG10-PG26 data can provide information on multiple variations of the product that was generally identified in the OI record:

```
OI        VARIOUS SOFT AND HARD CANDIES
PG01001FDAFDA
PG02PFDP 33LGT07A
...
PG10      SOFT CANDY KR CHERRY SOURS 6/8 OZ
...
PG01002FDAFDA
PG02PFDP 33LGT07A
...
PG10      SOFT CANDY CB GUMMI BEARS 24/6 OZ PEG
...
PG01003FDAFDA
PG02PFDP 33LGT07A
...
PG10      SOFT CANDY KR GUMMI BEARS 6/9 OZ
...
```

Appendix B: Food Facility Registration Exemption (FME)

Code	Description
A	Facility is out of business
B	Facility is a private residence (21 CFR 1.227)
C	Facility is a restaurant (21 CFR 1.226(d); 1.227)
D	Facility is a retail food establishment (21 CFR 1.226(c); 1.227)
E	Facility is a non-processing fishing vessel (21 CFR 1.226(f))
F	Facility is a non-bottled drinking water collection and distribution establishment (21 CFR 1.227)
K	Unable to determine the registration number of the manufacturer

Table B-1: Food Facility Registration Exemption Codes

Appendix C: Sample use of PG04 – Product Constituent Element

Using the non-prescription Drug, *Popular Product* with multiple APIs[§], the example below shows how PG04 can be used at the product-level for multiple constituent elements.

PG01	001	(Line#)
PG02	60LBF01	(Product Code)
PG06	39 Philippines	(Source Country Name)
PG07	Popular Product	(Brand Name)
PG10	Popular Product	(Modified Release Capsules)
PG04	API1	(Constituent Element #1)
PG04	API2	(Constituent Element #2)
PG04	API3	(Constituent Element #3)
PG19		

[§] API = Active Pharmaceutical Ingredient

The above example shows how the records PG06-PG07-PG10 are used at the **Product level**.

Currently, FDA processes PG06-PG07-PG10 records only at the Product-level (when under a PG02).

Avoid including PG06-PG07-PG10 under a PG04.
PG06-PG07-PG10 records immediately follow PG02; before any PG04 records.

Appendix D: FDA Unit of Measurement Codes

Valid FDA Units of Measure for Packaging Containers

Code	Description
AE	Aerosol
AM	Ampoule, Non-Protected
AP	Ampoule, Protected
AT	Atomizer
BA	Barrel (Container)
BB	Bobbin
BC	Bottlecrate, Bottlerack
BD	Board
BE	Bundle
BF	Balloon, Non-Protected
BG	Bag
BH	Bunch
BI	Bin
BJ	Bucket
BK	Basket
BL	Bale, Compressed
BN	Bale, Non-Compressed
BO	Bottle, Non-Protected,Cyl
BP	Balloon, Protected
BQ	Bottle, Protected, Cylnd
BR	Bar
BS	Bottle, Non-Prot Bulbous
BT	Bolt
BU	Butt
BV	Bottle, Protected Bulbous
BX	Box
BY	Board in Bndl/Bnch/Truss

Code	Description
BZ	Bars in Bundle/Bunch/Trus
CA	Can, Rectangular
CAG	Cage
CB	Crate, Beer
CC	Churn
CE	Creel
CF	Coffer
CH	Chest
CI	Canister
CJ	Coffin
CK	Cask
CL	Coil
CO	Carboy, Non-Protected
CON	Container
CP	Carboy, Protected
CTR	Cartridge
CR	Crate
CS	Case
CT	Carton
CU	Cup
CV	Cover
CX	Can, Cylindrical
CY	Cylinder
CZ	Canvas
DJ	Demijohn, Non-Protected
DP	Demijohn, Protected
DR	Drum
EN	Envelope
FC	Crate, Fruit
FD	Crate, Framed
FI	Firkin
FL	Flask
FO	Footlocker
FP	Filmpack
FR	Frame
GB	Bottle, Gas
GI	Girders

Code	Description
GZ	Girders in Bndl/Bnch/Trus
HG	Hogshead
HR	Hamper
ING	Ingot
IZ	Ingots in Bundle/Bnch/Trs
JC	Jerrycan, Rectangular
JG	Jug
JR	Jar
JT	Jutebag
JY	Jerrycan, Cylindrical
KEG	Keg
KIT	Kit
LG	Log
LZ	Logs In Bundle/Bunch/Trus
MB	Bag, Multi-ply
MC	Crate, Milk
MS	Sack, Multiwall
MT	Mat
MX	Matchbox
NE	Unpacked or Unpackaged
NS	Nest
NT	Net
PA	Packet
PAL	Pallet
PC	Parcel
PG	Plate
PH	Pitcher
PI	Pipe
PK	Package/Pack
PL	Pail
PN	Plank
PO	Pouch
PT	Pot
PU	Tray or Tray Pack
PY	Plates in Bndl/Bnch/Truss

Code	Description
PZ	Planks or Pipes, Bnd/Bnch
RD	Rod
RG	Ring
RL	Reel
RO	Roll
RT	Rednet
RZ	Rods in Bundle/Buch/Truss
SA	Sack
SC	Crate, Shallow
SD	Spindle
SE	Sea-chest
SH	Sachet
SK	Case, Skeleton
SL	Slipsheet
SM	Sheet metal
ST	Sheet
SU	Suitcase
SW	Shrinkwrapped
SY	Syringe
SZ	Sheets in Bndl/Bnch/Truss
TB	Tub
TC	Tea-Chest
TD	Tube, Collapsible
TK	Tank, Rectangular
TN	Tin
TO	Ton
TR	Trunk
TS	Truss
TU	Tube
TY	Tank, Cylindrical
TZ	Tubes in Bndl/Bnch/Truss
VA	Vat
VG	Bulk Gas at 1031 MBAR
VI	Vial

Code	Description
VL	Bulk Liquid
VO	Bulk,Solid,Lg Particles
VP	Vacuum-packed

Code	Description
VQ	Bulk Liquefied Gas
VR	Bulk,Solid,Granular Parti

Code	Description
VY	Bulk,Solid,Fine Particle
WB	Wickerbottle

Table D-0-1: UofM for Packaging Containers

Valid FDA Units of Measure for the Base Unit (Last Quantity Transmitted)

Code	Description	Measure Type
AU	Allergy Units (ml or tablet)	Dosage
BAU	Bioequivalent Allergy Units (ml or tablet)	Dosage
BBL	Barrels (42 Gallons Ea)	Volume
BOL	Boluses	Dosage
CAP	Capsules	Dosage
CAR	Carats	Weight
CFT	Cubic Feet	Volume
CG	Centigrams	Weight
CM	Centimeters	Length
CM3	Cubic Centimeters	Volume
CYD	Cubic Yards	Volume
DOZ	Dozen	Count
DPC	Dozen Pieces	Count
DPR	Dozen Pairs	Count
FOZ	Ounces, fluid	Volume
FT	Feet	Length
G	Grams	Weight
GAL	Gallons (US)	Volume
GR	Gross	Count
IN	Inch	Length
KG	Kilograms	Weight
KM	Kilometers	Length
KM2	1,000 Square Meters	Area
KM3	1,000 Cubic Meters	Volume
L	Liters	Volume
LB	Pounds (avdp)	Weight
LNM	Linear Meters	Length
M	Meters	Length
M2	Square Meters	Area
M3	Cubic Meters	Volume
MCG	Micrograms	Weight
MG	Milligrams	Weight
ML	Milliliters	Volume
NO	Number	Count
OZ	Ounces, weight (avdp)	Weight

Code	Description	Measure Type
PCS	Pieces	Count
PNU	Protein Nitrogen Units	Dosage
PRS	Pairs	Count
PTL	Pints, liquid (US)	Volume
QTL	Quarts, liquid (US)	Volume
SFT	Square Feet	Area
SQI	Square Inches	Area
STN	Short Ton (2000 LB)	Weight
SUP	Suppositories	Dosage
SYD	Square Yards	Area
T	Metric Ton	Weight
TAB	Tablets	Dosage
TON	Long Ton (2240 LB)	Weight
TOZ	Ounces, Troy or Apoth	Weight
YD	Yards	Length

Table D-0-2: UofM for Base Units

Appendix E: Intended Use Code Mapping: FDA Description to CBP Appendix R Definition

Code	FDA Commodity	FDA Description	CBP Appendix R Name	CBP Appendix R Definition
015.000	**FOO**	For Research Use as an Animal Food	For Research Use as an Animal Food	An animal food product intended for research in its present form, after processing, or as a food ingredient. Examples include feed ingredients such as experimental grain mixtures and supplements. Excludes veterinary drugs and vaccines that may be added to feed, animal food for commercial sale, and food for human consumption
080.000	**BIO**	CBER-regulated Final Product (includes licensed biological products, drugs or devices); ready for use	For Human Medical Use as a Non-Food Product under Controlled Distribution	A product or material distributed, with or without repackaging, by authorized medical or public health officials and intended for use in the medical treatment of humans. Examples include prescription drugs and biological products such as vaccines. Excludes human and animal food products, live plants and animals, chemicals for non-medicinal use, medical devices, and medical products distributed in the general public "over-the-counter" supply chain.
080.012	**DRU**	Prescription health or medical product for human use that is the subject of an approved new drug application, abbreviated new drug application, or biologics license application	Prescription health product subject to an approved application (FDA)	Prescription health or medical product that is subject to an approved human drug application. NOTE: This sub code is only for use with the Food and Drug Administration (FDA).
081.001	**DEV**	• Standard import of a foreign-manufactured device, accessories, or components regulated as a finished device • Import of refurbished device	Import of a device, accessory or component (regulated as a finished Medical Device) in-tended to be used as a finished medical device	Import of a device, accessory or component (regulated as a finished Medical Device) in-tended to be used as a finished medical device Import of a device, accessory or component intended to be used as a finished medical device. Examples include imports of gauze pads, humidifiers, or examination gloves

Code	FDA Commodity	FDA Description	CBP Appendix R Name	CBP Appendix R Definition
		• Import of a reprocessed device		
081.002	**DEV**	Import of a foreign-manufactured device for domestic refurbishing	Medical Device intended for domestic refurbishing	Intended to be processed to ensure safety and effectiveness without changing the performance or intended use as listed in the product's original registration
081.003	**DEV**	For Human Medical Use as Medical Device– domestically manufactured device that is part of a medical device convenience kit	Domestically-manufactured Medical Device intended for use as part of a medical de-vice convenience kit	Examples: US-Manufactured Devices that are and part of a First Aid Kits or Surgical Trays.
081.004	**DEV**	A foreign-manufactured device that is Part of a medical device convenience kit	Foreign-manufactured Medical Device intended for use as part of a medical device convenience kit	Examples: Foreign-manufactured devices that are part of First Aid Kits or Surgical Trays.
081.005	**DEV**	Importation of a device constituent part (finished device) for use in a medical product regulated under a drug (CDER) application type (e.g., for use in an NDA/ANDA/BLA drug-device combination product	Medical Device constituent part to be used in a device-drug combination product	Finished device to be used in a device-drug combination product. Ex-ample: the counter device of a drug filled inhaler to administer a drug product.
081.006	**DEV**	Import of a medical device under enforcement discretion provisions per final guidance: http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm401996.pdf Import of a General Wellness Product per final guidance:	Medical Device imported for use under enforcement discretion	See Appendix R

Code	FDA Commodity	FDA Description	CBP Appendix R Name	CBP Appendix R Definition
		https://www.fda.gov/regulatory-information/search-fda-guidance-documents/general-wellness-policy-low-risk-devices Applicable product codes for CBP business rule: 80O - - UG; 86N - - FF 86N - - FG; 80N - - XQ 90L - - MB; 90L - - MD 80P- -WC for General Wellness Products		
081.007	**DEV**	Component for further manufacturing into a finished medical device	Components for further manufacturing into a finished medical device.	Parts intended for use in the commercial assembly or further manufacturing of a Medical Device. Includes software components such as microcircuits and microprocessors, or parts to be assembled into a finished device such as an X-Ray machine.
081.008	**DEV**	Importation of a device component for use in a medical product regulated under a drug (CDER) application type (e.g., for use in an NDA/ANDA/BLA drug-device combination product).	Importation of a device component for use in a device-drug combination product.	Unfinished device to be used in a device-drug combination product. Example: the plunger of a syringe that will become a medical device, then filled with a drug and marketed as a filled syringe to administer a drug product
082.000	**BIO**	Human Cells, tissues, and cellular and tissue based products (HCT/Ps) for implant, transplant, infusion, or transfer into a human recipient	For Human Medical Use as a Transplanted Organ, Tissue, or Fluid	A human organ, tissue, or body fluid imported for immediate use by authorized medical officials in the medical treatment of humans. Examples include transplanted livers, hearts, bone marrow, musculo-

Code	FDA Commodity	FDA Description	CBP Appendix R Name	CBP Appendix R Definition
				skeletal tissue (bone, tendons), blood, and plasma. Excludes all plant and animal material.
085.000	**RAD**	For Veterinary Medical Use as a Non-Food Product under Controlled Distribution	For Veterinary Medical Use as a Non-Food Product	A product or material distributed, with or without repackaging, for use in the medical treatment of animals. Examples include veterinary medical devices, prescription drugs and vaccines. Excludes animal and human food products, live plants and animals, bulk chemicals, and veterinary products distributed in the general public "over-the-counter" supply chain.
	VME	For Vertinary Medical Use as a Non-Food Product		
085.003	**VME**	Drug subject of a new animal drug application, conditionally approved application, or Index listing	Finished Animal Drug product subject of an approved application (FDA)	Prescription health or medical product that is used for veterinary purposes subject to a new animal drug. NOTE: This sub code is only for use with the Food and Drug Administration (FDA).
090.000	**RAD**	For Military Use as a Non- Food Product	For Military Use as a Non-Food Product	A product intended for use by military organizations in the conduct of warfare or homeland protection. Examples include weapons, ammunition, and military uniforms. Excludes human and animal food products, live plants and animals, medical devices, and products intended for distribution in the general public supply chain.
100.000	**BIO**	Importation for Personal Use	For Personal Use as a Non-Food Product	A living or non-living animal, plant, organism, product, drug, or material intended for private, noncommercial use, including products purchased for personal use through Internet commerce. Includes Medical Devices imported in limited quantities intended for the use of the person importing the device. For example, corrective glasses or personal dialysis machines. Other examples include consumer goods and drugs for personal use, animals for use as pets, plants for home gardens, or hunting trophy
	DRU	Importation for Personal Use		
	DEV	For Personal Use as a Non-Food Product – for personal use as a medical device		
	VME	Importation for Personal Use		
	RAD	For Personal Use as a Non- Food Product		

Code	FDA Commodity	FDA Description	CBP Appendix R Name	CBP Appendix R Definition
	COS	For Personal Use as a Non-Food Product		animals for private display. Excludes human and animal food products, animals for breeding, and products intended for distribution in the general public supply chain.
110.000	**BIO**	Import of biological drug or device for trade show	For Public Exhibition or Display as a Non-Food Product	A living or non-living animal, product, or material intended for use in a public competitive or non-competitive event. Examples include zoo animals, flowering plants for flower shows, racing cars, fireworks, and race horses. Excludes human and animal food products and products intended for distribution in the general public supply chain.
	DEV	For Public Exhibition or Display as a Non-Food Product Includes import of device for trade show		
	TOB	For Public Exhibition or Display as a Non-Food Product		
	RAD	For Public Exhibition or Display as a Non-Food Product		
	COS	For Public Exhibition or Display as a Non-Food Product		
	DRU	For public exhibition or display of finished drug products, inactive ingredients, packing components or container closure systems for use with a pharmaceutical product. Excludes active pharmaceutical ingredients, and human drug products intended for distribution in the general public supply chain.		
120.000	**VME**	For Public Safety Use as a Non-Food Product	For Public Safety Use as a Non-Food Product	A product intended for use by police or fire organizations in protecting and providing for the public's safety. Examples include weapons, ammunition, forensics materials, fire-fighting equipment, and uniforms. Excludes human and animal food products, live plants and animals, medical devices, products intended for military use, and products intended for distribution in the general public supply chain.

Code	FDA Commodity	FDA Description	CBP Appendix R Name	CBP Appendix R Definition
130.000	**DRU**	For Consumer Use as a Non- Food Product – Over the Counter (OTC)	For Consumer Use as a Non-Food Product	A product or material ultimately intended in its present form, with or without repackaging, for distribution to consumers in the general supply chain. Examples include finished goods such as clothing, toys, furniture, electronic products, chemical substances or mixtures such as refined gasoline, cut flowers, over-the-counter medicines, dietary supplements, and live plants and animals. Excludes human or animal food products, raw materials for processing, and medical devices.
	RAD	For Consumer Use as a Non- Food Product		
	TOB	For Consumer Use as a Non-Food Product		
	COS	For Consumer Use as a Non-Food Product		
130.029	**CCW**	Chemical Substance for use in a food additive	Chemical substance for use in a food additive	Chemical substance for use in a food additive
130.033	**DRU**	Inactive ingredients and intermediates for use in a pharmaceutical product (PHN only).	Chemical substance for use in a pharmaceutical product	Chemical substance for use in a pharmaceutical product
130.037	**TOB**	For re-packaging and re-labelling**	Packaged tobacco for re-packaging and re-labelling	Tobacco for repackaging or changing the container, wrapper, or labeling in furtherance of the distribution of the product from the original place of manufacture to the person who makes final delivery or sale to the ultimate consumer or user. Examples of reasons for repackaging include packages soiled, damaged, or otherwise in a condition making the product unsalable
140.000	**BIO**	Standard import of a biological drug or device for non-commercial distribution in government and non-government organization support program	For Charitable Organization Use as Non-Food Product	A product or material intended for non-commercial distribution in government or non-govern-ment organization support programs. Examples include products distributed in time of natural disaster to improve the living conditions of targeted recipients and live service animals for search and rescue. Excludes human and animal food products.
	DEV	For Charitable Organization Use as a Non-Food Product		
	RAD	For Charitable Organization Use as Non-Food Product		

Code	FDA Commodity	FDA Description	CBP Appendix R Name	CBP Appendix R Definition
	TOB	For Charitable Organization Use as Non-Food Product		
150.000	**RAD**	For Commercial Processing as a Non-Food Product	For Commercial Processing as a Non-Food Product	A product or material intended for use in a process that changes the form or chemical composition of the product. Examples include raw materials such as crude oil, unrefined ore and rough timber and ingredients or components for further processing into finished products. Excludes ingredients or components for human or animal food products, pharmaceutical products, and medical devices.
	TOB	for commercial process as non-food		
	COS	For Commercial Processing as a Non-Food Product		
150.007	**BIO**	Bulk Drug Substance or CBER product for processing into a pharmaceutical product.	For processing into a pharmaceutical product	For processing into a pharmaceutical product, excludes device constituent parts
	DRU	Active Pharmaceutical Ingredient / Bulk Drug Substance for processing into a pharmaceutical product		
150.013	**DRU**	Active Pharmaceutical Ingredient / Bulk Drug Substance to be used for Pharmacy Compounding	For Pharmacy Compounding	Active Pharmaceutical Ingredient to be used in a pharmacy compounding.
	VME	Active Pharmaceutical Ingredient / Bulk Drug Substance to be used for Pharmacy Compounding		
150.017	**DRU**	Importation of a drug component (API) for use in a medical product regulated under a device (CDRH) application type (e.g., for use in a PMA/510(k) drug-device combination product)	Importation of a drug component for use in a drug-device combination product	Active Pharmaceutical Ingredient to be further processed before being added to a finished device to administer the drug product

Code	FDA Commodity	FDA Description	CBP Appendix R Name	CBP Appendix R Definition
150.020	**VME**	Active Pharmaceutical Ingredient / Bulk Drug Substance used to be further manufactured into a finished drug subject of a new animal drug application, conditionally approved application, or Index listing	Active Pharmaceutical Ingredient (API)/bulk animal drug substance for use in a finished animal drug product subject of an approved application (FDA)	An API used to be further manufactured into a finished animal drug product subject to an approved application. NOTE: This sub code is only for use with the Food and Drug Administration (FDA).
155.000	**BIO**	CBER product for further manufacture of a licensed biological product under a short supply agreement (21 CFR 601.22)	For Commercial Assembly as a Non-Food Product	A product or material intended for use as a component part to create a finished product. Examples include automotive and industrial parts for assembly, and disassembled all-terrain vehicles. Excludes plants and animals, bulk chemicals, raw materials for processing, components for human or animal food products, components for medical devices, and products for assembly by consumers.
	TOB	For Commercial Assembly as a Non-Food Product to be consumed		
	RAD	For Commercial Assembly as a Non-Food Product		
	DRU	Packaging component or a container closure system for use in a pharmaceutical product (PHN only). Excludes finished drugs for repacking and relabeling, active pharmaceutical ingredient / bulk drug substance, inactive ingredients, and intermediates.		
155.009	**DRU**	Importation of a drug constituent part (drug product) for use in a medical product regulated under a device (CDRH) application type (e.g., for use in a PMA/510(k) drug-device combination product)	Importation of a drug constituent part for use in a drug-device combination product.	Finished drug product to be used with a device to administer the drug product. Example: Finished Drug Product (Heparin) to be applied to a drug eluding stent
170.000	**BIO**	For reconditioning or repair of a Non-Food. Product	For Repair of a Non-Food Product	A product or material to be repaired or enhanced in order to restore it to a more useful

Code	FDA Commodity	FDA Description	CBP Appendix R Name	CBP Appendix R Definition
	DEV	For Repair of a Non-Food Product Repair of medical device and re-exportation		condition and for which there is no change in ownership. Examples include specialty machinery that is refurbished and returned to original owner. Excludes human and animal food products, medical devices, and products intended for distribution in the general public supply chain upon repair
	RAD	For Repair of a Non-Food Product		
180.000	**BIO**	Import of biologic for non-clinical research use only, bench testing, etc. These entries could be disclaimed if the HTS code allows it.	For Research and Development as a Non-Food Product	A product or material intended for private, educational, or government use to advance scientific knowledge for public benefit or to improve commercial products or services and create competitive advantage. Examples include products for commercial research and development, plant or animal specimens for scientific study, and human and animal drugs used in investigational stages of drug development. Excludes human and animal food products, and products intended for distribution in the general public supply chain.
	RAD	For Research and Development as a Non-Food Product		
	TOB	For Research and Development as a non-Food Product – All other Uses		
	DRU	For research and development of packaging components, containers closure systems, inactive pharmaceutical ingredients, and intermediates (PHN only).		
	COS	For Research and Development as a Non-Food Product		
180.001	**TOB**	For Research and Development as a non-Food Product - Animal or plant for biomedical research	Animal or plant for biomedical research	Animal or plant for biomedical research (FWS Code M)
180.009	**BIO**	Biological or chemical for research and development into a pharmaceutical product – Investigational New Drugs (IND); clinical trials or other human/animal use	Chemical for research and development in a pharmaceutical product	For research and development of a pharmaceutical product
	DRU	Chemical for research and development of a pharmaceutical		

Code	FDA Commodity	FDA Description	CBP Appendix R Name	CBP Appendix R Definition
		product – subject of an Investigational New Drug application (IND), including Placebos		
	VME	For research and development in a pharmaceutical product – clinical investigations in animals (INAD)		
180.010	**DEV**	For Research and Development as a Non-Food Product - For research and development as a medical device Import of research or investigational use in vitro diagnostic device	Chemical for research and development in a medical device	For research and development of a medical device
180.014	**DEV**	For Research and Development as a Non-Food Product – for bench testing or nonclinical research use • Import of a device for non-clinical use/bench testing Import of device sample for customer evaluation	For bench testing and non-clinical research use	For bench testing and non-clinical research use
180.015	**DEV**	For Research and Development as a Non-Food Product – import of a medical device for clinical investigational use	For clinical investigational use	For clinical research use as a medical device
180.016	**BIO**	CBER Product Sample for testing or lot release	For testing or lot release	For processing samples submitted to the Food and Drug Administration's Center for Biologics Evaluation and Research for testing and lot release

Code	FDA Commodity	FDA Description	CBP Appendix R Name	CBP Appendix R Definition
180.017	**DRU**	Chemical for research and development of a pharmaceutical product – laboratory testing only, no human/animal use	Chemicals for research and development in a pharmaceutical product – laboratory testing only; no human or animal use	Chemicals for research and development in a pharmaceutical product – laboratory testing only; no human or animal use
180.018	**DRU**	Chemical for research and development of a pharmaceutical product – investigational use in animals	For research and development in a pharmaceutical product – investigational use on animals	For research and development – investigational use on animals
	VME	For research and development in a pharmaceutical product – for tests in-vitro or in laboratory research animals.		
180.026	**DRU**	Finished drug or API intended for use in an in vivo bioequivalence or bioavailability study in humans that qualifies under 21 CFR 320.31 for an exemption from the Part 312 requirements; or, finished drug intended for use in clinical investigation in humans that qualifies for an exemption from Part 312 requirements	Finished drug or API intended for use in a bioequivalence or bioavailability study in humans.	Finished drug or API intended for use in a bioequivalence or bioavailability study in humans that qualifies under 21 CFR 320.31(d) for an exemption from the Part 312 requirements. NOTE: This sub code is only for use with the Food and Drug Administration (FDA).
210.000	**FOO**	Personal Importation	For Personal Use as Human Food	A human food product intended for personal use in its present form. Examples include food products imported in limited quantities by travelers for personal consumption or as a gift. Excludes food products intended for distribution in the general public supply chain
260.000	**FOO**	For Research Use as Human Food	For Research Use as Human Food	A human food product intended for commercial food research in its present form, after further processing, or as a food ingredient. Examples include food products for use in test

Code	FDA Commodity	FDA Description	CBP Appendix R Name	CBP Appendix R Definition
				kitchens and controlled focus group use. Excludes food products intended for commercial purchase or distribution in the general public supply chain
920.000	**BIO**	US Goods Returned	For Return to the United States (US Goods Returned)	Articles of the United States that are exported and returned without having been advanced in value or improved in condition by any manufacturing process or other means while abroad, as per 19 CFR 10.1 (a).
	DRU	US Goods Returned		
	VME	US Goods Returned		
	COS	US Goods Returned		
920.001	**DEV**	Import of a device that is US goods returned for refund/overstock (to manufacturer) • Refund/overstock • Bench Testing • Corrective Action Prevention Action (CAPA) Plan Investigation Recall	For refund/overstock to manufacturer	A medical device manufactured in the US and previously exported; must be returning to the original manufacturer or parent company
920.002	**DEV**	Import of a device that is US goods returned for sale to a third party	To be sold by party other than original manufacturer.	A medical device manufactured in the US and previously exported. Imported product must be labeled for US consumption and adhere to applicable regulations. To be sold by party other than original manufacturer.
940.000	**BIO**	Importation of a drug (including a biological product) or device for compassionate use/emergency use	For Compassionate/ Emergency Use of a Non-Food Product	To protect the life or physical well-being of a subject in an emergency when there is no time to use existing procedures to get approval for use. Example includes emergency use of an unapproved Medical Device under 21 CFR 812.35(a).
	DEV	Import of a Compassionate Use/Emergency Use Device		

Code	FDA Commodity	FDA Description	CBP Appendix R Name	CBP Appendix R Definition
950.001	**DEV**	Import of a single-use device for domestic reprocessing	Import of a single-use medical device for domestic reprocessing	Non-violative product or material intended for reprocessing (cleaning, sterilization, etc.) which was not originally intended to be used by more than one consumer imported for re-processing. Reprocessing includes steps performed to make a contaminated single-use device patient ready. Steps may include cleaning, functional testing, repackaging, relabeling, disinfection, and sterilization.
950.002	**DEV**	Import of a multi-use device for domestic reprocessing	Import of a multi-use medical device for domestic reprocessing	Non-violative product or material intended for reprocessing (cleaning, sterilization, etc.) which was originally intended to be used by more than one consumer. Reprocessing includes steps performed to make a contaminated reusable device patient ready. Steps may include cleaning, functional testing, repackaging, relabeling, disinfection, and sterilization.
970.000	**BIO**	CBER-Import for Export (IFE) under the import for export provisions 801(d) (3), & 801(d) (4) of the FD&C Act.	For Export	A product imported for export that is not intended for sale in the US market.
	DRU	Import for Export		
	DEV	Import for Export • Import of a medical device for further processing and re-exportation Import of medical device or accessory for further manufacturing into an export only medical device		
	RAD	For Import For Export		
	VME	Import for Export		
	COS	Import for Export		
	FOO	Import for Export		

Code	FDA Commodity	FDA Description	CBP Appendix R Name	CBP Appendix R Definition
970.001	**DEV**	Import for Export Import of a medical device component for further manufacturing into an export only medical device	For further manufacturing into an export-only product	Example is a medical device component for further processing into an export-only medical device.
980.000	**DRU**	For Other Use: (APIs or Finished Drugs not elsewhere classified)	For Other Use	A product or material for which the intended use is known but not defined by an intended use base code value.
	VME	For Other Use: (APIs or Finished Drugs not elsewhere classified)		
	RAD	For Other Use		
	COS	For Other Use		
	FOO	For Other Use		

Appendix F: Change Log History

Date	Version No.	Commodity	Description
11/9/2020	**2.5.2**	**DRU**	Added notes to chapters 4, 7, and 7.2 – port authorized by FDA for processing code 804. Added note to subchapter 7.11 – PLR is not allowed for processing code 804.
10/22/2020	**2.5.2**	**All**	Minor updates: Structured bookmarks; Fixed BIO PG01 note 1 hyperlinking; Renumbered subchapters 12.14-12.17; Dated change log
10/7/2020	**2.5.2**	**All**	Added status (Mandatory, Conditional, Optional) and repeatability information below the header for each PG record. PG01: Clarified PGA line number description PG01: Added a Note regarding use of "UNK" as an Intended Use Code for all applicable commodities PG02: Corrected "Class code" in the product code structure table to alphanumeric to match the product code builder PG23: Added a note regarding use of "UNK" as an Intended Use Code for applicable commodities where AoC information for IUCs are provided Appendix E: New. Added to provide a mapping of FDA IUC descriptions to CBP , Appendix R - Intended Use Codes for ACE IUC descriptions. Appendix F: New. Contains Change Log History from prior versions
10/7/2020	**2.5.2**	**Biologics**	Deleted the following from the Biologics Commodity Elements and Values page **Note** The Government Agency Processing Code "BRD", the corresponding Intended Use Code, and Affirmation of Compliance Codes (PM# and IDE) have been removed from the above Biologics Commodity Data Elements and Values section. These devices will be handled using the Medical Device Commodity Data Elements and Values in the ACE/ITDS environment. PG30: Updated PG30 table Data Elements labels to match CBP ACE CATAIR PGA Message Set document: 'Firms Code' to 'Inspection or Arrival Location Codes' and 'FTZ Location' to 'Inspection or Arrival Location'. Clarified description for clarity. PG30: Edits to Note 2, to provide additional clarity for Entry Type 21
10/7/2020	**2.5.2**	**Cosmetics**	See above under Commodity = ALL No other changes specific to Cosmetics
10/7/2020	**2.5.2**	**Drugs**	Section 4: Added Industry Code 58 & Processing Code and Commodity Subtype for Section 804 Importation program Drug Commodity Data Elements & Values main page: Added updates for Processing Code and Commodity Subtype for Section 804 Importation Program PG01: Added Note 5 regarding use of "UNK" as Intended Use Code PG01: Added Processing Code 804 for Section 804 Importation Program PG02: Added Industry Code 58 to Government Agency Processing Code logic & logic for Section 804 Importation program updates PG20: Added Note for Section 804 Importation program PG23: Added new AoC FSR and PRN and updated requirements for IUC 080.012 for Section 804 Importation program PG25: Added Note for Section 804 Importation program PG25: Corrected syntax for 'Lot Number Qualifier' to 1N, to match input value of "1" PG26: Added Note for Section 804 Importation program

Date	Version No.	Commodity	Description
			PG30: Updated PG30 table Data Elements labels to match CBP ACE CATAIR PGA Message Set document: 'Firms Code' to 'Inspection or Arrival Location Codes' and 'FTZ Location' to 'Inspection or Arrival Location'. Clarified description for clarity. PG30: Edits to Note 2, to provide additional clarity for Entry Type 21
10/7/2020	**2.5.2**	**Food: Stand-alone Prior Notice**	Section 4: Updates (removed Industry Code 47), to align with the FDA Product Code Builder PG19: Updates to descriptions and notes to improve clarity. PG23: Updates to descriptions and notes to improve clarity
10/7/2020	**2.5.2**	**Food: Combined Entry**	PG19: Updates to descriptions and notes to improve clarity. PG20: Updates to clarify FSV Country = US and State can only be 50 US States, DC & PR PG23: Updates to descriptions and notes to improve clarity PG23: Removed reference to FSV compliance date PG28: Updated to indicate that Container Dimensions or Container Volume must be provided; Measurement Type should reflect what is filed in the scheduled process
a10/7/2020	**2.5.2**	**Non-PN Food or PN Requirements Previously Met**	PG20: Updates to clarify FSV Country = US and State can only be 50 US States, DC & PR PG23: Removed reference to FSV compliance date PG28: Updated to indicate that Container Dimensions or Container Volume must be provided; Measurement Type should reflect what is filed in the scheduled process PG30: Updated PG30 table Data Elements labels to match CBP ACE CATAIR PGA Message Set document: 'Firms Code' to 'Inspection or Arrival Location Codes' and 'FTZ Location' to 'Inspection or Arrival Location'. Clarified description for clarity. PG30: Edits to Note 2, to provide additional clarity for Entry Type 21
10/7/2020	**2.5.2**	**Medical Devices**	PG30: Updated PG30 table Data Elements labels to match CBP ACE CATAIR PGA Message Set document: 'Firms Code' to 'Inspection or Arrival Location Codes' and 'FTZ Location' to 'Inspection or Arrival Location'. Clarified description for clarity. PG30: Edits to Note 2, to provide additional clarity for Entry Type 21
10/7/2020	**2.5.2**	**Tobacco**	PG07: Clarification that Trade/Brand name includes product Brand and Sub-brand name PG10: included "flavor and strength of nicotine" as part of commodity characteristics that may be submitted. PG23: Updates to descriptions and notes to improve clarity PG30: Updated PG30 table Data Elements labels to match CBP ACE CATAIR PGA Message Set document: 'Firms Code' to 'Inspection or Arrival Location Codes' and 'FTZ Location' to 'Inspection or Arrival Location'. Clarified description for clarity. PG30: Edits to Note 2, to provide additional clarity for Entry Type 21
10/7/2020	**2.5.2**	**Radiation Emitting Products**	PG30: Updated PG30 table Data Elements labels to match CBP ACE CATAIR PGA Message Set document: 'Firms Code' to 'Inspection or Arrival Location

Date	Version No.	Commodity	Description
			Codes' and 'FTZ Location' to 'Inspection or Arrival Location'. Clarified description for clarity. PG30: Edits to Note 2, to provide additional clarity for Entry Type 21
10/7/2020	**2.5.2**	**Animal Drugs and Devices**	PG30: Updated PG30 table Data Elements labels to match CBP ACE CATAIR PGA Message Set document: 'Firms Code' to 'Inspection or Arrival Location Codes' and 'FTZ Location' to 'Inspection or Arrival Location'. Clarified description for clarity. PG30: Edits to Note 2, to provide additional clarity for Entry Type 21
4/10/2018	**2.5.1**	**All**	Clarified the mapping between the Industry Codes and the various Government Agency Program Codes; OI record is removed; PG06: Clarified that Country of Refusal (294) may be used to indicate that a country has previously refused the line items; PG19: FEI can be between 1 and 10 characters long; PG23: Clarified that the AoC Qualifier cannot exceed 30 characters (30X); PG23: Clarified that any AoC code can be entered only once for the same FDA line unless if the AoC code is 'RNO' for Prior Notice; PG23: Clarified that for the 'indicator only' AoC codes, the corresponding Affirmation of Compliance Qualifier field should be left blank; PG24: Clarified that only one PG24 is allowed per FDA line and only Remarks Type Code GEN is accepted by FDA; additionally, PG24 is associated only to its preceding PG02; PG26: Clarified that Packaging Qualifier, Quantity and Unit of Measure are conditional – if Quantity is entered then the other two data elements are required – even when PG26 record is Optional; PG30: All chapters have been updated to reflect that Port of Entry is no longer collected in PG30. PG30 will be used to collect Anticipated Arrival Date and Time, and, for Prior Notice, the Anticipated Arrival Port. FTZ information is also sent through PG30 if applicable. All language in this record has been updated to reflect the collection of Arrival Information; Updated the presentation of the Unit of Measurements tables into a consistent style/font across all the chapters and the Appendix D; PG60: Corrected the Length/Class Column of 'Additional Information" data element due to typo in the CATAIR;
4/10/2018	**2.5.1**	**Biologics**	PG01: Edited Note numbering; PG04: Clarified instructions for submitting the data elements if choosing to submit the optional record; PG05: Removed this record from the chapter; PG19: Edited Note numbering; PG23: Edited Note numbering; PG23 AoC Codes table is edited to add 'BLD' to scenario #1 and to correct 'BAC' to 'VAC' in Scenario #19; BER and HCTER public FEI links are added to PG19;

Date	Version No.	Commodity	Description
			PG25: Removed Production Start/End date of the Lot, Degree Type, Negative Number, Actual Temperature, Location of Temperature Recording and Unit Value; PG30: Edited Note numbering.
4/10/2018	**2.5.1**	**Cosmetics**	PG23: Removed IFE from AoC list; PG25: Removed Production Start/End date of the Lot, Degree Type, Negative Number, Actual Temperature, Location of Temperature Recording and Unit Value; PG26: Removed reference to package identifier, packaging method, package material and packaging filler; PG26: Edit Note numbering; PG26: Added Ingot (ING) as a container unit of measure listed in Appendix D; PG30: Edited Note numbering.
4/10/2018	**2.5.1**	**Drugs**	Removed industry codes '50' and '55' from the Commodities table on page 21; Clarified that the PG01: IUC is not required when the Government Agency Processing Code is PHN; PG01: Edited Note numbering. PG02: IF Government Agency Processing Code = PHN THEN Industry Code should be 55 or various other codes could apply; PG04: UoM for the Constituent Ingredient is free text; does not use the same codes in the Master UoM reference table; PG04: Clarified instructions for submitting the data elements if choosing to submit the optional record; PG19: Clarified that the filer can enter only the allowed entity roles codes for drugs. PG25: Added Note 1 to Production Start/End date of the Lot, Degree Type, Negative Number, Actual Temperature and Location of Temperature Recording; removed Unit Value; PG26: Edited Note numbering; PG26: Added Ingot (ING) as a container unit of measure listed in Appendix D; PG30: Edited Note numbering.
4/10/2018	**2.5.1**	**Food Commodity Stand-alone Prior Notice**	PG01: Edited Note numbering; PG02: Updated the product code logic for PN; PG14: Clarified the information to be submitted when the carrier is a POV; PG19: Edited note numbering. Clarified condition for each entity; PG21, removed the Note 2 that defined a format for the Individual's Name; PG21: Edited note numbering; PG26: Removed reference to package identifier, packaging method, package material and packaging filler;

Date	Version No.	Commodity	Description
			PG28: Removed note 1.
4/10/2018	**2.5.1**	**Food Commodity Combined Entry**	PG02: Updated the product code logic for PN; PG05: Removed this record from the chapter; PG14: Clarified the information to be submitted when the carrier is a POV; PG19: Edited note numbering. Clarified condition for each entity; PG21: Removed section notes; PG21: removed the Note 2 that defined a format for the Individual's Name; PG23: Corrected syntax for FCE; FCE is 5 digit numeric; PG23: AoC codes JIF and SIF syntax should both be 1-10N; PG23: New AoC code VQI added; the corresponding qualifier is the 5 digit Approved Application Number; not valid until planned implementation, Oct. 2018; PG25: Removed Production Start/End date of the Lot, Degree Type, Negative Number, Actual Temperature, Location of Temperature Recording and Unit Value.
4/10/2018	**2.5.1**	**Non-PN Food Commodity or PN Requirements Previously Met:**	PG02: For FOO/CCW, the Industry Code is '52' and the Class Code is 'A', 'B', 'E' or 'Y'; PG05: Removed this record from the chapter; PG14: Clarified that PN Confirmation number must be 12N; PG23: Corrected syntax for FCE; FCE is 5 digit numeric; PG23: AoC codes JIF and SIF syntax should both be 1-10N; PG23: New AoC code VQI added; the corresponding qualifier is the 5 digit Approved Application Number; not valid until planned implementation, Oct. 2018; PG25: Removed Production Start/End date of the Lot, Degree Type, Negative Number, Actual Temperature, Location of Temperature Recording and Unit Value.
4/10/2018	**2.5.1**	**Medical Devices**	Clarified instructions all devices (radiation emitting and non-radiation emitting) are filed under program code DEV. Added information regarding radiation emitting products so all medical device information is available in this chapter; PG01: Added information about general wellness products for IUC 081.006; PG01: Added a new Note - If IUC is 081.001, 081.002, or 081.004, then Manufacturer must be foreign; Manufacturer's country code in PG19 cannot be = US; PG19: Clarified that the Device Initial Importer (DII) must be in the US; PG19: Provide link to medical device registration and listing database to obtain FEI #; PG23: Provided additional guidance on import of general wellness products under the intended use code 081.006; PG23: The AoC codes 'DEV', 'DFE' and 'LST' are now conditional AoC codes for the Intended Use Code: 081.005;

Date	Version No.	Commodity	Description
			PG23: If IUC is 081.001, 081.002, or 081.004, then Manufacturer must be foreign; Manufacturer's country code in PG20 cannot be US.; PG23: Edited Note numbering. Added radiation emitting AoCs; PG25: Removed Production Start/End date of the Lot, Degree Type, Negative Number, Actual Temperature, Location of Temperature Recording and Unit Value; PG30: Edited Note numbering.
4/10/2018	**2.5.1**	**Tobacco**	PG25: Removed Production Start/End date of the Lot, Degree Type, Negative Number, Actual Temperature, Location of Temperature Recording and Unit Value; PG26: Expanded the values for valid FDA Packaging Container and Base Units of Measure. refer to CSMS # 18-000092; PG30: Edited Note numbering.
4/10/2018	**2.5.1**	**Radiation Emitting Products**	Provided clarification if radiation emitting products are medical devices, filers should refer to medical device section; PG01: Edited Note numbering; PG01: Added Note 4 to provide information regarding the use of IUC 980.000; PG25: Removed Production Start/End date of the Lot, Degree Type, Negative Number, Actual Temperature, Location of Temperature Recording and Unit Value; PG26: Removed reference to package identifier, packaging method, package material and packaging filler; PG26: Corrected microwave unit of measure example.
4/10/2018	**2.5.1**	**Animal Drugs and Devices**	PG01: Specify IUC is mandatory for ADR but optional for ADE (in Note 3); PG04: Clarified instructions for submitting the data elements if choosing to submit the optional record; 'PG07 is marked as optional since the only data field in it is optional; PG25: Removed Production Start/End date of the Lot, Degree Type, Negative Number, Actual Temperature, Location of Temperature Recording and Unit Value; PG26: Removed reference to package identifier, packaging method, package material and packaging filler; PG26: Added Ingot (ING) as a container unit of measure listed in Appendix D.
12/28/2016	**2.5**	**Stand-alone Prior Notice**	PG19: FD1 conditional requirement has been re-added (Refer to 11/30/2016 changelog entry);
		Animal Drugs and Devices	PG07: Modified the Record Identifier table title. Also, modified the "Trade Name/Brand Name" data element's status and description on the Record Identifier table;

Date	Version No.	Commodity	Description
12/9/2016	**2.5**	**All**	PG21: Added sentence “If provided, there should be only one PK per line,” to introductory text; Appendix D: Added CTR code with description of Cartridge to the FDA Unit of Measurement Codes list;
12/9/2016	**2.5**	**Drugs**	Change Log: Added 50 and 55 to the list that should have a valid value for Industry Code in the FDA product code;/2016
12/9/2016	**2.5**	**Animal Drugs and Devices**	Deleted 50 and 55 from VME – Animal Drug in the FDA Commodities, Commodity Sub-Types & Corresponding Industry Codes chart; Change Log: Animal Drugs and Devices PG02: Deleted duplicate PG02 change log entry; PG02: Added 67 to the list that should have a valid value for Industry Code in the FDA product code;
11/30/2016	**2.5**	**All**	Clarified the mapping among the Government Agency Program Codes, Government Agency Processing Codes and the corresponding Industry Codes in the Commodity Type list; PG06: Relaxed the requirement for the Country Code for the Country of Production be the same reported in PG19:PG20:MF; PG21: Clarified the mandatory and optional requirement for this record type; PG23: Affirmation of Compliance Qualifier changed from 30AN to 30X; PG25: this record is optional since the line value is not required; PG25: Removed the Note 1 pertaining to a CBP validation of values for all the FDA lines within an entry; PG26: this record is optional, except for Prior Notice and Radiation Emitting Products that are subject to 2877 performance standards; PG29: This record type is removed; PG30: Port of Arrival/Entry is now correctly named as Anticipated Port of Arrival/Entry; PG30: For entry type 21 coming from a Foreign Trade Zone, a PG30 record with an "F" (Foreign Trade Zone) code and FIRMS code for the FTZ location is required; PG55: Moved the notice “Not Supported by the FDA at this time” to the front of the page for better readability; PG00: Clarified the use of this record type;
11/30/2016	**2.5**	**Biologics**	Edited this chapter based on CBER feedback in FDA Supplemental Guide 2.5 CBER Revisions & Comments - 31 OCT 2016.docx and FDA Supplemental Guide Release 2.5 draft CBER comments 111816 with tracking.docx; PG02: Added the requirement that the Industry Code in the FDA product code should be 57; PG23: Edited Import Scenarios #10 and #12 to reflect the most recent comments from CBER;

Date	Version No.	Commodity	Description
11/30/2016	**2.5**	**Cosmetics**	PG02: Added the requirement that the Industry Code in the FDA product code should be 50 or 53;
11/30/2016	**2.5**	**Drugs**	PG01: The list of Intended Use Codes is adjusted per feedback from CDER; mapped the new IUCs to Form/Type of drugs; PG02: Added the requirement that the Industry Code in the FDA product code should be a valid value in 50, 55, 56, 60, 61, 62, 63, 64, 65, 66 or 54 and (Subclass code is ('D', 'E', 'F', 'G', 'I'); PG04: updated the new applicable IUCs to the rules; PG19: adjusted the optional entities per CDER feedback; PG23: updated the IUC list based on changes to PG01 above; re-wrote the table of mapping between the IUCs and AoCs; PG26: replaced the UoM table per feedback from CDER;
11/30/2016	**2.5**	**Food**	PG02: Clarified the PN validation criteria to include Industry Code = 52; PG02: added a check for industry code (52) when the program/processing codes are FOO/CCW; PG02: re-stated the PN validation logic based on input from DFDT and ORA; PG21: added back the optional entry of filer/broker's Fax# using an optional PG21 record; PG19: added emphasis (highlighted) that **only one** of MF/DFI/FDC is allowed for Prior Notice; PG19: The entity role code FD1 is not required for PN-only chapter; Renamed the 3rd Food chapter to correctly state the intent of this chapter: Non-PN Food Commodity OR PN Requirements Previously Met; PG21: The entity role code FD1 is not required for PN-only and PN-Combined-Entry chapters; it is required for FOO-CCW entries; PG19-PG20-PG21: Added the role code FSV (Foreign Supplier Verification Program) for non-PN; PG23: Added new AoC codes FSX and RNE to support the entity role code FSV for non-PN;
11/30/2016	**2.5**	**Medical Devices**	PG02: Added the requirement that the Industry Codes in the FDA product code should be between 73 and 92; PG19: Clarified the requirement for entering the entity Device Initial Importer (DII); PG23: The AoC code DDM is now conditional for the Intended Use Code 170.000; PG23: The AoC code ERR is allowed;
11/30/2016	**2.5**	**Tobacco**	PG02: Added the requirement that the Industry Code in the FDA product code should be 98;

Date	Version No.	Commodity	Description
			PG07: the brand name is not required if the processing code is INV; PG19: Submitter (TB) is now an allowed entity - it is no longer mandatory;
11/30/2016	**2.5**	**Radiation Emitting Products**	PG02: Added the requirement that the Industry Codes in the FDA product code should be between 94 and 97; PG23: The AoC codes ERR and IFE are allowed;
11/30/2016	**2.5**	**Animal Drug and Devices**	PG01: updated the list of Intended Use Codes based on feedback from CVM; PG02: Added the requirement that the Industry Code in the FDA product code should be 68 for VME/ADE; added the requirement that the Industry Code in the FDA product code should be a valid value in 56, 60, 61, 62, 63, 64, 65, 66, 67 or 54 and (Subclass code is ('N', 'R') for VME/ADR; PG23: updated the IUC list based on changes to PG01 above; re-wrote the table of mapping between the IUCs and AoCs; PG23: removed the AoC code IFE from the VME chapter; PG26: deleted the UoM table for this chapter; Appendix D has the valid UoM codes; PG27: deleted this record to bring this chapter in sync, with DRU chapter;
3/31/2016	**2.4.1**	**All**	AoC Qualifier is 30 characters long; Sum of all PGA Line Value in PG25 cannot exceed CBP's entry value – this business rule is validated by CBP; In case of multiple PG25 records to enter different lot numbers, the line value must be entered in only the first PG25 record; Clarified that Quantity in PG26 is always entered with 2 implied decimals; Clarified the description of the Packaging Qualifier for PG26; Introduced the use of the new PG Message Record PG60 and the use of PG07, PG19, PG20 and PG21 records is affected by PG60; Deleted the Note for PG24 to include the effect of PG60 and removed PG24: NAM construct; Synchronized the Intended Use Codes to the Appendix R -DRAFT 2015-12-01H.docx; PG30: Inspection or Arrival Location Code is set to '2' and the valid port code is entered in the PG30: Arrival Location; The Entity role code UC is interpreted to be synonymous to DP for Prior Notice – Combined Entry; for all other chapters, text for this interpretation is removed; The disclaimer code 'B' is removed; PG06: Country Code should match the Country Code in PG19-PG20 record set depending on PG06: Source Type Code and PG19: Entity Role Code; Entity role code 'LG' is removed from the applicable roles list for all non-PN chapters; LG is used only for PN purposes; AoC codes CCN, UFC and HTS are removed;

Date	Version No.	Commodity	Description
			PG01: record layout changed to reflect CBP inclusion of 'Correction Indicator' in position 79; Clarified the title of PG30 to include Port of Arrival / Entry; adjusted the field names in PG30 accordingly; added the port of Entry data requirements to PG30 across all chapters; All the other applicable entity roles for PG19, except PK, are removed from all chapters; Removed all references to Fax Number for a POC in PG21;
3/31/2016	**2.4.1**	**Biologics**	Removed the requirement for lot# in PG25; Removed PG05 / PG07 notes not needed anymore; Added clarification to Note1 for PG07 regarding HCT products; Clarified that FEI is preferred over DUNS in PG19 similar to CDRH rules; Replaced the IUC codes table for PG01 based on CBER feedback dated 2/23/2016; Replaced the AoC codes table for PG23 based on CBER feedback dated 2/18/2016; Replaced the Import Scenario table for PG23 based on CBER feedback dated 2/23/2016; PG04 is optional;
3/31/2016	**2.4.1**	**Cosmetics**	Clarified the text for Government Agency Processing Code in PG01; Only 39 is allowed as a valid source type code in PG06; Country of Source is not applicable to PG06;
3/31/2016	**2.4.1**	**Drugs**	Removed Appendix B and Appendix C and re-named the rest of the appendices; this affects the references to appendices in other chapters as well Clarified the description to include multiple GD records in PG19 for multiple API producers; GD is optional; Expanded the definition of the processing code 'PHN' to include Pharmaceutical Necessities, Inactive Pharmaceutical Ingredients and Excipients; Clarified the use of PG04 for APIs and deleted the 2nd example for API; clarified the rules in Note2 and Note3 for PG04; Added UoM CAP (Capsules) and CTR (Cartridge) to PG26/PG29 and Appendix D; Restated the rule when PG23 will not be required; added notes to the AoC code 'DLS' in the case of a Private Label Distributor (PLD); Added syntax to the AoC code LST in PG23; Included the missing Intended Use Codes in the AoC code rules due to changes in CBP's Schedule R; Added a new editing rule for the PIC in the FDA product code based on Government Agency Processing Code (in PG01) and Intended Use Code (in PG01); Added capsules (CAP) and cartridges(CTR) as unit of measurement values in PG26/PG29

Date	Version No.	Commodity	Description
3/31/2016	**2.4.1**	**Prior Notice (PN)**	Program Code CCW is removed from the combined entry chapter; PG28 is edited to allow for the SCAC to be submitted; PE10: Ref. Qual. Code changed from BIL to BOL based on recent CBP changes; Clarified the use of Source Type Code in PG06; Clarified the rule for PG13: LPCO; Clarified the choice of Grower or Consolidator in PG19; Added the AoC code LFR for Location of Foods (Holding Facility); Govt. Agency Processing Code 'CCW' is not applicable to the Combined Entry chapter; Entity Role Code 'LG' was included in both the PN Stand-alone chapter and the Combined Entry chapter but with inconsistent condition; corrected this inconsistency to use the same description / condition in both these chapters; AoC code VFT is required when it exists. 'Does Not Exist' can be entered if Trip # is not known; AoC Code FME should be followed by a 1-letter code based on the newly named Appendix B; AoC Code RNO in PG23 can be repeated for multiple rail car numbers; if rail car number is not known, then 'Does Not Exist' can be entered; PG27 record is repeatable with 3 container numbers per record;
3/31/2016	**2.4.1**	**Food (non-PN)**	Clarified AoC code FCE can be from 5 to 10 digits; Clarified PNC# should be a 12 digit number; Clarified the use of Source Type Code in PG06; Clarified the format of AoC Code SID in PG23 as CCYYMMDDnnn for 11 digits; AoC Cods FCE and SID are required for LACF and AF; additionally, either the AoC code VOL or PG28 is required; this clarifies the use of AoC Codes SID, FCE and VOL to be in line with the most recent NPRM;
3/31/2016	**2.4.1**	**Medical Devices**	Added BD+6N to AoC code PM# in PG23 based on CBER feedback; Source Type Code of 30 is for components and 39 for finished devices in PG06; Brand Name is conditional for PG07 and added the condition in a note;
3/31/2016	**2.4.1**	**Tobacco**	Added 'PCS' as a valid Unit of Measure base unit; made PGA Unit Value optional; All AoC Codes are optional in PG23 based on CTP feedback; Correction: FEI is not required in PG19;
3/31/2016	**2.4.1**	**Radiation Emitting Products**	Clarified the rules for entering the AoC codes ACC and ANC in PG23; Brand Name is conditional for PG07 and added the condition in a note; Clarified AoC Codes 'ACC' and 'ANC': added the syntax and format; required if RB1 is entered;

Date	Version No.	Commodity	Description
			Clarified AoC Code RB1: required if either ACC or ANC is entered; no qualifier Added an optional AoC Code 'MDL' where the filer can enter the model number of the product; Added an optional AoC Code 'CCM' for Certified Component Manufacturer; Clarified that PG04 is not required for DRU/PHN but is optional for other processing codes within DRU;
3/31/2016	**2.4.1**	**Animal Drugs & Devices**	PG04 is not required for VME/ADE; it can be entered for VME/ADR; Clarified the description to include multiple GD records in PG19 for multiple API producers; GD is optional; AoC codes are conditional if the Government Agency Program Code = VME and Government Agency Processing Code = ADR; there are currently no AoC codes for ADE; AoC Code REG is conditional; AoC Code NDC is optional; AoC Code DLS is optional; AoC Code VFL is optional; AoC Code VFD (=Veterinary Feed Directive) is optional; Added UoM CAP (Capsules) and CTR (Cartridge) to PG26/PG29 and Appendix D;
10/29/2015	**2.4**	**All**	Corrected the footnotes in PG19 for Prior Notice chapters; clarified the percentage of constituent element in PG04 and added examples for DRU and VME chapters; AoC code is conditional for RAD chapter; new IUC codes are ordered to match the next release of Schedule R by CBP. Updated PG30 record for FOO+PNC chapter;
10/26/2015	**2.3.2**	**All**	Intended Use Description is optional; added Appendix F for the list of Unit of Measurement codes and included its reference in PG26 and PG29; Currently, FDA does not support PG29; clarified the use of PG04 for multiple constituent elements under PG02 and corrected Appendix E accordingly; Line Value in PG25 must be greater than zero; Quantity in PG26 must be greater than zero; PG19: Entity Number is optional; PG19: Entity Identification Code is Mandatory if PG19: Entity Number is entered; PG21: Telephone Number is 15X (alpha-numeric) to include global telephone numbers; added a national and an international telephone number as examples in PG21; At least one PG21 record is required;

Date	Version No.	Commodity	Description
10/26/2015	**2.3.2**	**For specific commodities**	Government Agency Processing codes have changed for VME; Reviewed and corrected the Intended Use Codes for BIO, DRU, DEV and VME – these changes will be in line with the next release of Schedule R by the CBP; corrected a typo in DRU:PG07; corrected Note3 text for Radiation Emitting Products:PG01; PG23: AoC codes are adjusted for BIO, DRU, DEV and VME; updated the mapping between the AoC codes and import scenarios for BIO and DRU chapters; PG01:Note3 for Cosmetics is deleted; PG04 is required for all DRU messages except PHN; Note5 is new in DRU:PG04; added the new AoC code PLR for drugs; added references to Carrier Name to PN-related chapters – the new AoC code CAN is added to PG23 for PN; Bulk (230.005) is not a valid IUC code for Food; all references to the AoC code PND are deleted in the Food chapters; clarified the rules for PG06, PG13 and PG14 for Food chapters; PG21:PK reference is added to all Food chapters; Food UoM tables are added to FOO chapters; PG28 is conditional for non-PN chapters – Note1 includes additional clarifications; for TOB:PG26, it is not required to enter 20 cigarettes in a pack – it may be entered if desired by the filer; IUC codes are optional for VME; the AoC code VMS is deleted from VME chapter; Clarified that ONE of MF/DFI/FDC is required for PN and only one of them is allowed; PG30 is used to collect Foreign Trade Zone (FTZ) information for the **FOO+PNC** chapter.
8/18/2015	**2.3.1**	**All**	Updated **PN**-related chapters based on feedback from DFDT's FDA Supplemental Guide Release 2 2 DFDT Edits 07-02-15.docx, FDA Supplemental Guide Release 2 3 draft DFDT Edits 7-13-15.docx, FDA Supplemental Guide Release 2 3 with tracking DFDT Edits 7-20-15.docx and FDA Supplemental Guide Release 2 3 with tracking DFDT Edits 7-24-15.docx; updated **Medical Devices** and **Radiation Editing Products** chapters based on feedback from CDRH's FDA Supplemental Guide Release 2.2 abg.docx and final - FDA Supplemental Guide Release 2 3 with tracking - Device Chapter_abg + ja 150814abg.docx; changed the use of FD1 entity role code to DII for **CDRH** use; updated **PG26** across all commodities based on CBP's new descriptions of product packaging; updated **PG05-06-07-10** throughout the document to reference the most recent PG02; re-arranged the appendices and updated their references throughout the document; updated the validation criteria for **FEI** numbers across all commodities based on its current range of

Date	Version No.	Commodity	Description
			values in FDA's databases; clarified the text for **PG21** and **PG30** record across all commodities; clarified the references to PE10 and SE15 in conjunction with the PG Message Set in the **PN-related** chapters; in the **Drugs** chapter, added BLA to the scope of the AoC code DA (formerly NDA and AND); removed the use of Intended Use Codes for Food-related commodities and added logic depending on parts of product codes at group level; **PG01** is not repeatable for different Intended Use Codes; added the FDA Product Code structure to all commodities and included logic based on product codes in **Food-related** chapters; renamed veterinary medicine chapter to **Animal Drugs and Devices** per feedback from CVM and replaced references to veterinary medications by animal drugs in the entire document; updated **Tobacco** chapter based on feedback in Tobacco Data Elements - June 2015 exw jw jma.doc; updated **Biologics** chapter using feedback from FDA Supplemental Guide Release 2 3 CBER Edits.docx; updated Devices and Drug chapters in lieu of the **Device+Drug Combination** chapter before removing it; updated Devices and Biologics chapters in lieu of the **Device+Biologics Combination** chapter before removing it; added business rules for **PG24**; added Appendix E showing the use of PG04 both at Product-level and at Constituent Element-level and updated all commodities accordingly; added new AoC codes in the **Tobacco** chapter; added new UoM codes for **Drugs**;
6/12/2015	**2.2**	**All**	PG55 is not supported at this time for all FDA commodities; CBER AoC codes & business rules updated; PG25 - line value is required in all the PG25 records (repeated for multiple lot #); FDA product code = 7 characters; Added references to a new entity role code: FDC = FDA Consolidator; Valid list of port codes link added to PG30; Medical Devices - PG01 Intended Use Codes and sub-codes – updated; Radiation Emitting Products - PG01 Intended Use Codes and sub-codes – updated; PG20 is mandatory with additional notes for all commodities; dropped Remarks Code and clarified the Note in PG24 for all commodities; added Prior Notice Non-PGA Data Elements by Mode of Transportation to PN chapters; external sample file is referenced to provide samples for all commodities; included additional rules for entering PG19 entity role codes;
5/18/2015	**2.1.1**	**All**	Updates to PG30 to make mandatory for anticipated arrival time. Updated Prior Notice section to include data elements in the PE records. Various cosmetic and formatting updates
5/12/2015	**2.1**	**All**	Updated **Drugs** chapter using 4/30/2015 & 5/8/2015 feedback from CDER; updated **Tobacco** chapter using 5/1/2015, 5/2/2015 & 5/7/2015 feedback from CTP; updated **Veterinary Medicine** chapter using 5/5/2015 & 5/8/2015 feedback from CVM; updated the **Biologics** chapter using 5/6/2015 feedback from CBER; updated Disclaimer in PG01 consistently across all the commodities; updated **Medical Devices** chapter using ACE ITDS Import Scenario Mapping19.xlsx from CDRH; updated **Cosmetics** chapter using feedback from CFSAN; updated **Radiation Emitting Products** chapter based on 5/7/2015 feedback from CDRH; updated **Prior Notice** chapter using 5/7/2015 feedback from DFDT;
4/27/2015	**2.0**	**All**	Updated PG19 Entity identification criteria across all commodities; added subtypes to Tobacco; added PG04 to Tobacco and included feedback from CTP; includes CBER feedback in Biologics; added the new chapter on Device and Drug Combination Products chapter; added the new chapter for Prior Notice; included additional text to Food chapter to connect PN and Food chapters; updated the context of the PN and Food chapters to describe a Stand-alone PN entry in the PN chapter and a combination entry (801a and 801m) in the Food chapter.
4/11/2015	**1.9**	**All**	Additional text added for PG30 record description based on the March 25th release of CATAIR; adjusted list of Intended Use Codes for PG01 in Radiation Emitting Products chapter per CDRH; changes to Drugs chapter PG01, PH02, PG04, PG19 and PG23 based on feedback from CDER; updates to Biologics chapter based on feedback from CBER;

Date	Version No.	Commodity	Description
4/2/2015	**1.8**	**All**	For VME, PG07 is conditional; for Cosmetics, Cosmetic Registration Number (COS) is optional; for FOO, PG23 AoC Codes FCE/SID requirements are updated; for DRU PG23, REG is not required for PHN; updated the processing codes for drugs; PG25 – all values except PGA Line Value are now optional for all commodities; PG27 record is now mandatory for PN but is optional for all commodities; PG26 is optional and PG29 is conditional for Drugs; added Appendix C for DRU;
3/19/2015	**1.7**	**All**	Removed references to ESS, SSN & TIN in PG19; Added 'DP' to PG19; the mandatory LOT# related fields in PG25 are now conditional; Improved rules for Item Type in PG02 record; Updates to Drugs chapter based on meeting with Philadelphia District Office; PG06 Notes are made consistent across all the commodities; added new Processing Codes for Radiation Emitting Products
3/5/2015	**1.6**	**All**	Updates to Drugs chapter based on CBP's feedback; removed references to MID as the identifier for Trade; re-aligned the Processing Codes for Medical Devices
2/9/2015	**1.4**	**All**	Updates based on feedback from CDRH on Medical Devices and from CBP on all chapters; enforced consistence of same PG record types across commodities where there is no special handling from one commodity to another (example, PG06, PG20, PG21); updates based on feedback from Trade in the 1/20, 1/27 and 2/3 meeting.
1/22/2015	**1.3**	**All**	Updates based on feedback from Trade in the 1/6 and 1/13 meetings; based on feedback from FDA's review of draft. Added Commodity type to Commodity sub-type mapping table.
1/02/2015	**1.2**	**All**	Updated all mandatory record types to match FDA business rules for CBP processing
11/25/2014	**1**	**All**	Initial Version