Tips for Importing FDA-Regulated Products in ACE

FDA Division of Compliance Systems, 2016

Diagram depicts mandatory data elements by commodity type. For certain products, additional data elements may apply. Refer to FDA's Supplemental Guide for further specificity on requirements.

Drugs:

Intended Use Code

Active Ingredient Name(s) & Dosage

Brand Name

Name & Address of API Producer(s), Sponsor (if applicable)

Affirmations of Compliance*

Medical Devices & Radiation-Emitting Products:

Intended Use Code

Brand Name (if available)

Name and Address of Device Initial Importer (medical devices only)

Affirmations of Compliance*

Animal Drugs & Devices:

Active Ingredient Name(s) & Dosage (Drugs only)

Brand Name

Affirmations of Compliance*

Required Data Elements for all FDA Products:

Line Number, Commodity, Subtype

Product Code

Country of Production or Source

Invoice Description

Names & Addresses of Manufacturer, Shipper, Importer, Delivered To Party

Point of Contact Name, Phone Number, Email

Quantity , Packaging, Line Value

Arrival Date & Time

Biologics:

Intended Use Code

Affirmations of Compliance*

Food Products requiring Prior Notice:

Country of Shipment; Place of Growth (if applicable)

Names and Addresses of PN Transmitter, Submitter, Owner, Ultimate Consignee; Grower or Consolidator if Applicable

Contact Information for Transmitter & Submitter

Affirmations of Compliance*

Container Number

Lot Number*

Tobacco:

Intended Use Code

Affirmations of Compliance*

**FEI or DUNS numbers are not mandatory but may expedite review process if provided.

*Affirmations of Compliance and Lot Numbers are mandatory in some instances but are not required for all scenarios. Cosmetics and food contact surfaces do not require any additional data elements other than those listed in the center of the diagram. For further information email: ACE_Support@fda.hhs.gov