Food and Drug Administration Webinar on Single Window Progress
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Good afternoon. Thank you for joining us today for our webinar with the United States Food and Drug Administration, or FDA. My name is Maria Luisa Boyce and I am with U.S. Customs and Border Protection and also part of the Border Interagency Executive Council (BIEC) External Engagement Committee and I am here joined by Mr. Bruce Harsh from the Department of Commerce. We will be leading the discussion and would like to go through some of the ground rules. We look forward to this interaction and hope to answer as many questions as possible. Bruce will now give you the ground rules and I will turn it over to Bruce. Thank you.

Thank you, Maria Luisa. Please mute your telephones and please do not put your telephone on hold. Questions will be answered at the end of the final presentation. Please type your questions into the question and answer section. For any unanswered questions during the webinar, answers will be provided at a later date. Thank you.

Today we have two presentations, the first presenter is Elizabeth McQueen from the Automated Commercial Environment (ACE) office at U.S. Customs and Border Protection. Ms. McQueen will share an overview of the Participating Government Agencies, or PGAs, onboarding process, including some enablers to implementing the Single Window processes and also plans.

Thank you, Bruce. Hello everyone, and thank you for joining us today. I am told that we will have quite a few folks on the phone who are not all that familiar with the Single Window effort that we are currently undertaking. So for those of you who are intimately familiar with it, bear with us while we go through some of the basics here. This first slide that kind of shows the entire -- what I like to call the ecosystem that we are changing with the U.S. Single Window -- I think is very valuable. You can see that we have a lot of stakeholders and a lot of players involved here. We have a 2013 figure there that shows the amount of goods that are being imported and exported into and out of the United States at $2.4 trillion in imports and $1.6 trillion in exports. Obviously, each year, we are going to have much more probably and so all of this is happening every day, even as we are putting into place the new U.S. Single Window for trade. But we cannot ask the world to stop while we do the development and get our software in place so we have to be very careful how we roll this out.

In the center here, we can see the ACE (Automated Commercial Environment) and ITDS which stands for International Trade Data System. Sometimes folks are concerned as to whether they are two different things and essentially ACE is a software that will fulfill the notion of the International Trade Data System and what that means is that a single entry point or a Single Window for all of international trade into the U.S. government. So today, there are a number of different agencies who have their own systems and traders must interact with, in addition to the Customs and Border Protection ACE system, the legacy ACE ITDS system and Partner Government Agencies -- and you can see them on the left side of the chart there of which FDA is one. And all of those 47 government agencies have some sort of interest in imports and exports in the United States. Some of them are much, much more involved than others and

some of them are merely users of data so we exchange data with them and they do not really have real-time needs and some of them, like FDA, actually have the ability to hold shipments at the port if they do not get the information that they need. So for each of them, we have a little bit of a unique development effort undergoing at CBP right now to connect them to the ACE system.

Next slide. So we are rolling out several mandatory dates for this transition. I should actually back up and say that, although this effort has been underway in various forms of for quite some time, over 10 years, it was in February of last year, 2014, that President Obama signed an Executive Order that said all of the transition into the International Trade Data System would be complete by the end of 2016. That does not necessarily mean that nothing happens between now and then, and in fact we are quickly coming up on the first mandatory date which is the use of the ACE system for all electronic import and export manifest. That is May 1, 2015. Right around the corner. Actually, that is not one week but one month. Sorry. One month and one week. But we have already got the software place and that is pretty well ready and I want to point out that it says electronic import and export manifest so to the extent that these things are being shared electronically today, they will need to be done electronically in ACE rather than a legacy system. That actually holds true for the next major milestone as well which is November 1, 2015. This is a very big one.

All entry and entry summary related filings our cargo release and entry summary filings will need to be entered into ACE if they are submitted electronically. So the big distinction here is that we had a legacy system automated commercial system that you may have heard of which is being retired. It is a mainframe system, written in archaic language and we are moving forward into the future onto the new ACE so that is part of why this earlier date is in place so that is November 1, 2015, just seven months from now. I did not check my math on that one, but it is definitely this year November 1, 2015 and that the last one on this sheet is the mandatory use of ACE for all remaining portions of the cargo process, beyond entry and entry summary so the November date is a big one but we still have a lot to do over the next 20 months for that and, of course, we gave ourselves a bit of cushion here between now and October 1, 2016 and the end of 2016 to just be sure that every last little thing is where it should be.

On the next slide, what we have put in place in order to bring all of these Partner Government Agencies into the fold with ACE are a few -- we did not want to build 47 completely different solutions but we have a sort of an a-la-carte menu of functionality that we can develop for the Partner Government Agencies. In many cases, they currently have paper forms being used today so that if you import a vehicle, for example, you have to fill out a paper form for the Environmental Protection Agency and you also have to fill out a form for the National Highway Transportation Safety Administration a lot of the information on that form is actually identical to what CBP already asked for today. Things along the lines of what is being imported, who is importing it, where it is going, how much of it is there and so on and so forth.

So 99% of entries are already being filed electronically through an automated broker interface (ABI). So what we are doing is saying, well, do we care about that piece of paper or do we care about the few unique data elements on that piece of paper? So, rather than hand over a paper form, what if I could just add to the electronic submission that I am already given for an entry

and say, here is the unique data element from that form, such as the license number of the import. Because, as long as that license number is acceptable, we are going to approve this shipment. This allows us to do things like approve that entry for release, even before it gets to our shores in the case of something that is shipped so it is a sea change, no pun intended, because previously, you had to wait until the ship got to ports and look at all of those forms so it is going to be a great improvement in efficiency so what I am describing here is the Partner Government Agency, or PGA, message set. This notion of a pending electronic submission already been filed with a few data elements so we are expanding the [Indiscernible] for those of you who have heard about another option is rather than handing over a piece of paper at the port, to go through the electronic submission with an image of the form. So there are certain forms that, for example, by virtue of our treaty with another country we are still going to be required to see the form itself, see perhaps the signature on it or the seal on it and in these cases, we can submit that image electronically and we still have the advantage of seeing it prior to when the ship gets to port in that example.

Then, this third bullet here, it refers to the interoperability web services, which essentially is an open connection between our system and one of the PGA systems so that we can share and exchange data. Real-time if they need it or on a cyclical basis if they just regularly need an exchange of data. If the Partner Government Agency does not have their own system for us to connect to, they can see the information in the ACE System, in the ACE portal, so it is a graphical user interface that allows them to see data in ACE and search on it and run reports and so forth and it looks the same for every agency, other than being different according to what data they are allowed to see.

Now, this should not be confused with the software that the public traders use in order to submit their entries to ACE. That is not under Customs and Border Protection to create and of course there are dozens of software vendors out there who create software for brokers to use to submit their files into ACE. So the next slide. This is kind of a graphic of the process for onboarding. So each Partner Government Agency has its own process so what does the future world look like when we are going from paper submission to all electronic submission? It is not up to CBP to determine what that would be, although we certainly can help them walk through the operational facts on the CBP site. When they know that they are to be processed, we can help determine the process necessary to allow the job or so if they're using the PGA message set, we can help them work through that with some working groups to make sure that it is understood by the trading community, what needs to be done in order for them to successfully file in ACE.

So we start with a Memorandum of Understanding (MOU) between CBP and the other agency about the data sharing and get our interfaces together and we define our requirements. If there is legal and policy changes that need to happen, we make sure to get those started early, they have very long lead time and there are in fact quite a few agencies who have it written right into the regulations that a paper form must be handed over to a CBP field officer upon entry, obviously those kinds of things need to change in order for us to automate and we move from they are to our developing and testing and training and outreach.

So this very webinar would be considered outreach to inform some of our stakeholder groups what is going to happen in the future and in this case specifically with FDA. And then we also do some pilots where we do a controlled test in the live environment, with real filers and brokers and both CBP on the particular partner government agency paying very close attention to how the system is performing and so forth. Then, we roll out the whole thing.

So part of this -- each PGA creates an onboarding plan that lays out their intention for working with CBP to get onboarded to ITDS. So let's look at the next slide. In an onboarding plan, the PGA determines whether they are going to use the PGA message set, document imaging system, or a combination for their inputs of data and documents. Also, whether they are going to use IWS or ACE for their data access, and then, how ACE should behave according to various events. An example here would be that the ACE system should send such and such notification if certain data is not submitted. Or if certain data files under certain parameters, then we actually are going to put a hold on that shipment.

Since we are here to talk about FDA specifically, I should point out that they uniquely have hold authority even outside of CBP's purview and in most cases, for those agencies who have full authority, CBP puts a hold on a shipment at their request. Then of course we have our plan for coordinating and communicating with their trade customers and vendors. So the FDA plans in hosting this webinar, which we thank them for, and another thing that I want to point out that is unique to FDA is that they have actually been automated for years so we are not at the point now where we are moving from a paper form to an electronic format for the first time so a lot different than some of the other PGAs, however, this is the first time we're automating them with the new ACE system so the PGA message set is still new and being worked out currently with a working group looking through FDA supplemental guidance to trade to ensure that they understand exactly how they are going to need to file in order to meet the requirements of FDA and for us to know that we have what we need. We have got various points of contact, of course, in the onboarding plan and then whether we are engaging in a pilot, as I described, a small-scale operation of whatever solution that we built for the PGA.

To test and be sure that all of the parties know that the business process is going to work for them and we will actually soon be engaging in a pilot with FDA. So this next slide -- it might be not for all depending on what size screen you are looking at, but this is a shot out of our PGA pilot process documents. There is actually quite a few players here and the main reason why I really wanted to show this to everyone is that there are a lot of teams, a lot of coordination going on within CBP and external to CBP, with a particular PGA, and the FDA, as well as trade and field officers both for the PGAs and for CBP at all of the ports. A lot of activities and right now in the middle of the screen, you might be able to see the series of steps under the heading 2.0, conduct working groups.

As we speak, there is a working group underway, actually, literally as we speak as we are recording this, they are having a meeting and what they are doing is reviewing in great detail the guidance that FDA has put out for their technical solution to ensure that trade fully understands what they need to do to submit their entries. As we work through that, it is software being an iterative and recursive process, possible that we will make some slight changes so we do this and ensure that we are at a place with all of the stakeholder groups before we engage in

a pilot, before we begin to conduct live filings so that we know that we should be able to, other than -- if it comes up in the pilot, we need to tweak a little bit as well, then we should be in good shape for when we need to go live and of course we all know that that is in November so things are coming quickly. That is the ACE one. Thank you.

Thank you so much, Elizabeth. This is great information and to those of you, we are going to post this PowerPoint online so you will have it available afterwards. Also, I may remind you that to please start writing your questions in the Q&A area so that we can address the questions afterwards.

Thank you. Captain Domenic Veneziano, Director of Import Operations, U.S. Public Health Service, will provide some background on the Border Interagency Executive Council (BIEC), the current operational input, import processes for FDA and some changes being made for automated commercial environment or ACE transition. Thank you, Captain.

Thank you, Bruce. And I want to thank the BIEC External Engagement Committee for coordinating this webinar and I'm happy to be here and provide a status on the FDA's efforts on the implementation of the Single Window or ACE ITDS and I also want to thank all of you for participating in the call today and look forward to questions that you may bring forward related to this and that endeavor. Next slide. What I do want to cover is a little bit about the Border Interagency Executive Council. First, I think that that is kind of the backbone of everything that is going on and there are a couple of avenues of that we are dealing with which is the Border Interagency Executive Council or the Executive Order that was issued by the President in February 2014. That is the setting the stage and putting all agencies with a tremendous amount of work so I want to cover those very quickly, and Executive Order, 13659 or streamlining the export/import process for American businesses.

It has three main components. The implementation of ACE ITDS, the establishment of a Border Interagency Executive Council, and to identify new regulations or changes to regulations to make sure that this Executive Order is a success. The Border Interagency Executive Council -- their objective is to enhance coordination across the agencies, to improve the importation/ exportation of goods, to enhance communication with trade, to measurably improve supply chain processes and improve identification of illicit shipments, consult on policies and processes with the International Trade Data System Board of Directors, and provide to the President a report on the implementation of the duties of the BIEC on July 1, 2014 and every year thereafter until July 2016.

Let me say that the Border Interagency Executive Council is chaired by the Deputy Secretary of Homeland Security and that is the highest level and one of the main purposes is to ensure that any obstacles that come into play are quickly handled by the Deputy Secretaries of all the agencies. So it is very effective in its purpose and it allows for all agencies to move quickly to get to the end result which is the implementation of ACE and the Executive Order.

Under the Border Interagency Executive Council, there are three working groups and the first is a Risk Management committee, chaired by FDA, and its purpose is to develop common principles among all of the agencies, and to work together on how we target and release

products into the U.S. I should also say that that includes the export part of it as well. On all of these committees. The second is the Process Coordination committee. It is chaired by U.S. Customs and Border Protection and it is responsible -- its responsibility is to come up with common principles and methods associated with a disposition of cargo at the border and enhance compliance. Its goal is to work together with all of the 47 agencies, again for imports and exports and to make sure that we are being efficient in the work that we do. The Border Interagency Executive Council charged both the Risk Management committee and the Process Coordination committee with developing principal documents and that will inform or to help streamline and coordinate agency operations related to import and export. Those documents have been completed and were approved by the Border Interagency Executive Council in September 2014.

Since that time, the two working groups -- the Process Coordination committee and the Risk Communication committee has since combined efforts to move forward in terms of looking at the entire process from start to finish. On October 30, 2014, we did a tabletalk exercise based upon products to identify potential pain points along the process that would have to be looked at for the process and risk management. That exercise identified six points that need to be explored, the first is to explore timely access to import data. The potential utilization of unique facility and entity identifiers. The pivotal role of data quality and validation, transparency on agencies targeting rules, enhanced communication on hold and release decisions, both the two agencies and the trade, and transparency between agencies on final disposition and enforcement actions. These pain points have been evaluated and proposed solutions have been identified and submitted to the Border Interagency Executive Council.

The External Engagement Committee is chaired by the Department of Commerce. They have done an excellent job to date and are responsible for putting on this webinar and other webinars with the other agencies. The committee is actively working on six categories identified as priorities which is the pilot program, creation of a website, improved coordination of ITDS engagement with the ITDS Board of Directors, and the Automated Commercial Environment support office, industry engagement, congressional engagement and international engagement. This group is doing a tremendous amount of work with the Department of Commerce, CBP, and other agencies to make sure that the transparency of these efforts is being communicated to the industry and they have created a tremendous website. That is available on www.CBP.gov/BIEC and a lot of the information and the additional rollout of visits to ports and engagement can be found on that website.

So I want to talk about the current process and I think that this is where a lot of the questions are going to come from the industry and from all of you. The FDA, as Ms. Elizabeth McQueen mentioned, has had admissibility data from CBP since 1998. We were the only agency to do so for a very long time so we have a tremendous amount of knowledge and experience dealing with electronic submissions through at the time the automated commercial system which is being retired in November 2015. A file or a broker must file an entry and an entry [Indiscernible] with customers pending a decision to allow the goods into the United States and that is based on that harmonized tariff schedule and the entry is sent to FDA if it is under our jurisdiction and we make a determination of whether that shipment should be admitted into the United States based upon our laws and regulations. The investigators or the entry reviewer's

that review the data electronically have the capability of releasing the product or in future term, they proceed, request examination of the product, request additional information for -- or recommend attention of the product itself. The decision is sent back to Customs and Border Protection to the filers by FDA and FDA notices are currently mailed [Indiscernible] through the postal service. The biggest change coming down the road is going to be the data quality and additional information. We look at certain requirements and their called affirmation of compliance. That information has to do with the commodities that are being imported.

The four main aspects that FDA has is country of origin, name and address of manufacturer, name and address of shipper, and the FDA product code is currently mandated to be provided with every shipment that comes in. Those are the four mandatory elements that we currently receive during an entry. The other ones are all by volunteer. Or we call them voluntary. I am going to use that word lightly because it is used as an affirmation of compliance but in order for a product to be imported into the United States, it still has to be -- come from a registered facility and it has to have a drug listing number if it is a drug, and it has to have an INT with it so part of our review process is to verify this information. In the future, we want to do that all electronically. And a lot of the delays that we deal with on the FDA side is the process of verifying that the manufacturers are registered, that the products are listed, and that numbers are available. In the future, we hope that those all of the information is going to be submitted at the time of entry and the systems electronically validate that information to help expedite the entire process.

I am going to skip this slide. This was covered by Elizabeth McQueen and very eloquently so you should all be aware of those dates and we cannot stress them enough. But please know those dates are extremely important. On behalf of CBP, I know that they stress them. Looking at the mandatory dates, we will cover them again, just for repetition and make sure that everyone is aware. So May 1, 2015, ACE, it will be mandatory for all electronic manifest filing and as stated, it is right around the corner. November 1, 2015, the ACE mandatory for all electronic cargo release and related entry summary filing. Again, that is when the retirement of ACS will occur and then on October 1, 2016, ACE will be mandatory for all remaining electronic portions of the CBP cargo process. I will throw in another date just for FDA purposes. We will cover on the next slide as well. But if you want to write something down, July 1, 2015 is when our pilot is going to be started and we will be asking for volunteers to participate in that pilot between July and November 2015.

Looking at this slide, in terms of what our status is and what is being implemented, you heard Elizabeth McQueen talk about the IWS or the Interoperable Web Services. We are happy to say that FDA has completed that and they are talking to each other. The computers between FDA and CBP have said hello and FDA would love to say and they haven't said hello and they have shaken hands and we have completed the PGA message set for the supplemental guide in -- and business rules and we're working with the trade support network (TSN) on implementing that and making sure that the software developers understand what those requirements are so that they can build a software to give to the filers and the brokers so that they can start the implementation or the use of ACE for FDA purposes.

The document imaging system is ongoing, as many of you know. FDA has the import trade education system which allows the submission of documents to be submitted directly through FDA and directly into the line level of an entry. It allows the entry reviewer's to see these documents and to make decisions based upon that information. FDA is working with CBP to try to implement the document imaging system. We foresee that that will happen after the November date and we want to make sure that what we implement it does go down to the line level for FDA purposes so that we can expedite any requested documents that are needed. The other aspect of it is the FDA pilot testing which is major. Again, we are starting the pilot in July 2015. There will be different aspects of it and we are still working internally to iron all of that out and identifying the ports, the commodities, and there is going to be a couple of aspects, obviously, the IT, that is one of the big pilot to make sure that it is working correctly and then we are working with the BIEC to identify cross agency work. We need to test to make sure that the agencies that have jurisdiction over a commodity and are working together and seeing the information so that we can be more efficient in what we review, what we examine, and how we communicate together. Internal activities are ongoing. So we are briefing our field staff and also briefing our senior leaders on all of the efforts. We are working closely with them to get the direction of moving forward and as to communications, I have spoken very briefly about the work that the external communication group is doing in terms of rolling it out externally both at the Hill and the port of entries and as I mentioned, it is extremely important that you look at that website at the hill and the port of entries and as I mentioned, it is extremely important that you look at that website www.CBP.gov/BIEC and to get a list of where we will be in next day -- external engagement group across the country over the next couple of months.

We are continuing to do webinars so today is FDA's but there will be others coming down the road. I also want to bring up a couple of the administrative and legal requirements that we are currently dealing with so, as was mentioned earlier, we are working on an MOU of sharing data that has been completed and we are just waiting for signatures so we are moving along quickly with that and there is also some internal aspects for security purposes. We have also completed that and are awaiting the pictures and we are also awaiting signatures and also working on several Federal Register Notices and one of them is going to be by Customs and Border Protection to talk about the pilot coming in July and we are working on language for that and still finalizing some of that work. Then we are also going to be issuing a Federal Register Notice for some of the data elements that we are looking at coming down the road and, as I mentioned previously, they were affirmation of compliances and they are now PGA message set or data elements that have to be submitted at the time of entry. So that is very quick brief overview of the status of the work that we are doing and I look forward to the questions that you may have in terms of this. Thank you very much.

Thank you so much. We are going to move to the questions. We may not have time to answer all of the questions and that is why we do want to leave enough time for that part. So we are going to go ahead and start. The first question:

What is the status of the PGA MOUs who have the hold authority or admissibility authority? (I do not need names but rather just a general feel – are they all signed or 50/50?

Elizabeth McQueen: So I did not study for this question and I cannot tell you the exact -- every last one but the vast majority of our MOUs have been signed and are in place and we are actively working the few remaining ones that are out there. As Domenic said, the FDA one is completed and just awaiting signatures and I believe that there may only be one more with old authority that is not finalized. But they are all of the signature process. 80-90% are signed, right? Yes, about 90%? Right. In a couple of cases, there is some information and an appendix that we want to be absolutely sure cannot be misconstrued so really nothing is in the way of holding that up there.

Maria Luisa Boyce: Okay. Great. Thank you so much. The next question:

The PGA message set document contains additional FDA affirmation of compliance code for medical devices. For example, lot number, lot production, and start and end date. Will there be an opportunity for the trade community to provide comment on this additional element prior to November?

Captain Domenic Veneziano: Thank you for the question. The data elements are still being looked at, so they are in the process of getting the supplemental guidelines down and there was opportunity to identify what data elements are needed for admissibility purposes only. Those data elements are being currently reviewed and they will be looked at in terms of what is actually required, simply for the admissibility aspect of it so, for instance, something like a lot number for production can be followed up after the admissibility process or can be followed up during an inspection of a facility that might be an optional field so it will not be a mandatory field as part of a requirement. So we are going through that supplemental guide for all data elements associated with all FDA regulated commodities and we will be ironing them out to only those that are required for admissibility purposes. So, again, consider the document that is out there right now and that is being discussed a draft as we go through and whittle them down to only data elements that is going to be required for admissibility purposes only.

Maria Luisa Boyce: Thank you. Next question.

What is the underlying computer platform for ACE?

Maria Luisa Boyce: I do appreciate the question, but we did not invite an IT person to today's webinar and I can tell you that we're using an agile approach to ACE. That is as technical as I'm going to get on that one, but we will be more than happy to send you more information. By the way, let me make a commercial announcement that I think Elizabeth and Domenic mentioned: we are having a software vendor conference this Friday, March 27, and so that will be a great opportunity. If you are interested in finding out that information, please go to the CBP.gov webpage and you can find information on it, but we will send you that information and figure out how we can email that to the group. We will email you the information for the software vendor conference where we are discussing more in detail the information.

Maria Luisa Boyce: Next question.

What will happen to the marked ITAC (Import Trade Auxiliary Communications System) Systems for FDA?

Captain Domenic Veneziano: So currently, ITACs is up and running and we are making some improvements to ITACs. As many of you know, it gives you the availability and provides you the capability of telling FDA when things are available for sampling. It also provides the ability to submit documents electronically to us and it provides you the ability to know the status of any entry by going in with the entry number. It is also going to be improved so that you can actually go in and take a look at the FDA notice of actions electronically if you wish to and to print them out. So it will not be going away immediately and it will probably be there for other purposes. When the document imaging system gets completed, we hope that it will be a seamless transition from DIS into ITACs for FDA so the capability will be through the cloud, per se, where you submit it in one location which would be DIS and it would go to all agencies through a signal window concept, but it would still come into FDA through ITACs into our system and be linked directly into the line entry. So it still is not going away. It is hopefully going to still be enhanced right now and then, as the document imaging system comes on play, we will figure out what it means in terms of ITACs in its current state.

Maria Luisa Boyce: Thank you so much. The next question:

Will standalone the Bioterrorism Act (BTA) be part of ACE?

Captain Domenic Veneziano: The Bioterrorism Act, as you all know, is the prior notice requirements which is still part of the import process for FDA in terms of admissibility. It is the first aspect of food coming into the United States, to ensure that those requirements are satisfied before it moves into the admissibility part. That will not change. It will be incorporated into ACE so it will still be the same process as we currently have -- however it will not be through ACS but it will be through the ACE environment.

Maria Luisa Boyce: Thank you. Next question:

The deadline for brokers to file ACE is November 1, 2015. What day will everything be online for brokers to be able to file?

Elizabeth McQueen: So part of the reason why, as Domenic mentioned, we will be ready to do the pilot for FDA on July 1, 2015, is that it is in the July deployment when we will have everything that we are building for that November deadline out. So actually, there are quite a few Partner Government Agencies whose pilots will begin in July and it is going to be very much like the starting gun of the horse race, even though we have had a few around the tracks a couple of times so the thought is that, in the very early part of the pilots, hopefully within certainly the first month, we will have a very good feel for the extent to which some slight changes might need to be done and still leave our software vendors out in the private space

several months to get their coding completed in time for everyone to be able to meet the mandatory day.

Maria Luisa Boyce: Thank you so much, Elizabeth. Next question:

How will the Single Window system affect the import/export of investigational drug products especially those consigned to investigational sites covered under an existing IND?

Captain Domenic Veneziano: We hope that it is going to be more efficient. Currently, as many of you know, during an investigational drug product, you have to provide a number for the agency to actually verify that it is under an investigational drug. During the process, if that information is provided at the time of entry under the new PGA message set, then hopefully the system itself will verify all of that data electronically and release it in a much quicker time period and prevent the delays that currently happen in terms of human intervention of verification of that information. So that is where it is going. In terms of export, obviously, there is not much that we do for FDA wise in terms of the exportation of drugs or raw commodities.

Maria Luisa Boyce: Thank you so much. For the next question:

Please advise, what does the acronym FACA stand for?

Maria Luisa Boyce: That would be Federal Advisory Committee Act. That is what FACA stands for.

Thank you for the question. Next question and I think that we already addressed this.

Are ITACs still going to be in place and will entering in information remain the same?

Maria Luisa Boyce: I think that the Captain Veneziano already addressed that in his previous response. Next question:

How will the foreign supplier verification system undated by FISMA be implemented through this system?

Captain Domenic Veneziano: So they are two new regulations that are coming down the road. Obviously the Food Safety Modernization Act is one, and the FDA Safety and Innovative Act is the second that is being worked on. With each of those, we have already identified placeholders for the data elements that are going to be required when the rule gets issued. So we are aware that there will be some additional data elements that might be required because of the new legislation. The MOUs that have been signed address that so we are aware of it and they will be incorporated into the data – or the PGA message set - when all of the rules are finalized and we can make decisions on what is needed. Again, one thing that I will say, to piggy-back off of my last answer related to data elements and the affirmation of compliance, we are looking at what is required at the time of entry to make admissibility decisions in what is needed for the law and regulations that we enforce. So we are going to be prudent on what is

required under FISMA and what is required to make it available for filers and manufacturers to get the information and quickly so that we can turn it around.

Maria Luisa Boyce: Thank you so much. We have another question:

What about medical devices?

Maria Luisa Boyce: Could you please be more specific about what which medical devices you would like to know more about? Thank you and we will be happy to answer the question then. Next question:

How do we volunteer to be a test volunteer?

Elizabeth McQueen: The simplest way is to go to the website ITDS.gov and there is, in the red menu, a button called ITDS Pilot Programs and if you click on that button, you will actually get instructions for how you can express your interest in participating in the pilot and that is across the board for all of the pilots that we have. Also, if you happen to be a subscriber to the CSMS messaging service, we do put out CSMS messages when we are going to engage in a pilot requesting volunteers for the pilot.

Maria Luisa Boyce: Thank you so much, Elizabeth. I think that when we send the email to all of today's attendees, we will send a direct link to that so that everybody can have it and do that. The next question:

If you would like to be a part of the pilots, as a volunteer or tester, can you select what entries to do this with?

Elizabeth McQueen: That is actually a very good question. When we engage in a pilot, we specifically do a very finite small scale testing effort so that we can be absolutely certain of what we are looking at. So we do not open the floodgates and engage in that at every single port through every single mode of transportation for every single commodity. What we do is choose a subset of commodities that we are going to be looking at and we choose the subset of the ports that they are going to come in, and even as the case may be depending on the PGA, a subset of modes so the folks who will be participating in the pilot will be well aware of what specific items that we will be testing. So we do that limited and controlled small scale effort and then we expand that. So we might add commodities or we might go with the same commodities, but add more ports or add more minutes of transportation so that we can throw that in a controlled fashion and be sure that we do not have any surprises as we expand.

Maria Luisa Boyce: Thank you so much. Next question:

With DIS in effect, will ITACs be obsolete?

Captain Domenic Veneziano: I do not think so, but I think ITACs is a great tool for the industry and the industry likes it. It is a way for them to know the status of any entry very quickly. We also are making changes to that so you will have an idea of laboratory statuses as well which

might not be available through ACE directly. Obviously, what we would love to do, is to have everything go to the filers as much as possible through ACE. So, the future is to kind of identify what kind of tests we are sampling and have that be something for our notices.

And the long-term goal would be that, in the FDA notice of actions that we issue, we would be specific in identifying what is being sampled for, and what it is being laboratory tested and being issued through ACE. I think that that is going to be a long-term goal so in the interim, I do not think that ITACs will be obsolete in its entirety. But we have to figure out how it is going to be utilized down the road.

What does ITW stand for?

Maria Luisa Boyce: Elizabeth, is that one of your acronyms?

Elizabeth McQueen: No, it is not familiar to me.

Maria Luisa Boyce: If you can please give us a little bit of framework of where you found the ITW acronym, we will be more than happy to help you, but we do not recognize it.

When will FDA implementation guidelines for use of PGA message set be published in the CUTAIR?

Elizabeth McQueen: Currently the working group is reviewing that guidance and as I showed when I put the graphic of the process up on the screen, we go through that process of the working group thoroughly reviewing the IG so that we can do any iterative and recursive work on tweaking those before we put them up – generally, that is the preference.

That said, there is a place now in the CUTAIR where we have, separately, a group of chapters for PGAs who have already gone through that and a group for where they are draft and so, they are put up there for future use. We should have put the FDA one up on the site for future use and I believe that it may be there now. […] Yes. It is there, under "supporting documentation" for future use under PGA message set.

Maria Luisa Boyce: Thank you so much.

When will the webinar be available online for others to view?

Maria Luisa Boyce: Within 48 hours, the webinar will be available for you to forward and send around. Please do so that a lot of people can listen and have the information. Next question.

I have heard that FDA's proposed message set includes a lot of new data elements that are not currently provided, including lot numbers and production, start and end dates. Are those still included and if so isn't that contrary to the Executive Order or have they been dropped?

Captain Domenic Veneziano: They will be addressed so most likely, they will not be mandatory but they will be optional as I mentioned earlier we are going to all of the data elements to make sure that only those that are required for admissibility purposes will be covered under the data element requirements.

Will there be a need for a Federal Register Notice for the FDA pilot? If so, when can we expect to see these?

Elizabeth McQueen: I think we are doing a combined one. Yes. It is actually going to be under CBP.

Captain Domenic Veneziano: And we are in the process of reviewing that document, the Federal Register Notice, and it will be again under CBP but it will include specifically what the pilot will look like, probably contain links to ports because the pilot is going to be probably run from July through November and, as was mentioned earlier, we want to start small and ramp up so as the ports come online, we want to have a link as to how we are going to roll it out and that is what we are in the process of doing so it should come out, I would imagine, I think it is within maybe the next month or so but it is coming through a review process right now.

Elizabeth McQueen: Worst-case scenario, the FRNs are put out 30 days prior to a pilot starting so it will be before then. So we will say, May, probably or April/May.

Maria Luisa Boyce: We will look into that. Next question:

We have heard you (Captain Veneziano) speak before about FDA moving towards a more risk-based process versus treating all FDA regulated parts the same. Has there been improvement in this area and will ACE/ITDS help in this effort?

Captain Domenic Veneziano: I think it will help the process in terms of, I think we will be able to release on a line level, so what the future is going to deal with – let me back up a little. Currently, when we hold a line, that entire entry is held. So it prevents products from getting into commerce as quickly as they can. ACE/ITDS will change that and it will allow to release on a line level in the future and only allow FDA to hold those products that we really want to look at.

So we currently do have a risk-based system in place and, as many of you know, it is called PREDICT where it targets just based upon certain elements and based upon business rules so inherent risk of a product is weighed against each other to determine which ones have the highest need or have the highest risk to public health and we tie it against those. But ACE will improve the process and the work that we do, as well as working with other agencies together.

So if there is a concern from another agency or if FDA holds a product, that will be visible to other people who have jurisdiction over it. If we are holding something, you will have to do two exams, one for Customs maybe and then one for FDA. We will know at the same time that there is an interest of that shipment and it can kind of expedite the review process or the examination process of the shipment. It will help get products to the market a lot quicker. But

we do already have a risk-based approach in terms of the work that we do so I hope that that answers the question.

Maria Luisa Boyce: Thank you so much and thank you for the question. Next question:

Will this new process increase the efficiency of the import and release of fresh fruit and vegetable perishable shipments?

Captain Domenic Veneziano: I believe that it will. I believe that with the new ACE/ITDS implementation, I think the efficiencies will be quicker and I think there are a lot of aspects to that question and you have the Voluntary Qualified Importer Program, down the road, and the Border Interagency Executive Council Process and Risk Committee looking at trusted trade programs to help expedite shipments coming for us and recognizing who is C-TPAT and ISA certified. So I think that in the long run, looking at what the Executive Order is intended to do and the work that is going to be shared through ACE/ITDS, I think that will help expedite not only fruits and vegetables or food, but I think for all commodities that we regulate.

Maria Luisa Boyce: Next question.

How will the PGA message set impact and/or work with PREDICT?

Captain Domenic Veneziano: Thank you for this question. This is pretty much the heart of why it is important for the PGA message set of the data elements to be submitted at the time of entry. PREDICT takes a look at the information that comes across and utilizes or searches other databases within FDA, if you will, to verify that the affirmation of compliance are accurate and efficient.

By providing them upfront, we are going to do a couple of things. First of all, CBP will be in the validation when it comes to them and they can validate that the data is in the right syntax, the number of characters are correct, and it will first screen it before it ever comes to FDA. It will provide you a warning just to let you know that this commodity needs a specific data element. Once it comes over to FDA, again, it will come in, it will go through PREDICT and it will go into our databases and verify that information and if everything is correct and the product is not a risk to FDA, or we do not have a concern over it, then it will be preceded by the system instantaneously. So you are talking about seconds versus days of a release if everything goes smoothly.

Maria Luisa Boyce: Thank you so much. Next question.

We are currently self-filing our customs entries in ACS. Do you anticipate any issue if we move to filing in ACE and are not part of the pilot? Do you foresee any complications that might arise if the FDA portion is not completely tested before the November 1, 2015 deadline?

Elizabeth McQueen: If I understand the question correctly, it sounds as though this person does not want to officially participate in the pilot but will still want to start filing in ACE?

So in the beginning, when we are just in the pilot phase, I do not believe that we are going to let just anybody and everybody file. They have to be a pilot participant. Yes, but we do encourage you, from a Customs perceptive, to file in ACE now and there is not going to be a problem on that part if you move to ACE.

Captain Domenic Veneziano: On the FDA side, let me address: do you see foresee any complications that might arise if the FDA portion is not completely tested before the November 1, 2015 deadline.

I can guarantee that it will be tested before that day. So we are working on that and to test if the system side of things – the ACE/ITDS working group and the technical people have worked hard at making sure the systems are working together and the pilot is going to start in July. That is going to verify that everything is working and we will turn it off quickly if we need be but between July and November, we are going to be testing and having metrics to determine what success is going to be and to make sure that it is working smoothly before we ever finish in November. There are a lot of conversations that have to happen in that time period and to monitor the success of the program so I can guarantee you that it will be tested to its fullest extent between July and November before ACS is turned off.

Maria Luisa Boyce: Yes, we are going to be doing a lot of outreach, not only through webinars like this, but also going to different ports of entry so that we can have outreach with the community to help facilitate that participation and testing.

Elizabeth McQueen: We are encouraging everybody to file in ACE – my apologies for the confusion.

Captain Domenic Veneziano: One of the big aspects of the pilots and I need to emphasize is the impact on industry. So yes, the systems have to be working for the agencies, but we also want there to be impact on the industry and focus on what changes have to be made and how it is working for you all in terms of submitting the entries and what difficulties you are having.

That is part of the BIEC role in terms of the rollout, to capture that and to get the input from the industry in terms of how it is affecting you as we transition from ACS to ACE.

Maria Luisa Boyce: That input is important for us and that status.

How does the electronic interface address the USDA requirements for original documents for VS permits?

Maria Luisa Boyce: With that question, actually, I would have loved you to ask that in the webinar we had with APHIS but we will get back to you on that question. We are not able to answer that now but we will get back to and provide you the information. Next question.

Why does the FDA propose rulemaking to require those remaining voluntary items to achieve uniform filings for affirmation of compliance? Seems [Indiscernible – static] to have all of the information at the same time.

Captain Domenic Veneziano: We are going to put out a Federal Register Notice rulemaking and it can be a little bit more difficult in terms of the client. With 7-2-713 -- for FDASIA, where we have to make it a rulemaking in terms of requiring data element and for a product that is subject to review. So it is a little bit difficult in terms of the rulemaking process versus a Federal Register Notice so it is a lot quicker, I think, to go through a Federal Register Notice asking for these data elements to be submitted at the time of the entry so that we can accomplish the goal of expediting shipments in the long run and that is what our goal is to try to expedite as quickly as possible and to kind of let the systems do our work for us rather than the human interventions. With 34 million lines of shipments each year, we have to find a better way and a more efficient way to do our job and through the implementation of ACE/ITDS and the Executive Order, I think that we can get there.

Maria Luisa Boyce: Thank you. Next question:

When an FDA hold for documentation is requested in ACE after a Customs entry has been transmitted, will the documents be uploaded into ACE or will we still upload them on the MARCS website?

Captain Domenic Veneziano: Currently, they will still be uploaded into the MARCS website until DIS comes into play and then there will be procedures and we will be communicating how that will get done in the future.

What additional data elements are mandatory for November 1, 2015?

Captain Domenic Veneziano: That will be in the supplemental guide and we will be communicating on many aspects on this. We will have that on a website on what is required. We will also send out a CSMS Notice to the filer on all the requirements that are going to be changing. It will also be part of the Federal Register Notice when it gets issued.

When the Federal Register Notice goes out regarding the pilot in July, when does the request for volunteers for this pilot go out?

Elizabeth McQueen: They are really sort of one-in-the-same because we have to know what commodities are going to be part of that pilot before we can know who ought to be participating in the pilot. Anyone who is interested is certainly welcome to express their interest as early as possible and as soon as we know what commodities we are talking about, we can validate that it makes sense for you to take part in the pilot at that point. But as soon as the FRN goes out which will hopefully be soon.

Has the FDA-PGA message set been finalized and will all data elements be mandatory?

Captain Domenic Veneziano: It is still a draft and we're still doing the review and we are in the process of going through each one of them.

Any anticipated changes to the ITACs functionality and availability plan?

Captain Domenic Veneziano: Yes and we are working on additional functionality for that.

Will ACE allow for port code changes for FDA regulated goods?

Captain Domenic Veneziano: Yes. So this is going to be a big change and one of the big issues we have had are one of the big concerns that the industry has said is they cannot make changes for port codes or for any mistakes that have been made and in order to make the change, they have to delete the entry or cancel the entry and then resubmit. The beauty, I think, of some of the new changes to the system is that you will have the capability of submitting an entry 60 days in advance and it is going to go to the validation process and we hope to notify you if there is an issue.

Between 60 days and, I want to say a lockout time period for the mode of transportation, you will have the capability of making edits all along that way and we are trying to make sure that you have the capability of getting information or warnings from both CBP early on with the submission of them and then from FDA up to that cutoff date. You can always make changes after that cutoff date but at some point, the agency has to consider the information that was submitted and make a final decision.

We are identifying when things are going to be locked out for the entry review process. So you will have the capability of making it. The port code is a little bit difficult because often times, it is kind of at the time of arrival to make a port change so you do not know your change in ports due to a traffic or accident or something in that aspect so we have been working with the CBP to identify that. When possible, that port change can be made. But when not possible, we will deal with it operationally and the only major concern that we have is if we have set something up for examination and we -- FDA -- will work on making sure that the port that it is going to, as long as you notify us of the change, we can look at it.

Again, with ACE, one of the beauties of it is that everybody will know across the country that we are looking at that entry. If you make an entry at another port, it should be flagged accordingly that we want it to be stopped or set for examination. So we are working at it operationally with the changes cannot be made because of last minute issues but you will have a capability from 60 days up until the time of a lock down to make any changes.

Elizabeth McQueen: Let me add one little piece to that. Just by attending our demonstrations of our software under development, I am aware about another piece of functionality that people might be interested in which is if we have a serious scenario, before you gave the example of an accident or a hurricane, and you cannot come into Houston, there is a feature that has been built into ACE where all of those shipments that are on ships that we are going to go into that

the port, can be redirected to another port without you having to redo the entry. So that is going to be a great thing and I do not remember what they called that...It is "diversion."

Will any advance drafts of the FDA FRNs be available for review?

Elizabeth McQueen: No. We cannot share that but you are welcome to provide comments once the FRN has been made available to the public.

What about samples or codes which are not approved in the U.S.?

Maria Luisa Boyce: If you could please maybe give us a little bit more context for the question, then we will be more than happy to address it.

What about medical devices?

Captain Domenic Veneziano: I apologize. I excluded them. So medical devices have similar things and there are requirements for device registration numbers, device listing numbers, as well. I apologize, but I will amend the slide and make sure that Steve incorporates it into what we currently need for admissibility today. I apologize for that.

What are the challenges in communicating recommendations back to CBP through the Single Window?

Maria Luisa Boyce: Are you referring to messages back and forth? Are you talking about when the agencies are sending a message back to you that some information is still needed? Are there challenges with that? Please let us know a little bit more context with that question.

It appears that FDA uses HTS as the guidance for flagging commodities. Will this list get updated?

Captain Domenic Veneziano: The answer is yes. We look at harmonized tariff schedules often so we go through them on a yearly basis but we continuously update them to make sure that anything that is FDA regulated gets hit with an FDA flag to make sure that it comes into our jurisdiction.

Are we able to have the ability to correct errors made with FDA, such as FDA code or MIDs at the time of entry once it has already been transmitted?

Captain Domenic Veneziano: As I mentioned, you will have a lot of time between the 60 days and the lock-out time that we are establishing to make changes if you have made mistakes.

Will local customs field agents be ready for the full, mandatory agency ACE-implementation by November 2015 for full cargo release process?

Maria Luisa Boyce: Yes, they will be and they are ready. We are doing the internal training. This is from a Customs perspective and we are working on the training. As everything gets

more ready and we have more information, we are scheduling the local training with our offices and you may understand that this is a big effort that we are working on.

Maria Luisa Boyce: Thank you for the question.

It was mentioned that during the tabletop exercise there was some pain points identified. Have these been addressed? Will this be shared with the trade? Will further tabletop exercises be conducted that include trade participants and if so when might it occur?

Captain Domenic Veneziano: So the six pain points have been addressed, but they have not been addressed in their entirety. We have explored the timely access to import data and as I mentioned, one of the big successes is getting it the 60 days in advance and working through the process of how we maximize data. We are also in the process of implementing or I should say CBP is in the process of issuing ATS-GC which is the capability of other agencies that are co-located with CBP to look at manifest data or other data that usually the agencies do not get access to so we are in the process of doing that.

We do have solutions to some of the other things. The third one is the federal role of data quality and validation and we have addressed that as I mentioned and there will be a validation step by Customs and Border Protection when the entry gets first submitted to verify that the data elements and PGA message set for admissibility decisions are there and not left blank if needed so based upon the commodity if there is a requirement that has to be submitted or filled out, it can be done with the warning going back so that has been completed.

The other four are scheduled to move forward and we are trying to address them moving forward but they all have kind of potential solutions and we will be working through them between now and December 2016.

Maria Luisa Boyce: And as far as interaction with the industry, we will try to find a venue to be able to do it and at least post the information and if we can, facilitate the dialogue. We will look into that part and see how we can assist.

Captain Domenic Veneziano: I would say that one of the major things, and Maria Luisa can speak to this, but the work of the Advisory Committee on Commercial Operations (COAC) has been instrumental and the FACA committees have been instrumental in the work that we have done in identifying some of the pain points, on their behalf, that they have seen and bringing them to the forefront for the agencies to address. So that work will continue and I expect that you will and the COAC will continue to play a major role going forward.

Maria Luisa Boyce: I think that will be a good way to connect with industry and we are going to be posting all of this information online and that way you can also send your questions.

What is the status of the USDA-APHIS Lacey Act information?

Elizabeth McQueen: So for the APHIS-Lacey Act program, the working group has already gone through their supplemental guidance and that guidance has been uploaded to CBP.gov in the CUTAIR and the PGA message set chapter but it is under the supporting documentation for future use section. Only because APHIS has not internally finalized the approval of the implementation guidance but it is there.

On shipments that the importer pays by check, how is Customs going to handle that? Since ACE rejects these entries now.

Maria Luisa Boyce: That is a very good question and we are going to look into that it to send you an answer via email.

Will the DIS be done through the ACE portal? That is another technical question that we will get back to.

Elizabeth McQueen: I don't believe so. It will actually be appended to the electronic section.

Maria Luisa Boyce: I think that that is where we are going to stop at this moment because we are getting a lot of questions. Thank you so much for all of the participation and all of the questions. What we are going to do is post this information online and for some of the questions that we did not answer, we will make certain to write an answer and send you that information.

Maria Luisa Boyce: There is one last question here:

Are all the BIEC reports to the President or made in part to the public record?

Maria Luisa Boyce: As Domenic mentioned, we have the www.CBP.gov/BIEC webpage and we will be posting more information as it becomes available, but thank you so much for all of the questions. We look forward to continuing to have this outreach and we will be in touch.

I want to thank especially Elizabeth McQueen and Captain Domenic Veneziano for their time and Bruce Harsh for his time. We look forward to continuing this coordination. Thank you.