Food Facility Registration and Prior Notice

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(Sousan Altaie): All right, I'd like to introduce to you Mr. Taube. He's the Director of the Division of Food Defense Targeting and he's very savvy in showing you how you could go do a prior notice easily on the Web page. So please welcome him. Thank you.

(Tony Taube): Good morning, everybody. Let me make sure. Can everyone hear? Okay? In the back? All right. Thank you. I want to thank the Office of International Programs for inviting me out to talk a little bit about food facility registration and their prior notice of imported foods, Captain Veneziano mentioned a couple times during his presentation our process related to food defense and specifically related to the food facility registration requirement and the prior notice of imported foods.

So I wanted to talk a little bit about how to navigate on our Web site to obtain additional information on both of those and then give you a little information on both registration and prior notice as we go along. So as you can see, right now we're on the FDA.gov Web site and the primary link you want to click on to get to the - both the food facility registration and the prior notice of imported foods is that food tab.

So right here on the commodity tab, you see the food, so I'm going to click on that particular tab and that'll take me to the food portion of the FDA Web site. And before it comes up, I will let you know that periodically the site of the next link I'm going to show you change. I think they do it to throw us off or just like they do it at the stores when they rotate where you

find your favorite cereal or something, they move it somewhere else to draw your attention to those things as well.

So, they do that periodically on our Web site, but right now the two links that I want to show you in popular topics, we are one of the most popular topics, is the prior notice of imported foods over here on the right. And then if you scroll down a little bit under spotlight, there's the section on registration of food facilities.

And I'm going to go ahead and go to the registration of food facilities first. If I click on that, that'll take me to the registration of food facilities Web site or page. And there's a lot of good information on this particular page. Domenic mentioned that, you know, the food facility registration requirement came out of the Bioterrorism Act of 2002.

At that time, the only food facilities worldwide that had to register with FDA were low-acid canned food firms and infant formula firms, and that was probably less than 1000 firms worldwide. With the Bioterrorism Act requirement, any food facility that prepares, packs, or holds food for intended consumption in the United States or transits through the United States -- actually it's only just for the intended consumption, let me go back -- has to register with FDA.

So that opened it up to just thousands and thousands of food facilities who want to bring their products into the United States and the requirement to register with FDA. And at that time it was a one-time registration. You registered and as long as your operation didn't change, you never had to go back in and re-register.

Well, the Food Safety Modernization Act changed that and now requires a biennial re-registration and it happens or it occurs in the even numbered years. So last year 2012 was the first biennial re-registration and the actual period, the normal period for registration or biennial update is October 1 through December 31 of those even years.

The first period, our Web site wasn't quite ready. Where did you hear that before? And we actually delayed the - but we delayed. We delayed the implementation of the biennial re-registration for about 21 days and I think it opened up on October 21 or 22 of 2012. And because we were delayed, we actually extended it into the end of January 2013. But I would expect 2014, so next - this coming year that biennial update to stick to the schedule October 1 through the end of the year, 12/31.

So, what does FSMA also -- the Food Safety Modernization Act -- also require? It requires - well, we updated the registration process by clarifying some of the information about facilities, about what you do at that facility, what products are manufactured or held at that facility, and it also requires facilities to acknowledge that by registering and by having their products in the United States, they are subject to FDA inspection and you're basically acknowledging that - you're acknowledging that you'll permit FDA to inspect your facility.

And that's really important because if something Domenic brought up during his presentation about persons registering companies where they really - the company itself may have had no intent for their product to ever be consumed in the United States, and we are seeing some of that occurring, Domenic mentioned the gray market where, you know, someone buys a product in a foreign country and they are just a distributor and then they sell it to the United States and then it’s imported, and that

manufacturer has no idea that their product is now entering the United States or attempting to enter the United States.

And they never had any intent so they don't want to be inspected by FDA, they don't want to register, and that product should be held at the border and refused entry under 801(l), which is the registration requirement. So, what is happening in some cases is you have importers registering those foreign facilities on behalf of the manufacturer.

And I bring that up because and when I brought up a search on the actual regulation for registration, which is 21 CFR Part 1 Subpart H. I'm going to do a quick search so I can bring up the language. And I always use the Cornell Law because it's easy to navigate. But Subpart H of 21 CFR Part 1 is the registration of food facilities under who must register, it describes who is authorized.

So, it says, "You," -- and you is defined as the owner or operator agent in charge of that facility -- "must register." But it also gives under C that you as the owner and operator in charge may authorize an individual to register your facility on your behalf. With that comes some responsible relationship between the person you authorize and you, the owner/operator/agent in charge, so it shouldn't be some third party importer who you have no idea who they are, you've never had any kind of business dealings with them. They shouldn't be registering you and committing your facility to FDA inspection.

And our agency, we're working with our Center for Food Safety and Applied Nutrition to look at some of the registrations where we think these third parties are actually registering facilities unbeknownst to the manufacturers themselves.

And again, we're looking to invalidate and have invalidated some of those registrations for that reason. So, it’s very important for you to advise your industry folks that, you know, they're the ones that should register or if they want to choose to use someone to register for them, that they have that business relationship and authorize it and recognize that they are also subject to an FDA inspection.

There's businesses out there who are set up to promote to industry that we'll register you for FDA for a price, of course. The beauty of it is registration is free, so any facility could do it on their own for free. And so again, you should also advise your industry folks that FDA registration is free, you don't have to pay someone to do it but if, you know, you're certain - they're certainly welcome to do so under the regulation under §1.225 (c) is to have that business relationship.

So, the first area you're going to want to go into if you're working to register a facility is on the left hand side you'll see this link to user guides for online registration, and I really recommend going through this first to have all the information at your fingertips when you go to register a facility. They're under the second link here in the middle of the page, registration for facility step-by-step instructions.

If you click on that link, it actually goes through, shows you the screens, what they look like, and step by step tells you what you need to have in front of you when you register a facility. So you can see the first thing it asks what type of registration and the type by type it means is it a domestic facility or is it a foreign facility?

So, all of this information, if you scroll down -- and it goes down quite a ways -- shows you and tells you what each field you're going to need to fill out and what information is required in those fields. So, this is really a good tutorial on how to register and what you're going to need once you enter the system.

I will go down to - I mentioned the food products. So here it gives the opportunity to tell us what kind of food and there's - you can scroll down in here what kind of food you're manufacturing and then what your facility does. Are you a warehouse holding facility? Are you a acidified low-acid canned food manufacturer? And I understand it’s really hard to read up here, it’s a little blurry. I have glasses and I can barely read it.

But you can then check each of the boxes, if I'm a manufacturer/processor I can check this box, which says that I'm a manufacturer of alcoholic beverages, for instance. So you kind of just go and check which products and what kind of process your facility does with that kind of food.

But I want to also go down to the section 12. This is that inspection statement. So, by checking or selecting this box and you have to, to get a registration, you acknowledge that FDA will be permitted to inspect a facility at a time and the manner permitted by the FD&C Act. So, that's where if you don't you have a business relationship with a company who is registering your facility, they have no business making that commitment to your facility.

So again, you want to advise the folks you guys deal with that again, it’s free and they're going to want to make their own registration or, again, have their authorized agent do it but with the understanding that they're giving them approval to do that.

And then Section 13 is that certification statement that you have that business relationship, that if you're not the firm itself, if you're not the owner/operator/agent in charge, that you have authorization to act for that owner, agent, or operator.

And it also gives that warning about the 18 US Code 1001, and I think both sites or both this and the prior notice have that warning that if you're giving false information to the government, you're giving - you're actually committing an 18 US Code violation, which is a felony.

So, you know, again, you want to make sure the information is accurate and again, that you have authority to do so. So, like I said, I only bring this up really because we've had this rash of these importers and third parties just registering companies willy nilly as if it was just an administrator filling out a piece of paper and they shouldn't be doing so unless they have that business relationship.

So again, this is that step-by-step instructions are really good place to start if you're going to register a facility. We're going to jump back. You can see there's information about the biennial registration renewal in this particular field and then additional capabilities in the FFRM, which is the Food Facility Registration Module.

Then you can see that there's a summary of fields in the food facility registration and then important there is a contact for help with food facility registration, that's our “FURLS”, or our FDA Industry Systems Help Desk. There's a phone number, two different phone numbers, an 800 number and a 301 number, and there's a Web address where you can send

emails to that staff to answer questions with respect to food facility registrations.

They are the staff that can also help you with accounts, so if you have an account to register because just like everything else you have to create an account first and then you can go register a facility. So, they can help you with creating your account or if you have problems logging in, they can help troubleshoot why you're having trouble logging into your account, so this is a great resource to have as well and it’s at your fingertips here on the Web site.

Want to point a couple other things out before we log in and show you how you get to the registration. There's guidance down here on the right hand column, there's guidance for industry related to food facility registration. I believe we're in the process of updating some of this guidance as it was linked to the Food Safety Modernization Act, so this is a good place to go as guidance is made new.

Here's a link on registration under Food Safety Modernization Act. And then compliance policy guide for FDA staff when it comes to enforcement. And again, that's a good link or a good document to read as well. So, to log in, to register a facility it's just log in, create an account. This is our FDA Industry Systems page and this is the same page you'll see in a minute when we go to do a prior notice that you would log in to file a prior notice.

So, my particular account has the ability to do both. I'm going to log in and put my super-secret password. And why did it give me that error? Because “I didn't understand.” So you have to click “I understand” and I make this mistake all the time. You have to understand that your 18 US

Code, that thing I just mentioned, so I didn't click the “I understand.” So hopefully it'll work this time. All right.

Okay, it liked it that time. So, once you get into this account management, you can see this particular account was signed up to do both registrations and prior notices. So, we're going to use it now, I'm just going to show you real quick how you would go in. So once I'm in my account, tells me my account name, I can go into the food facility registration, and then it gives me a number of links.

This is now in our FFRM or Food Facility Registration Module. I can register a food facility, a new facility, I can update an existing food facility, maybe we move two doors down and our address changed, that would require you to go in and make an update to your registration outside of that biennial requirement.

You can cancel, maybe your firm went out of business or you sold it, you want to cancel your registration because you didn't want to convey that registration number, you can cancel registration. You can search for one of your registrations. You can't search for any. As Domenic mentioned earlier, some of this firm information we're required by the law to keep confidential and so if you - you can't call up the FURLS help desk and say, you know, “What's the registration number for firm XYZ in Japan?” We're not allowed to give that kind of information out.

We can link a registration and then confirm. I'm not even sure what that means. But again, most people would go in to register, and I will add during the biennial, there is a link to update the biennial update because some of the folks in the first round went in and created a new one and thought they were doing an update and some used the update function and

what they really wanted to do was do the biennial update so you're really going to want to advise your folks to use the right button that it's abundantly clear, it says biennial registration update.

So we're pretending like we're going to register a new facility. And again, it just goes through step by step just like most Web sites, you know, this is going to be a foreign, are you a new owner of a previously… no, we're going to say no, and we hit continue, it takes us to step two. And this is where, again, if you have all the information, if you are the owner/operator in charge, you've probably got all the information right up in your head and, you know, you can do this with probably 10/15 minutes.

If you're an authorized agent to do it and you have all the information, you know, it might take you 30 minutes. If you don't have the information, that's where you're, you know, you're going to get stuck at certain points in this registration process. But it just goes step by step and asks you to enter all the information and I'm not going to go through it because it's pretty self-explanatory. I will note that there's starred (*) fields, those are mandatory fields, so it's going to not let you move forward until you have each and every one of those starred (*) fields filled out.

So we are actually going to go back to our FFRM home and, again, that's essentially the process of registering a facility and I always say, "Why pay someone $500?" And some of them charge it annually to register your facility when it's free. And it's not that difficult of facilities to do on their own, so - and quite frankly we like it that way because we feel like we're getting the best information if someone from the facility themselves is actually doing the registration.

Now we are going to go back to the FURLS home. So getting out of that particular site can be a little tricky. I had to click on “FURLS Home”- there was no - back button doesn't work, you have to go to FURLS Home, which takes you back to your account. I will note that you can edit or change your password or edit your account profile from this particular site as well and, again, it’s a good way to go in and manage your own account if you need to add things to it.

And FDA is really using this as a home. I don't know that if ITACS that Domenic mentioned earlier will use this account management system but I think it’s a good chance that they will because this is an existing account management system FDA has and you can see if you do medical devices you can set up your account to do medical device registration and export certification for devices, so depending on what kind of business you are, this is your account home right now for FDA systems.

So right now we're going to log out and go back to the FDA Web site to finish our… I think the “back” won’t work now, so I'm going to go back to the home page here and we'll go back to food, and we're going to go to one of the most popular topics, which is the prior notice of imported foods.

So Domenic mentioned some of the time frames. Are you guys familiar with prior notice at all? Show of hands. No? Okay. So I'll give you the quick background behind prior notice. Before prior notice of imported foods just came out of the Bioterrorism Act, and the Bioterrorism Act that you may be familiar with is a huge act, it has many, many requirements in it.

But one section Title 3 relates to protecting the US food and drug supply and a couple of new requirements within Title 3 were the prior notice of imported foods and the previously mentioned registration of food facilities.

Before the prior notice of imported foods, FDA often got notified of food shipments coming into the country long after the food was already in the country, and you can see that that's problematic in protecting the food and drug supply because foods would come in, you know, it could be 500 miles in the country under bond before FDA even knew it existed.

And, you know, with the threat of terrorism and unsafe products, you know, Congress said, “That's not - that's something that doesn't make sense.” FDA needs to be notified of those shipments before they arrive in the country so that we have the opportunity to target inspections of those shipments at the port of arrival to protect the US food supply.

And so with prior notice, we get that notification within, depending on the mode of transportation, two, four, or eight hours before that food shipment arrives into the country. So for land by road shipments, so truck-type shipments on land borders it’s two hours before arrival, and that's minimum time. They can submit it - it can be submitted up to 30 days in advance of arrival, but that's the minimum time frame is two hours before arrival.

For air and rail the minimum time is four hours and for sea shipments the minimum time is eight hours before arrival. And we are committed to having the answer for US Customs or our border staff whether or not we want to examine that shipment upon arrival.

So my staff is there 24/7, 365 days a year receiving prior notices, making those decisions so that the Customs and Border Protection officers and the FDA officers at the port know if we need to inspect those goods from a food defense perspective at arrival.

And if it can move into the country and move to the admissibility side of the house that Domenic mentioned earlier, then it can move in under that process. So again, you know, the process is twofold. We don't do the same thing the field staff in that admissibility process that Domenic talked about earlier. My folks look at the food defense side of the house. We're looking for intentional - effectively looking at signs that lead to intentional or could lead to the food was intentionally adulterated or signs that the shipment may be linked to terrorism.

So, those are the kind of things we're looking for. So that's prior notice of imported foods in a nutshell. And what I'm going to show you now is what - to see the information surrounding prior notice of imported foods, what are our policies and how to file prior notices. And I'm going to show you actually one of - only one of the two ways.

The way I'm going to show you is through our FDA Web site, our prior notice system interface, which again is free, it’s a way anyone can submit a prior notice for a food shipment.

Again, they're going to have to have the information about the food shipment to file the prior notice but they can file it on their own for free. The other option is to use a Customs broker, which is probably 80% of the way imported food and imports come into the country probably in most other areas it’s near 100% go through a Customs house broker.

That is a licensed broker by US Customs and Border Protection who are licensed to file all the paperwork and all the information with Customs to make sure that that shipment can legally move into the country. Those licensed brokers can also file prior notice as well and, you know, some companies, commercial shipments, they just prefer to give the entire package to that broker to say, “Do all of the things you need to do to file for this shipment coming into the country,” and that would include the prior notice.

This system is available largely for informal shipments, so low-value shipments or, like, land where I came from the Detroit office of FDA, where you can almost throw a rock into Canada across the Detroit River, and there's a lot of informal shipments that flow across that border and mean informal is less than $2500 worth of goods. So, stuff manufactured in Canada coming over the border to be sold in Michigan and the surrounding areas and Customs says under value of $2500 there's no formal entry that has to be filed.

That doesn't negate the requirement for prior notice. Prior notice still has to be filed for those shipments and so this system allows companies who are in that kind of business to file prior notice. Customs sometimes does force low-value shipments to file formal entry but it’s usually based on violative histories or problematic histories of, you know, the importer or the supplier source, but there are policies related to low-value shipments.

So, the Prior Notice System Interface about 16% to 20% of those prior notices filed come through this system. The information is the same regardless of if you go through a Customs house broker or the Prior Notice System Interface, but the actual process is a little different and I'm going to take you through that process.

But I do want to show you again we have a step-by-step instructions so that if you haven't done it before, you can do that first, go through those instructions so you understand what are the - what's the information you're going to need prior to filing a prior notice and there's also further on down you can click the information on the final rule related to prior notice. The Food Safety Modernization Act modified the requirements for prior notice one small area.

The Act said that now with prior notice if the food being imported was ever refused entry by any other country, you have to tell us what country that was. They don't have to tell us why, but they have to tell us the country that refused that particular food. And by that particular food, I mean the food in that shipment, not this commodity was once refused entry by Germany 10 years ago.

No, it's the food in - that's coming into the United States, this particular shipment, if it was refused entry, they have to tell us what country refused that food. And of course, what are we going to ask? Why?

So, typically that's going to be the next question coming to the importer or the filer before we allow it to move into our country. But even US goods, so if some food that's manufactured in the United States goes over and is refused by Japan and it comes back into the United States, it has to have prior notice and they have to tell us that Japan refused that food when they file the prior notice.

So, it’s a small change but it did require us to go through the rulemaking process again and add that requirement into the rule and the prior notice final rule became effective again May of 2013 so it’s about six months, the

final rule became effective again. The actual rule has been in place. We're coming up on our 10th year anniversary of the prior notice of imported food requirement, it was December 12, 2003, when this process started, so we've been going at this for about 10 years.

The other two important guidance documents that are helpful are questions and answers. This is commonly-asked questions, so if you have something that you have a question about prior notice is a good first stop to see if that question has been asked and what FDA's policy is on that particular issue.

This particular guidance document, these question and answers, is under revision because of the Food Safety Modernization Act change and that refusal country, and we hope to get that out, our goal was to get it out by the end of the calendar year 2013.

It's under final review. I can't predict whether it's going to come out by the end of the calendar year but I would expect if not by the end of the calendar year in the first couple of months in 2014.

The other good piece is the Compliance Policy Guide, which I will click on, which talks about some enforcement discretion areas with respect to prior notice. And I bring this up because one of the questions I heard asked earlier about samples and I think the question more related to trade samples or for show, a trade show, and as Domenic correctly pointed out, those would still require prior notice.

Samples going to a laboratory for testing may not. So if you're, you know, someone sending one can of soup in to a laboratory for analytical testing, we're generally not going to require prior notice for that particular shipment because it's not intended to be consumed, it's intended for

laboratory analysis. But this talks about some of those - some discretionary areas.

Let's see, what's another one? Seeds for cultivation are mentioned in here. What's another one we get common questions on? Here's food for quality assurance research and testing is under B, and then food for noncommercial purposes with a noncommercial shipper irrespective of type of carrier. So, person-to-person shipments, so if I send something to a family member.

And again, it's I'm sending it, it's not a business, I'm not a business and they're not a business, I'm sending a person-to-person shipment, will generally not require prior notice. It doesn't mean it's not required, and that's a distinction. It's just an enforcement discretionary, we're not going to enforce it if it's a person-to-person shipment.

But if you have a mail order business or if someone goes on Amazon and orders it or eBay or whatever or company's Web site and the company ships it to a person, that's a commercial shipment, prior notice is required, and we don't waive - we don't exercise discretion, I should say, in those cases, so prior notice would be required.

So again, this is a good policy document. This has been updated periodically so again, if you read it once, you know, it's good to come here periodically and see if the policy has changed.

All right. So I'm going to - how are we doing on time Sousan? Okay. All right. Doing good. So, I'm going to go ahead and log into our account again. Hopefully I can get it right the first time. So this, I'm going to go ahead and click on the prior notice of imported foods. And that takes us

into, you can see the name of this system is the Prior Notice System Interface or PNSY, you might hear that term, PNSY, that's just the acronym, fancy way of saying the acronym.

So again, there's, you can use a number of links, you can use the Get Started, which gives you an overview. There's a link for new features. And this particular system is updated periodically but typically it's only when there's either a bug identified and/or a new requirement, like we had to modify it for that Food Safety Modernization Act change for refusal country, but other than those changes it's pretty static because the prior notice rule, the information that's required hasn't changed all that much and this has been a pretty stable system for the last several years.

Typically if you're going to create a new prior notice for a shipment you're going to use the click the "Create New Web Entry." I know that isn't really necessarily intuitive but that's effectively - again, these helpful hints here are invaluable if you actually go read them but, you know, if you're like anybody, I do the same thing, I'm, you know, you just, you wildly click, you do things without reading all the fine details of, but this will really tell you - this is where you start if you want to file a new shipment.

If you're going to - maybe you started one and you need to finish filing the prior notice, that's where you might want to find an existing Web entry or find an existing prior notice that you started and didn't finish. So, we'll go ahead and click create new Web entry, and again, it's going to take us step by step. And I'm going to actually go through this process.

So, the first thing it asks us for is the entry type. And if you need help on entry types, you hover over the need help and it's going to tell you what each of those entry types mean.

So in this case, we're going to choose consumption, almost all the shipments that come in, you know, it’s a probably good 80% that come in are actually consumption entries. That means they are intended to be consumed within the United States. Obviously, there's more specific things like baggage or mail, that means it’s coming in either through someone's baggage or through the mail.

There's transportation and exportation. Because for prior notice, even food transiting the United States has to have prior notice before it crosses our border. So if something is manufactured in Mexico, for example, but its destination is Canada but it’s going to be trucked through the United States, they have to file prior notice to actually move that food through the country.

So they would choose transportation and exportation. But like I said, most of the shipments would be either consumption or consumption express courier, which is if it was coming in through one of the express couriers like FedEx or UPS or something like that. We're going to actually use consumption so we select that off the list of values and then we click next.

The next thing it’s going to ask us for is entry information and it asks us for an entry identifier. If you are not a Customs broker or you're not working with a Customs broker, you're probably not going to have an entry identifier. The nice part is if you don't have one, you can click this not known and the system will generate for you an entry identifier. We're real nice, like that, you know. We don't stress you out. If you don't know it, we'll create one for you.

It’s a joke because that's about the only thing wrong within the system. So, but we will generate one if you don't have one. If you're working with a

filer, maybe they're going to do the rest of the shipment documentation for you.

You can ask them, “Does this shipment have an entry identifier.” And if they give it to you, you can actually enter it in to this field and entry identifiers are set up with a three-digit filer code, each filer license customs filer has a three-digit code and then the rest of the digits on the code or the entry identifier are the entry numbers.

So, in our entry identifiers are set up similar but you'll see a pound, pound, pound in front instead of the filer code if it’s a consumption entry or any of the others other than mail, which will show up as plus, plus, plus as an entry identifier. So, we're going to then select how many prior notices. In this case we're just going to select one.

Prior notices are dependent on the food coming in, in the shipment. So each food that has a unique manufacturer FDA product code or package size requires a separate prior notice. So for instance, if you're bringing in canned tuna and you have six-ounce cans, eight-ounce cans, and 12-ounce cans, they're all manufactured by the same company and they all have the same FDA product code, but it’s because of three sizes, that's three prior notices.

If you have waffles and soup, that's two prior notices. If you have strawberry waffles, blueberry waffles, and cinnamon waffles, how many is that? Anyone want to guess? I heard one. I heard two. I had cinnamon, blueberry, and strawberry waffles. All manufactured by the same company, all 16-ounce packages.

The actual answer is one. A lot of people say three because I have three flavors. The difference here is FDA only has one product code for waffles, so regardless of flavor, we only have one waffle product code. So technically speaking you only have to file one prior notice. But in this case, we always encourage folks you can file one each for the different flavors because if FDA decides they want to sample just the strawberry, then - and analyze it and release the other two, you can release the other flavors without holding it.

If you file it all under one, you're probably going to get stuck holding all your waffles. So, again, you know, under the rule prior notice is required if you have unique manufacturer, a package size, and/or an FDA product code. I'm going to make it simple for us, we're going to just do one.

So we'll enter one there, go down to the next section, which is the port of arrival. In this case I'm going to say it's going to come in through Detroit, so I'm going to select Michigan and then I'm going to ask if I don't know the port code, I'm going to ask to find the port code. I use the list of values for all the ports in Michigan and I can select Detroit, which is 3801, and then click next, and it actually entered the port code for Detroit 3801.

Next thing it's asking me for is the anticipated arrival date, and again, this is what it says, anticipated arrival. It doesn't have to be exact. So, I think it's coming in I was told by the shipper it's going to come in on Friday so I'm going to put 12/6, and then and I'm told it's going to be there by 9:00 am so I'm going to select 900 hours.

So again, just anticipated, doesn't mean you have to be exact when it comes through anticipated date and time of arrival. The one thing it will bounce out is if I say it's, you know, 60 days from now, it won't let me do

that because I can only file at the max for Prior Notice System Interface 15 days in advance. So it will only let me put a date 15 days from the current date.

All right. So then I go to submitter. Who can submit a prior notice? Anyone care to guess or read the regulation? Stay up late and read prior notice regulation? Anyone can submit a prior notice. Anyone with the information is allowed to submit prior notice. In this case, I'm the submitter and I'm also what's called the transmitter. I'm the one punching the keys here so I can actually say that I'm the submitter for this Web entry, I can click yes, and it's going to take the information from my account as the transmitter and copy it into the submitter field.

If I'm not the submitter, I click no and then I can go to the enter submitter information and enter my name, company name, if applicable, and address. But in this case I'm just going to say "Yes", and I'm the submitter as well as being the transmitter, the person clicking the button. Now, for importer, is the importer the same as the submitter? Might be but in often cases no.

So in this case I'm going to enter the importer, and again, and I didn't show you the other one because the field pretty much looks the same and I can enter the importer information so I'm going to enter Tony's Imports, date, and the zip code.

Now, the field at the top, food facility registration number, if Tony's Imports is registered and I know the registration number, I can enter it here. It's not a required field so I can leave it blank. The other thing you'll see there's another thing, add to my favorite list, maybe I do prior notices all the time for Tony's Imports and I want to add it to my favorite lists.

Well, I can only add it to my favorite list if I have their registration number.

So, in this case I'm not going to be able to because I don't have Tony's Imports' registration number so I'm just going to hit save here and then it's going to enter Tony's Imports in my importer section of my prior notice or Web entry in this case.

And then the last thing on the Web entry it asked me for is the "Carrier." It's going to ask me first for the "Mode of Transportation" so I'm going to say land, by truck, and then I'm going to enter the carrier information on the next page. And the first thing it's going to ask me for is the SCAC code, which is the Standard Carrier Alpha Code. What if I don't have this but I know it's FedEx Ground, for instance?

I can actually, let's see, I can actually find a code by putting the carrier's name in, do a search, and there's my carrier listed here. So any firm that has a SCAC, and most common carriers have a SCAC, it's probably 95% of shipments come in using a common carrier so they would be able to find them in here, so if you have that information you can find it.

If not, if it's a privately-owned vehicle, you can put the license number, the issuing state or country, province of that license number in these fields, and then go without a carrier name and SCAC code. A "Trip Identifier" is, you know, just like on a flight, a flight has a flight number, you would put that here if a shipping line has this is, you know, trip identifier 456 you would put that here. A lot of truck shipments don't have trip identifiers so I can leave that blank.

And then for a “Bill of Lading,” I would want to put the bill of lading in the documents, bill of ladings all start with, if they're a common carrier, start with that SCAC code and then it’s a series of numbers. So I'm just going to make one up and then save that carrier information. So once I have the carrier information entered, I'm ready to go ahead and move to file the actual prior notice for the food that's coming in on the shipment that we just told you about the actual shipping information.

So I'll click “Save,” it takes me to this new screen where then I can create a prior notice. It shows me all the information I just entered as well. So I'll click “Create a Prior Notice” and now it’s going to start asking me for information about the food and the shipment. So first is what is the country from which the article is shipped? And we're actually going to say Japan, put in the first letter, it will take me down to the J, there we go.

Next is “FDA Product Code;” Domenic mentioned that ITACS is hopefully soon have the product code builder, PNSI has the product code builder right in it so if I don't know it I can find or do a search. In this case I'm going to say I have soup so I'm going to look up soup. I'm actually going to say I have vegetable soup, and you can see all the different soups that are in. So I'm going to find the best one that fits my particular product and I'm going to say this is actually mixed vegetable soup and it’s concentrated so you have to add water to it as a canned soup.

Once I select that, it selects a part of the code for me. All I have to do is build the last two parts, first being the packaging method, so my soup’s in a can so it’s metal, so I'm going to select the metal E and then the process that applies and that's commercially sterile because it’s low acid canned food. The packaging method is what's touching the product, so what is physically touching the product, in this case it’s metal.

If it was packaged in plastic, you would choose plastic or flexible plastic, non-flexible plastic, depending on the case. If it was in class you would choose glass. If it's, like, boxed macaroni and cheese where you have multiple surface, you can choose multiple. But in this case we have metal and our process that the soup is manufactured is commercially sterile. So I select those two, hit the select button, and now it's told me my code is 38BBEE28.

If I know that, I could have typed it right in, and a lot of companies keep those handy so that if they do the same thing over and over they can type them right in. So, I can put in if it's a corrected description, vegetable soup. If you want to put the brand in, you can put that in as well and the common or usual market name for it.

"Production Identifier", this is like lock codes, so a canned soup typically has some kind of number stamped into the code or onto the lid or jet coded onto the lid. I'm going to enter what I find at the end of that can, Hit save, and then it goes to quantity and packaging, and this particular section can be a little tricky so if you haven't done it before I suggest using the wizard, which kind of graphically tells you that you start with the smallest package, so that's the base unit, in this case a can size. There's so many cans to a carton and so many cartons to a box.

And so the process, this will actually walk you right through it. So I'm going to say we've got a 12-ounce can. I can enter 12 in the quantity and then select ounces in the measure, click next, and then I'm going to say how many cans are in a box, and I'm going to go with 24 as well. Click next and I'll say that there are 12 boxes per case. And then once I do that, I can click finish and you can see it tells me again 12 ounces is the base

unit, 24 boxes, 12 cases per box, and it does a quantity of 3400 total ounces in that shipment.

And click okay. And again, I could have done it without going to the wizard but the wizard kind of walks me through the process in a more easy way. So, if you have experience in the system, it's pretty easy. And the last section on this particular page is the refusal information, has this article been refused entry by any other country? If I say no, which is the default, I don't have to enter a country. If I say yes, then I can click on the particular countries.

And you can actually, if it was refused entry in multiple countries, you can use the control click to select multiples. In this case I'm going to go back to no, and it's going to take those out for me, hopefully. Hit save. Now it took me to the next field and you'll be glad to know this is the last part of filing a prior notice, and that is the facilities associated to that shipment.

So in this case it's asking me first for the manufacturer, it's going to ask me what country that's from. I'm going to say Japan again. And then I can enter the manufacturer. In this case you see food facility registration number is asterisk because it's required. A little bit of a misnomer because if I don't have it, I can use this field down here and I'll talk about that in a minute but I want to enter I'm going to say I got the Tokyo Soup Company.

Does Tokyo have Oak Street? I figure most cities have an Oak Street, at least most cities in the United States. Does Tokyo has zip codes? I don't know. Does anyone know. You can see it's not a mandatory field because not all countries use zip codes, but if you do, again, you can enter it.

So, if I don't have the food facility registration number, I can use either the manufacturer is not required or registration number is not known. If I choose that, I have to put a reason I'm not giving a registration number. And in this case there's a choice called unable to determine registration number of the manufacturer, and that is a perfectly legal way to do it. This is where you get into that tricky part of manufacturers who aren't registered, foods coming in because the registration number is not a required data element.

But we went through a long battle with the rule because originally it was required and we kind of lost out in requiring it as a final element in the final rule and so it’s no longer required. We- if we- what we tell this trade is that if you don't give us the registration number it may take us longer to process those shipments and you may not have the answer when it hits the border.

So, again, it behooves those in that supply chain to have those registration numbers where they apply and put those in the prior notices so that they can be processed in a timely manner. But it’s legal under the rule to submit it without. It'll also ask us if the manufacturer would be the default for new prior notices for this web entry if we had multiples coming from the same, if we had mushroom soup and tomato soup, we could say yes and then it would copy that information in for us.

In this case we're going to say no. Again, we can't add it to our favorite because we don't have a registration number so we'll just hit save here, and it enters that information for us. For the shipper, I'm going to say that the shipper is the same as the manufacturer so I'm going to enter the country. If I go to shipper, I'm going to say shipper same facility as manufacturer, hit save, and then I don't have to reenter that information.

The owner, I'm going to do the same. The owner is who owns the goods at the time of the shipment and I'm going to say they're still officially owned by the manufacturer. Let's say maybe because maybe the importer hasn't paid for them yet. So it's the same as the owner and then the ultimate company. In this case I'm going to say they're being delivered right to the importer so I can say ultimate company is the same as the importer.

Don't have to waste my time reentering it, hit save, and I've just buzzed through entering all that information. So you can see we do help a little, you don't have to reenter those things multiple times if you've entered it already under one of the other parties.

The last thing on this page is the holding facility. This only has to be entered post-refusal. So if we refuse this for some reason and the shipment has to be held at the border and moved to a holding facility, you would have to come back in and enter a holding facility.

Most prior notices don't have to have a holding facility entered, so I can leave this blank and move on. So once I'm done with that, I can go ahead and submit my prior notice by clicking that button. It's going to summarize all the information I just entered. If I'm cool with it, if I don't have any other edits, I can say yes, submit the prior notice, and it's going to ask me if I want to complete my Web entry so that if I want to enter additional prior notices, I could.

I'm going to say no, that's it. But you can see it's already given me a prior notice confirmation number, and you can tell the nomenclature for the confirmation numbers always start with the last two digits of the year so

we're in 2013 so the first two digits are 13 and then a numeric sequence of numbers for my prior notice confirmation number.

So I'm going to go ahead and hit yes here. I can complete my Web entry and I just submitted a prior notice to the FDA. If I want to print a summary for my records, I can do that by clicking the “Print Summary” button.

For shipments where someone's bringing it over, this is a good way to hand carry something either a truck driver could carry this, present it to Customs at the border. It has a confirmation and a barcode that they can scan so they can easily process the answer or get the answer on FDA’s answer on can this shipment move past the border, so this is a useful thing.

This isn't required if, you know, it’s being loaded into a container, do you have to have this inside the container? The answer is no. But it is a useful tool for more of those informal-type shipments. So if I want to go back to the home screen and find that existing Web entry I just submitted, I can click on that button and it’s going to show me - or actually I'm going to do completed because that's one I just completed, and then search.

I should be able to see the prior notice we just filed. Did anyone get the Web entry number? Is this it here? 3801, probably it right there. No, that's a different one. Oh yes, it’s this one then 12/6/2013, right? Isn’t that what we said? Here it is, vegetable soup.

So again, if I have this shipment over and over again, I can use this copy function and it will copy all that information into a new shipment and all I have to do is update things like anticipated date of arrival, maybe the quantity, maybe the next shipment isn't quite the same quantity, any

information that changes I have to go back in and update but it does save me the time in retyping it.

The thing you want to warn about copy, using the copy function is you have to go back in and make sure those fields, that change are updated with the new information, but it is for time purposes you cut 75% off if all the rest of the information stays the same, if you have that supply chain constant, you know, you can use existing prior notices to quickly file new ones.

So that's pretty much Prior Notice System Interface in a nutshell. Any questions? Either on prior notice of import of food, food facility registrations, or filing a registration or filing a prior notice? I've done a great job.

Import Operations

Captain, Domenic Veneziano, Director, Import Operations
Office of Enforcement and Import Operations

(Domenic Veneziano): Get you a better understanding of the process on Import Operations because it can be very confusing and give you the opportunity to put faces or contacts as we mentioned. It is extremely important to know who to contact to get answers to certain things. And we're going to give you an organizational structure; we're going to talk about products that we regulate. I'm going to talk a little about the field process and how everything comes together and how it works and import alerts and understanding what an import alert is.

How to get off the import alert so that you can do a better job or communicate to your constituents in terms of how the process works related to FDA. We are going to hold questions, I guess, to the end. And I welcome any question that you have related to Import Operations or FDA in general because it can be a very confusing thing. And we'll talk a little about the structure and how it all works together.

The products that we regulate: human food, animal feed, cosmetics, drugs, biologics, medical devices, electronic products that emit radiation and tobacco. This can also be confusing.

I was speaking to the theatre earlier about some of the products that they bring in. There are times when products have joint jurisdiction so a medical device that coded with heparin can both be regulated by the Center for Device and Radiological Health as well as the Center of Drug Evaluation and Research. So you do have the understanding of how each of them play in - play together.

Our responsibility in terms of FDA, obviously, is to ensure that food is safe wholesome and sanitary. That human and veterinary drugs, medical devices, and human biologics are safe and effective. Cosmetics and electronic products that emit radiation are safe. Tobacco products comply with the new regulations and labeling of those products.

Within ORA our mission is to protect consumers and enhance public health by maximizing compliance and FDA regulated products and maximizing risk associated or minimizing risk associated with those commodities. And the way we do that is - it all comes together.

Whether it's an import or whether it's domestic inspections or foreign inspections we all work together in terms of making sure that products that are imported are safe and making sure that we have the controls in place to do that.

I know that you're going to get a presentation later from one of my co-leads, Brian Pendleton, on the Foreign Supply Verification Program. We're going to talk a little bit about FISMA, the Food Safety Modernization Act. And talk about what it means. And the whole intent of FISMA and the other laws that are coming out like FDASIA which is a Food and Drug Administration Safety and Innovative Act.

Is that gives a relationship both in the foreign arena as well as the domestic arena. And how they all link together and how they all work together in terms of protecting the consumers from products that are imported or that are made domestically.

We do have a new structure within FDA and that's from the Office of the Commissioner, she started - Commissioner Hamburg, began and wanted to, kind of, condense the Agency so that it was better managed.

It is now broken up into three directorates: the Office of Foods, the Office of Medical Products and Global Regulatory Operations and Policy. The Office of Regulatory Affairs and the Office of International Programs that put together this program are linked together because we all work together. So the inspections and the people within countries like the Asia Pacific Office and the Office of Regulatory Affairs work closely together to make sure that inspections are conducted, that we're communicating closely together, that anything that might be emerging within different countries are also comes back the Office of Regulatory Affairs into other centers so that we can take the appropriate actions.

Again the structure is seven centers. One of them, the National Center of Toxicology and Research, it's kind of a research laboratory aspect of it but the rest of them are centers where they are product specific.

The only one that isn't, and it's highlighted in red, is the Office of Regulatory Affairs where we have oversight with all the inspectional process and the import process of all commodities so we work every closely with each of the centers to make sure that the policies are in place and that we communicate with them in terms of the inspection process, the priorities in terms of products, as well as said in the policy that we have to utilize in order to do the inspections.

And this is a very, kind of, a busy slide but it's how the Office of Regulatory Affairs is structured. We have five regions in the field. So we have a headquarters office as well as the field offices. We have the Office of Resource Management that handles the work plan and aspects and all of the budgetary issues.

Then we have the Office of Criminal Investigations. They're the arm that handles criminal activity. And anything that leads from a regulatory aspect, get turned over the Office of Criminal Investigation if there's criminal activities that are ongoing.

They also do a lot of work in terms of counterfeit products and intentional fraud and aspects in terms of misconduct in terms of criminal activities. They also have offices and have connections both on the international aspect too. So they have an arm to reach out to overseas if needed.

The Office of Operations, which is where I fall under. And we'll talk a little bit more about them later on and then we have, obviously, the IT staff. Our Associate Commissioner of Regulatory Affairs is Melinda Plaisier. She is fairly new and she's been acting for over a year but is now permanent in that position and the Director of the Office of Operations is currently in an acting position is Ellen Morrison.

Underneath the Office of Operations, we have several offices. The Office of Enforcement and Import Operations, is where I fall under. We handle both the enforcement aspects as well as everything related to the importation of products. And again, it crosses all product categories.

Office of Food and Feed, as it sounds, it specifically handles the investigations and inspections of facilities related to feed. They are also the ones that handle all foreign inspections associated with the food or feed overseas. They set up the plan and they do the contact to the manufacturers and they're the ones that send out the investigators or identify who the investigators are going to be to do those inspections.

Office of Medical Products and Tobacco, very similar to the Office of Food and Feed where they handle all the medical products aspect whether

it’s a drug or devise. They handle and work with those centers, to deal with the inspection processes and the foreign inspections as well.

Now, Office of Regulatory Science that’s our laboratories arms. They are the headquarter component that works closely with all of our fields to handle all of the science behind the commodities so if something has to go to the laboratory they're the ones that buy the equipment, make sure that the field gets it and handles it that way.

And then we have the fields which are the regions. Those are - they're broken up into five. There's the Northeast Region, there's the Southeast, the Central, Southwest, and Pacific. Five separate regions across the county that handle Import Operations as well as inspections. So those district offices are where the inspections get done. They are the people on the ground that stop the products, that inspect the products, that collect the samples, send them to the laboratories on the import side.

Again the field that's five regions. We have 19 districts and one called the Southwest Import District so 20 districts all together. Sixteen of those districts are related to Import Operations. So although products we have ports in all across the country 16 of them really have responsibilities associated with looking at Import Operations.

We have several resident posts and border stations. And the component within the district office, obviously, there's Investigations, there's Compliance and then there's Administrations within the office.

This is how it's broken up in terms of locations. So you see the different regions and how it's separated. Office of Operations, I talked a little about. The Director of the Office of Food and Feed is currently David Glasgow who's in the acting position. The Office of Medical Products and Tobacco

is Alonza Cruse and he is also acting. Office of Regulatory Science, Brian Baker, also acting. And the Office of Enforcement and Import Operations is a new person who just got hired, Doug Stearn, most recently.

So I just wanted to give you a little overview of some of the stats. So Import Operations, we handle things called lines. So every shipment that comes into the United States as it's defined by its commodity. So if you're bringing in a tomato and you're bringing in some pasta, each one of those has to be separated within the entry on a line, and we call it line.

So over the past, in FY 2013, we saw approximately 30 million lines of entries that we have to manage. And that number is increasingly going up as you can see from a 10-year period.

Broken down by categories, historically, food has always been the highest percentage that we've always seen. It's always been about 60%. And all the other commodities, devices, being the second largest was always next. As you can see, it's kind of shifting. Where devices is increasing on the importation side and food is kind of leveling up. And it isn't because foods is decreasing, it's because everything else is going up and there's been some changes to how things have to be submitted.

So recently, I want to say two years ago now, components had to be identified on a separate line for devices and as a result of that, those numbers increased, obviously, in terms of our counts. So that was part of the process and the difference of how it's going up.

Just a little bit about my organization, as I mentioned, I oversee the entire field and provide guidance to the field. We're broken up into a couple of branches. One is the Implementation and the Development Branch and the other one is an Operations Branch. We have several people within that

branch. I do want to let you know that if you have questions about how to import product into the United States, we are happy to help you.

We have an individual who answers the phone, and their sole duty on a weekly basis, is called a Rotational Duty Officer. Their responsibility is to answer questions related to Import Operations or they can direct you to the right person.

So I'm going to give you my number, I don't think I have enough cards to go around to everyone, so I'm going to give you my number, and you can - it will be at the front desk, and if you do have a question, they can, or anybody that has questions will be happy to help you. That number is 301-796-0356.

And just ask for the Rotational Duty Officer or let them know that you have a question related to the importation of a commodity or you have a question and they will make sure that they back to you, and that's their sole responsibility. So if they don't get back to you immediately, they will do that, usually, if not that same day, it'll be the next day.

I do want to mention, we do have a Systems Branch as well. So when people are looking for data, and we have IT systems, these are the individuals that we go to in terms of extracting that data and providing it to individuals in terms of certain commodities.

I would ask that if you are looking for data that you work through the Office of International Programs and (Leigh) and (Sema) can help you do that, in terms of getting the right person if you are looking for information. There's a process most times. You have to go through the Freedom of Information but there are times other things are public and they can help you or at least help facilitate the need for data if you're looking for it.

Our responsibility obviously is to direct and provide leadership to the field as well as provide consultation to senior management all the way up to Congress. We have testified to Congress on the importation process as well as developed a lot of the operations related to the new laws that are coming out.

One of the other big responsibilities we have is to be the liaison to Customs and Border Protection. So as part of that process when you import products, the first you thing you have to do is submit information to Customs. Customs and FDA have an interface through our IT.

We were the only agency for the longest time to have the only interface with CBP so that we could get real time data on anything that's FDA regulated. So when you submit it to Customs, you do it through the tariff number and it also identifies whether that product is FDA regulated or not FDA regulated and it's called a flag and there's different types of flags.

You also have the capability of disclaiming that shipment so if you believe that that shipment is not one that regulated by the agency you can click a button and it says it's not for use for FDA; it's not an FDA regulated product or I'm not going to provide the agency with information.

And I'll going to give you an example. Rock salt, for one, salt, table salt is regulated by FDA and you would have to provide information to the agency related to the importation of table salt. However salt for the road, is not regulated by FDA, so if you're importing that, you could disclaim it and say the use of that product is not being, is not for FDA purposes and therefore we don’t have to submit any information to the agency.

So a little bit about the import process. The field activity, they're the ones that see the entire process. They see all of the entries and they make the decisions on what should be looked at and what shouldn't be looked at.

The Prior Notice Center, or I should say, the Division of Food Defense and Targeting now, conducts what we call Prior Notice Reviews. One of the things under the Bioterrorism Act of 2002, created a office so that we could look for emergency or death or serious injuries related to food to protect the consumers from terrorist related activities.

That office was founded in 2002. I had the pleasure of actually opening that office and running it back then. It is only for food. The main purpose behind that is because we never had an approval process for food. We do have an approval process for all other commodities. So there is a big difference between what gets reviewed and is allowed into the country for drugs and devices whereas there's an application process and review process but for food there really isn't.

So they created this under the Bioterrorism Act to make sure that we could screen before products arrived. A big difference between the admissibility process. Prior Notice takes a look at all of these high risk shipments and screens them and we have to do it based upon the, a certain amount of time so two hours, four hours, eight hours. And we'll talk a little bit about that later dependant upon the mode of transportation.

They look at it for high risk issues and terrorist related products before the products arrive at the United States so we try to make sure that we screen everything out. And we don't utilize it or stop shipments often related to that, because if we do have a major concern it is a big event in terms of stopping something.

We have what we call entry reviewers and investigators out in the field. The Entry Reviewers take a look at the submissions of all of the data that is submitted to Customs and that ultimately comes to FDA.

They look at screens and they can set up field exams, label exams, sample collections and analysis. The investigators are the ones that actually go out and do the work but the entry reviewers are the ones that make those decisions.

We also have a Compliance Branch. So when a shipment is detained by the agency, it goes over to the compliance staff that makes - that looks at the detentions. They make the decisions whether something should be released. They make the decisions and work with the importer on the hearings and the reviews so we'll talk a little bit about the hearing process. They look at the reconditioning, they'll do some of the supervisions and reviews of those applications and they do the refusals.

We have post refusals. That is the Export Division. So when a product is refused, one of the requirements is that you have to work with Customs to have it exported out of the country within a certain amount of time. One of the things we want to do is make sure that the product that was actually refused is the product that actually is being exported.

Often times we have people that would substitute those products and get the ones and change the products that were refused to products that they really don't care about and let them get exported. So we verify what's going out.

We also make sure that we do the same thing for destruction. So you usually have the option of destroying your products or exporting the products. If products are going to be destroyed, again we want to make

sure that the product that is being destroyed is the product that we have concerns with.

We also do entry filer evaluations, they're called. So one of the biggest things because the import side is so heavily reliant on the data that we get we audit or we conduct evaluations on the filers or the brokers that put in that information. So we look at things like disclaims, "What are you disclaiming?"

Is it something that FDA should've looked at and did you, the filer, disclaim it intentionally. Did you do it by accident? Did you circumvent our system? Did you provide the wrong product code or the wrong information to us in terms of everything. So we do any evaluation on that.

And is there, is - we'll talk a little bit about the relationship again between the manufacturer, the importer of record, and the filer because it's extremely important, if the evaluation is a bad evaluation, it affects the timeliness for the releases for shipments.

Because if we can't trust the data we're going to stop the shipment and we're going to look at it. And now through our transparency initiatives, those filers and those brokers that are found to be out of compliance, if you will, are publicized. So you can go online and you can see the status of whether a broker is doing things correctly or doing things incorrectly.

This is a very busy slide, which is something that the Agency has to do it seems like all the time put up something that's really not understandable. But this is actually the process of importation. And we're going to walk through this but this is what it really looks like. It starts from an importer, it goes through the prior notice part of it, which is in blue, goes through an

entry reviewer, a decision is made. If it gets held up it goes to compliance officer, looking at things.

The product is detained. You have 10 days to overcome that appearance of a violation which is called a hearing or a testimony and then if you provide information that does overcome that appearance the product can be released. If not, the product is refused. And we'll walk through each one of these steps as we go through the presentation.

So again, starting from the beginning, an importer, or designated Representative must file an entry and an entry bond with Customs pending a decision to allow the goods into the United States. You have to notify FDA of certain things if it's an FDA-regulated commodity and being used for FDA purposes. Investigators evaluate the admissibility of the product electronically. So we look at all the data on screen.

And again the entry reviewers can make several decisions. They can release the product into commerce. They can request examination of the product, they can request additional information or documents and they can recommend a detention on the spot. So additional documents can be in the line of invoices, purchase orders, who reg - whatever, if the company is registered. And we call an End User Letter, meaning that if it is a drug, we want to know that it's actually going to a facility that’s within the approved application.

It could be a number of things, so they make all those decisions to determine what happens next. If FDA allows the product to may proceed, the product may be distributed. Big difference, it may be distributed if we allow it to be -may proceed. If it does get distributed, one way or the other whether we look at it or whether we don’t look at it, FDA doesn't lose jurisdiction over that product.

So we have two different criterias. One, an Import Status, and then it's in Domestic Status. Once it's in Domestic Status we still have jurisdiction. We can do recalls, we can seize product, we can take appropriate action if we find that there are violations.

Just because we release commodities, doesn’t mean that that product is actually in compliance with all FDA laws and regulations, so it's a big difference. We do look at it for certain aspects in terms of the importation process. And while we are looking at it, it's still in Import Status. Until we actually provide a release, to the importer of record, letting them know it's been released, that product is still considered to be in Import Status. Again, that does not preclude FDA action if a problem is found later.

So let's talk about section 801 of the Food and Drug Cosmetic Act because that's where the import provisions lie. If it appears from examination of such samples or otherwise that such articles have been manufactured, processed or packed in unsanitary condition, such article is forbidden or restricted in sale in the country in which it is produced or such article is adulterated, misbranded or in violation of Section 505, which has to do with the drug provisions, or the Importer is in violation of Section 805.

That sentence came out of FISMA. So that's a new provision that's within there. Or prohibited for introduction or delivery for introduction into interstate commerce under 301II which has to do with the prior notice requirements.

The record keeping requirements under section 204 of FISMA again, a new provision that's in there. Then that article shall be refused admission. So it's important; take a look at the word appears. It means I don’t actually need a violation to prevent products from coming into the United States. I

only need the appearance of a violation which is a big difference from the domestic side.

On the domestic side, if we were going to recall a product, we need an actual violation, in order to do that. In the import world, I don’t need that. But I will explain that a little more because it's not just as simple as saying, "I need an appearance of a violation". The Agency does work on evidence. So when we do things we still need evidence to take appropriate actions.

So looking back at this, if it appears, from the examination of such sample or otherwise - now lets talk about the or otherwise - or otherwise means, that I can get information from almost anywhere, so a facility inspection can show that a facility is in violation or is not following GMP, Good Manufacturing Practices.

It could show that the facility has insanitary conditions. As a result of that, I could take the appropriate action of any products coming in from that facility. So we'll talk about import alerts and that’s the process of stopping products at the border for things that come in.

So if we get a facility inspection that shows violations, if there's an examination, if we sample a product and we find the product that's contaminated with salmonella, we can stop that product. Laboratory examinations, historical data, if routinely an importer continuously brings in violated products, over and over again, that has a death - that could cause death or serious injury we could actually debar them under the prohibited acts of 306.

Lack of required processes or approvals. So for low-acid canned food, one of the things that you need is to have a process filed with the Center of

Food Safety and Nutrition in order to come in. If you don’t have that, again, we could stop products at the border.

Any other source. We can actually take a look at inspections that are done from other foreign countries and if we, if the observations are such that we believe that we would've taken the same action we could use that information to say we have a concern with products being imported to the United States and stop them at the borders as a result of that.

So, we use state data, we use a number of ways to do things, in terms of that otherwise action. But again, the appearance, although we can use the appearance standard, I still need evidence to start that process. And that evidence can come from a lot of places. So we can detain based on the appearance of a violation. And again that appearance can come from a number of things.

Regardless of the nature of the detention, so the first process is the importer would get a notice saying, "We detained your shipment," which means it's subject to a refusal. But they have a right to refute that. It's called a hearing period, and they have 10 days to submit documentation to us in the term of evidence or testimony or laboratory findings or anything to say, "We disagree with your findings. We believe that the product should be allowed to enter the United States, and here's why." And that could be a number of reasons.

That hearing doesn’t have to be just on documentation. You can request to meet with the districts. So, people - most of the time people don’t realize that the hearing can take on many shapes and forms. If you do that, they should reply and be able to talk to you about why their product is being detained.

But do understand that there's a time period on that. There's a 10-day turnaround time period form when the detention started. And you need to get that to them. You can ask for an extension. They can extend it. So if you think it's going to take a little bit longer to get your stuff together. You ask for an extension and they should grant it. You should tell them how long you think the extension should be needed for.

And that’s extremely important because most times, they're not going to give you a second extension. So the policy is usually, one extension and make sure you get enough sufficient time to get all of the information together.

Importer can also petition to recondition the goods. So there are some things that can be reconditioned. So if the shipment is detained for a labeling purpose, you can recondition that by taking the label off and re-labeling it. And now it comes into compliance.

You can - if there - a product contains filth, you can have it cleaned. If there's an issue with GMPs, Good Manufacturing Practices within a plant. That can't be reconditioned. The only way to get that done is to have an inspection done and show that it's in compliance, so that's one that you can't have re-conditioned.

But you can, if its, for instance, medical gowns, and we find it violative; you can deem it a not an FDA regulated commodity. You can take it out of its packaging and use it for painting. And now it's not one that regulated by FDA. So there are things you can do in terms of that. In order to recondition, FDA must approve it and there's an application that must be filed. It called an Application for Reconditioning. It's called Form 766.

So we refer it as a 766 process, you have to submit that to the Compliance Officer, the Compliance Officer will work with the Center to make sure that it either gets approved or doesn't get approved. And that will go back to the importer. If a product cannot be brought into compliance the product will be refused admission. Refused products have to be exported or destroyed within 90 days.

What usually happens is we would issue you a - each step along the way we issue what we call an FDA notice. So if we detain the product, you'll receive a notice. When we refuse the product you'll receive a notice. Once it's refused, you will also get a notice from Customs and Border Protection asking the product to be re-delivered to the port of entry so that it can be exported.

If it is not exported or destroyed, there's a civil money penalty, that get's issued by the Customs and Border Protection. It's usually three times the liquidated damages of the bond - or the value of the goods - so that's why the bond is in place. And again FDA still has the authority the seize product if certain criteria has met. So we can go out and seize it.

What we would normally do if the product hasn’t been exported or destroyed, or we have concerns about the product, we will work with Customs and Border Protection and have them seize it. And the reason being is if FDA conducts the seizure, we have to go through the Department of Justice and go for a warrant and do all of that. CBP has the right to do it on the spot, as long as it hasn't left the port of entry.

One thing I do want to mention - I want to go back a little bit about, before I talk about the import alert process - so I had mentioned that products cannot be distributed until it gets released. Under the law under section 801(b) of the Act products are allowed to move to destination under that

bond. So you have to issue a bond with Customs in order to import product. And it means that you don't have to keep the product at the border. It actually can move to destination until it gets released.

So that's why there's a big distinction between distributing products and then moving them from the borders. And that's why the re-delivery notice has to be issued. So if an entry comes in, in Los Angeles, then a shipment comes in, in Los Angeles, it makes entry in Los Angeles, it can be trucked from Los Angeles to Chicago, under bond, and be stored in Chicago.

However if FDA wants that, want to conduct an examination or conduct - or collect a sample of that product we will ask that it gets re- delivered to the port of entry. Meaning it would have to go back to Los Angeles so that they can collect the sample.

There are times when we would work with our Chicago office and ask them to do the work for us. But overall it comes back to the port of entry so that we can collect a sample. So most times what they'll do, what businesses will do is they wont move it. They'll have it stored until they get a release from FDA before they move it forward.

The import alert process, I did talk about, this is the mechanism that we use to, kind of, prevent potentially violative products from coming into the country. So, it also frees up the agency resources. So we've talked a little bit about the number of lies that we regulate every year; over 30 million lines that we have to look at. We don't have the resources to look at all of them especially if something is violative.

So what we do is it allows us to detain without physical examination or an import alert. You get placed on an import alert because that product is subject to detention without physical examination. Meaning, I don't have

to look at it anymore. I already have sufficient evidence to say that future shipments have the appearance of the violation. And again, this is where we go back to that appearance clause. We had a violation; we placed it on detention without physical exam and put it on an import alert.

And now FDA can say, it's no longer up to us to stop that product because I believe it's going to be violative. Therefore, it gets detained without physical examination. And now, the responsibility is back on the importer to overcome that appearance of a violation and ensure to the Agency that that product is in compliance. And that means you would have to overcome the reason why you were placed on an import alert or what that violation is.

So for example, if a product, and I'll use seafood coming in, that is - we find adulterated with unapproved drugs, so contains nitro furans or something like that in terms of aqua cultured products, aqua cultured seafood. And we stop that and we find it violative, we place it on an import alert for that purpose.

The next shipment that comes in is going to be detained without physical examination. A notice will be sent out saying it's detained and subject to refusal for the presence of under import alert, whatever that might be, and it's up to you to overcome the appearance of that violation.

You can have that shipment tested to show that it does not contain nitro furans and you provide a private laboratory report to the agency, we conduct a review, we agree that it was collected, that the sample was collected properly, that you used the right method and the results show that it's clean of that violation then we would release that product into commerce. So that’s the major purpose of the import alert system.

There are currently 274 import alerts. And there is a Web site for all of them. Broken down, and again the import alert provide guidances to the field that we already have sufficient evidence to detain goods without physical examination. There's a number of import alerts, like I said there's 274 currently active and the break down by commodity is there.

All of them, all online and you can see all of them just by going into that Website. And I think we're going to go through and I will show you where they are from the Website.

Again the import alert system, we've talked about, you know, how I can use or what information I can use for the apparent standard or the otherwise type of information. And again the violation history could be based upon commodities. It can be manufacturer or shipper. It could be growers, it could be the geographical area, it can be a country, it can be importers or any combination.

So when you, we'll get an import alert, majority of the time you will see a product that is placed on the import alert as well as who the manufacturer is. So that when the shipment comes in we want to stop that product, only that product from that manufacturer. We don't want to stop every product coming in because we would back up the borders and it would cost a lot of resources.

So we want to target and be specific. That's why the filer evaluation process is so important. Each of our commodities are screened by what we call product code. The first two digits of a product code identifies the industry. So 16 would be a food and more specifically a seafood, I believe. The 60's are drugs, so and then it goes into how it's packaged and other information.

If a filer provides the wrong product code it means they could circumvent our import alert system and potentially violative products would be allowed into the country. That’s why it's extremely important that they do things right, and that's why it's important for the agency to go out and do these evaluations to hold them accountable to make sure they are doing things right and not circumvent on our capabilities and providing false data to the agency and possibly harming consumers.

Adding firms and products to an import alert can be based again on evidence from our field offices, from foreign inspections, from any other source that we deem to be appropriate.

Removing a Firm. The firm or the importer may petition my office to be removed from the detention without physical examination. You submit a petition to my office. Usually it's over a course of time. And dependent upon how you were placed on there. It would also tell you how to get off of it.

So for instance, if it had to do with salmonella, you would probably require five clean shipments over a period of time showing that you fixed the problem one way or the other. If it had to do with a GMP violation, a good manufacturing issue, or an insanitary issue of the facility, it may be that you have to provide documentation showing that your water systems have been cleaned. That you did an inspection, that you found that root cause of the problem, before you are to be removed from that import alert.

FDA reviews the petition. It goes from my office and we work closely with the centers in terms of making sure the corrections have been done. And again it requires usually non violative shipments all depends upon the alert. And documentation showing it was completed.

The bottom line that the FDA, do we have the assurance that the cause of the violation, the reason why it was stopped, has it been corrected? And as long as we have that confidence then we will remove you from the import alert and you would go back to the normal screening process.

So we're going talk a little bit about the requirements associated with that. Tony Taube is here from the Division of Food Defense and Targeting. He's going to talk a lot about the prior notice process so I'm not going to go over this. But we did talk a little bit about the Bioterrorism Act and the requirement.

For Food and Feed there's a two-tier process. One that starts off with the Prior Notice review so food that's being shipped that's imported or offered for import into the United States has to have prior notice requirements and that review gets done within a few amount of time period and I'll leave that kind of to Tony to explain and go over.

That's the time requirements associated with it based upon the mode of transportation. And there's many data elements associated with that that have to be acquired and I'm sure that Tony will explain that anybody with knowledge has the right to submit prior notice requirements.

And then it moves to the tier two, which is the admissibility. So you have the food defense aspect of it and then you have the food safety aspect of it, which is what we call the admissibility portion. There are certain requirements that's needed.

There's four actual requirements: Country of origin which is different from the Customs Country of Origin and I'll give you an example of the differences between the two. Something that originates in Germany, for

example, gets shipped over to Italy from manufacturing and then gets exported into the United States.

The country of origin for FDA is Italy because that's where it was last manufactured or had substantial events to make it into a product. For Customs, it could be it is Germany that the country of origin would be. So they look, they go back to kind of the ingredients to where the products come from before it gets manufactured.

So there's a big difference between the two, you should understand the differences between them. We also want the name and address of the manufacturer. Not only the name and address, of the corporation but we want the site specific manufacture. We want to know where it was manufactured. What location.

So, if it's a big company, like a Kraft, I don't want the, we don't want the corporate office, we want that location where if we wanted to go do an inspection, we can go directly to that location and do the inspection.

Name and address of the shipper, and again the FDA Product Code. Very important in identifying what that product is. Certain foods products require additional information to be submitted as I mentioned, low-acid canned food, you have to have a canning establishing number as well as a process that's filed with the Center of Food Safety and Nutrition. We will look at that to make sure that that information is provided during the entry process. If it's not there, that product will get stopped.

Medical products, human drugs require a drug registration number, a drug listing number, an investigational new drug application number, new drug application or an abbreviated new drug application number. These are all voluntary. The only ones that are required are those four major ones. But I

could tell you that if this information is not there, you're product's not coming in.

One of the things that we're required to do is to verify, for drugs, that all manufacturers are registered and their products are listed. We have what we call an affirmation of compliance. So there is the capability of putting in a registration number and a listing number.

We're going to talk a little bit about some of our IT systems and how, by doing this, it can help facilitate the process. But by putting this information in the system during the entry process it will go a lot smoother, where we won't have to stop, we may not have to ask you for more additional documentation. By putting it in it would go a lot faster.

Same thing with animal drugs, same type of requirements would be needed. You have the four major elements that are required under the law to make sure that it is an FDA regulated commodity. And then you have these added ones. Same thing with the biologics, manufacturing US biologic license number, and the product license application number or the submission tracking number.

Medical devices, very similar to the drug process, we're still looking for certain types of things, A pre-market approval number or a substantially equivalent number or also known as a 510(k). And then human device exemption numbers, or investigational device exemption numbers.

We're looking for that information to make sure that we can make the right decision on whether a shipment should come in or not. Radiological health products, again, looking for radiological health declarations or what we call an accession number for radiation control.

That’s pretty much an overview of the import process, some of the requirements associated with the different types of commodities. And again, if you have questions about that process, we're happy to help in terms of getting you to the right person to speak to or at least providing you with some additional information in terms of doing it.

There was a lot of talk about our IT systems and some of the new things so I'm trying to look at, what time is it, (Sousan)? We've got plenty of time right?

Domenic Veneziano: What time do I have to? What time?

(Sousan Altaie): Ten forty five.

Domenic Veneziano: Ten forty five. Great. So there's been a lot of talk about our PREDICT System and how we screen things and wanted to just touch base about what PREDICT is and what it isn't. as well as some of our IT system so you get a better understanding of how we do our job day to day.

We have a system that’s called MARCS. People confuse it and MARCS stand for Mission Accomplishment Report and Compliance System. Just another acronym that FDA throws around, we have a lot of them, unfortunately.

PREDICT is one application and there's a long name to PREDICT, but Predict is an application that's based upon risk of shipments that come in. and it helps screen those shipments and we also have something called MARCS Entry Review. That is where the entry reviewers, that’s the screen that they look at to make decisions on whether something should be held or not. The entry review incorporates the risks that get screened through the PREDICT application.

PREDICT is a system that works behind the scenes. So, its purpose is to prevent the entry of adulterated, misprinted or otherwise violative goods. While expediting goods that we have confidence in. So ones that are low risk, we want to make sure we want to screen them out effectively and allow them to move more quickly into commerce. And we want to focus our efforts and our limited resources on the ones that are the highest risk.

Again another process and it just shows where PREDICT actually works in the process. So PREDICT uses a different type of thing. It's an Automated Data Mind and Inpatent Discovery. So it actually teaches itself on things that have come over time. And as it grows and it was implemented nationally in 2012. December of 2011, fiscal year of 2012 for us. It was rolled out nationally in terms of doing it.

It also uses open source technology. So our staffs have the capability of putting information in. So a disaster that happened out in a certain country. We can screen all of those products and raise the risk associated with those products, whether it’s a region, whether it's a country, whether it’s a certain product itself. To say, there was an event, based on what we heard in the news, that could affect this region.

And therefore the facilities that manufacture FDA regulated goods may be contaminated or may be at a higher risk than in the past. So for the next 60 days or the next three months, we're going to increase our oversight of those commodities by performing examinations on them or looking at them as they come across.

It provides automated queries of center databases. I spoke about how important it is to provide the registration number of the things that are

voluntary. Well if you put that information in for devices, if you put the 510(k) number or the approval number in for it it'll ping.

PREDICT will ping off the center databases and say, here, this is an effective number that goes with this manufacturer and therefore an entry reviewer doesn't have to look it up. The system will do it for us. And again, maximizing our efforts, maximization our resources to focus on things we really care about.

Improving the target of lines, scoring each line based upon the risk factors in surveillance, increases the number of automated real time risk based may proceeds. Again the system does a lot more work for us now than human review. And for those lines that aren't given a may proceed. It provides all the information on a screen for the entry reviewer.

And here's what it does. So when an entry gets stopped in the past, we never knew how many times it got sampled. So now the entry reviewer will know, by clicking a button, how many times that product, from that manufacturer was sampled and you can find violative or not violative.

And the not violative is actually more important. Because if we have confidence, if we sample something a hundred times and it came back non violative why do I want to look at it again. Even if it’s a high-risk product, I want to focus on things that I really haven't seen. So unless there is a need. It's very possible that an entry reviewer who's looking at those 30 million lines, has to make a decision, "Do I look at this one, or do I look at this shipment?" this helps.

It also provides some information about the manufacturer. And that site specific manufacturer. And the consignee, or where it's going. Are they in violation or are they not in violation? If they’ve been- had a bad history-

it's very possible that the products that are leaving that facility may have the potential of being violative. Which would increase the likelihood that we want to take a look at that shipment.

Inherent risk of the product. Obviously products have different risks. Ready-to-eat product will cause a greater risk to public health then something that we know is going to be baked or boiled and salmonella is going to be, kind of, cooked out of that. So there is inherent risk to that product that gets evaluated within the PREDICT system.

Again, accuracy of the data. We talked about the Filer evaluation. Well the importance of the relationship between the manufacturer, the importer and the broker, or the filer is extremely important. Because if you're not providing us with the right information, we do our filer evaluation and we find the information is incorrect.

That’s going to raise the risk of those, of that score, because we can't trust the data. And therefore we're going to verify that it's correct by going out and doing a physical examination. Stopping that product and making sure that it's correct.

It looks for data anomalies within the current entry. So if a fish is actually caught, it only is actually within a certain region of the country, but yet the description of the product doesn't match the product code, or its usually one that’s not caught in a certain region. It'll flag it, it'll say, it'll teach itself that capability that this product shouldn't be coming from this area of the country. And it'll flag it that way and will alert an entry reviewer that this might be something that they want to take a look at.

Looks at the admissibility history and again, it looks at open source technology. It looks at the compliance risk of firms associated with the

imported line and again it looks at the product related increments. The incremental health and risk associated with it and a lot of the inherent risks associated with all those commodities.

Again, to expedite product, put in the right information. We talked about the affirmation of compliance. It's very important to put it in. It helps expedite the process of getting things in the system and that’s what this is just saying.

I want to talk a little bit about a system that we have that’s called the Import Trade Auxiliary Communications System, or ITACS. ITACS has the capability of allowing companies to put in documents electronically. Usually we had to fax them in or email them to people and we got a lot of complaints about FDA losing products or never receiving them or not being able to get a hold of a compliance officer in the field to determine what the status is.

And you can imagine what the workload of the field. The compliance officers are extremely busy. Thirty million lines that they have to deal with on many refusals and detentions and they have to process those cases. We get phone calls from the industry whether something's been released or not can be overwhelming.

So we had to figure out a way to notify or to allow the industry to do that electronically and this system allows that to be done. So if you submit documents electronically, at the time of entry. The system actually links it directly to the line that we have a concern with or the line that's being entered.

So if you do it at the same time and your shipment is released, there's no issue. If you do it at the same time and we hold the product, we don’t have

to ask for the documents, and we already have the documents. So that again, speeds the process up. It gives us the ability now to tell the Importer exactly what the status of a line is. So with the entry number anybody who has access that entry number can find out the status of that line.

So you don’t have to call the field anymore or call the office and say "Is it going to be released, is it going to be released?" You can go in there, type in the entry number and know the status of the line.

Again, it allows you submit documents directly to that, and it provides availability of targeting, of the shipment. So, for instance, if we want to collect a sample what usually happens, especially in the cargo arena is you have to tell us where it's located or you have to call someone, tell us where it's located and schedule an appointment so that the cargo, the container can be taken down and we can go get it.

Now you can do everything electronically. You could submit the information in, it comes to us and it, again, clears it up, there is not communication or no one getting a hold of other people, it actually speeds the process up tremendously.

It's internet access and there's a security. There's no account that’s needed at this time. But we are going to get to an account base and I'll tell you a little about where the future lies and the future is an account management system.

So for all of you, I know that a lot people want information about, you know, companies and there's confidential information that has to be controlled, specifically the manufacturer, the importer and the consignee. That relationship has to be, is confidential and trade secret.

So we cant have people going in there and looking information just for anything so we have to have an account based system. Right now, when we issue those FDA notices, we have to mail them out and we usually mail out three at a time. One to the owner or consignee which is the importer of record, we send one to the consignee and we send one the filer.

We want to have the capability of having an individual who has the right to that knowledge log in and get that information directly. They can either have it emailed directly to them or they can print that out if they want. It would save the agency a tremendous amount of resources of getting that done.

It's file size limits is open, service storage capacity is plenty, documents is a PDF and we're making improvements all the time. We're also working with CBP so, one of the things that Customs and Border Protection is working on is a system called ACE and I'm not sure you all heard of that. It's called the Automated Commercial Environment. It's going to replace their current system called Automated Commercial System, ACS. What we're trying to get to is a single window approach for the industry so that you don’t have to submit information to FDA and USDA and CPSC and all of the government agencies.

This single window will allow you to submit information directly to CBP and it will go to all the agencies as appropriate same thing with the documents. So right now we have the capability of getting documents sent to us electronically through our ITACS system and gets linked to a line specific.

CBP is coming up with what they call a Digital Imaging System. So you can submit documents thorough them. And it goes to an entry, it doesn't

go to the line level yet, we are working with them and in the future what will happen, is it'll go through CBP and through the interface it will come to our ITACS system directly.

So again, now you submitted documents to all of the other agencies, as well as FDA. You only have to submit them once. It saves a tremendous amount of time for the industry. Again, it allows quick time.

So that's pretty much an overview of ITACS . There's a lot of slides, but it just talks about the benefits to the agency and to the industry and the fact that we're no longer losing things, we're no longer faxing things, we have better communication with the industry and it reduces the phone calls. Just a better improvement overall.

This is what it currently looks like, that’s the view, it contains product code information, it contains the line entry. Provides origins associated with the country. Gives us status dates. So when you go in there you can see all this type of information of where it stands.

Future functionality, we've talked a little bit already about transmission of notices. And that’s going to be through an account management system. Again, you'll be able to query, firm identifiers. And I think the future is going to be a unique facility identifier.

Right now we use what we call firm establishment identifiers or FEIs. You'll be able to do that hopefully through a unique identifier which may be a Dun and Bradstreet number. You can query product codes. Again, we talked about how important product codes are in the system.

This will give you, or give the industry one stop shop. They can go into the system and query product codes. The biggest thing that capability, we

talked about the status. So right now if you go in and we collected a sample it will say something like, it's under review, or it's pending. We want you to know why it's being collected, we want you to anticipate when it's going to be released

So if something's going from microanalysis you should know that that microanalysis take approximately three to five days to come up with a preliminary result or it can't rule out. Then there's confirmatory testing. So you can expect that if it's positive, if it says CRO or Can't Rule Out, it's going to take another 7 to 12 days for Confirmatory Testing. You know that there's a problem right there. You know three to five days out, by going to out system that this product is most likely be refused. It may not, but moist likely it's going to be.

And again, submission of all other types of documents. We're also using it for some of the FISMA requirements. So applications, we'll talk a little about the Food Safety Modernization act. One of the things is the Voluntary Qualified Importer Program. We're thinking of using ITACS as that capability. We're also going to be using ITACS for private laboratory submissions, or thinking of that process as well.

And, there's the link associated with ITACS, and again we have a point of contact associated with that so there is a, if you have any questions, you'll get these slides so you'll have the contact people as well. So there's our support person, support people, or our help desk that will provide more guidance to you in terms of that.

That's it on the import side, I did, I know that you're going to have a talk about FISMA so I'm not going to go over this. We can talk about it this afternoon. I may be here for awhile, Brian Pendleton and Sharon Mayl, who I work closely with are giving the presentations on the Foreign

Supply Verification Program, I believe, as well as (Charlotte Christian) who is giving a presentation on the third party, so I think I'll leave that to that time period. And I just want to thank you for your attention. I'm happy to take any questions that you have. So thank you.

No questions on imports? Yes.

Woman: Is this on?

Woman: It's on.

Woman: Good morning. Thank you for your presentation. Question about the importation of products for research purposes not on human beings. What is required for the supplier to generate? For importation?

Domenic Veneziano: So what, so what you do. You still have to provide all the information. But you should put - you would expect that we're going to see a small quantity, we're not going to see a large quantity. If you put on the documents that it's for research only, that should allow it to go in smoothly. So it's, there's an exemption within FISMA for our research only now, but you have to declare it to be for research only and it should go back, and you should be okay.

Woman: Does the end user need to also provide a letter that - describing what it will be used for?

Domenic Veneziano: Is it for food?

Woman: No, scientific research, medical.

Domenic Veneziano: No.

Woman: Okay.

Domenic Veneziano: for medical purposes.

Woman: Yes, on mice.

Domenic Veneziano: If it's for research only, its going to have to go through a process, so yes, you're going to have to find out. If it's for research only, it still has to come in and it has to be from a manufacturer and its going to have to be declared appropriately.

So medical products just can't come in. that way they have to be a process for research only. It has to be going to a laboratory, it has to be identified. They have to be, probably an IDE if it's going to be doing that. So yes, there are specific requirements associated with that and we can help you with the what's needed on the importation part of it if you'd like.

Sousan Altaie: Domenic, she mentioned the research is for mice, not human, so IDE would not be required.

Domenic Veneziano: But there's still a, find a way, there's still a requirement. Not an IDE for humans, but for, even for animals, there's a process that has to be followed that’s very similar to research only. So we don’t know how it's going to be utilized., right? So we want to verify that its going to be used for research and may require, not something from the end user but it might have to be submitted to the entry reviewer so that they know its going for research only. And that can come from multiple purposes.

Woman: Thank you. I have a question on samples that are shipped for exhibitions. I know that there are some exemptions but, for instance, on the labeling, but

you have a guidance and in this guidance it's written that the products or samples should comply with FDA regulation but, and this is the question, but the office or the office, the agent, the FDA agent of the field office can decide whether a non-compliance sample for an exhibition would be released or not. So it's in your guidance, it's something...

Domenic Veneziano: Yes...

Woman: Also I would like to, so when I have some question from an exporter, I want to present their product for an exhibition I told them their product must comply with FDA regulations.

Domenic Veneziano: Right.

Woman: But you can...

Domenic Veneziano: Yes, there's...

Woman: ...and ask...

Domenic Veneziano: Right, there's little things that can be done. So there's enforcement discretion that will be used. So first of all I will say that any product that’s being imported for an exhibition, even if its samples, they have to be tested. Have to go through the prior notice process. So if it's for food, it has to still comply and have to submit prior notice requirements so if they can take a look at that. There are some things that we are concerned with. So labeling violations, per say. At times the field does have discretion to allow something to come in even though it's in violation of a labeling requirement.

So if it's for that purposes, they can use their discretion to get it in. I will say that you need to be aware that changes are coming down the road with the Foreign Supply Verification Program and with FSMA. The Importer has to comply with or verify the products that are in compliance with preventive controls and labeling laws under FSVP, which you'll hear about.

One of the questions your comment that we're getting from the industry is what happens during exhibitions? So, usually people want to, it'll be the first time that they're presenting this type of commodity as a sample. They want people to taste it, they want to test it so they can sell it or that people can purchase their product. We're not sure yet how to handle that. so there is a question moving in. Currently its allowed to come in and go to exhibitions as long as it's in compliance with our laws.

And there is some guidance to allow that to happen. But I think that you need to be aware, and one of the advice that I give a lot of people is stay up to date with the current regulations and know how things can be stopped. But yes, I mean, if there's an issue, I would reach out to the district and say this is coming in.

If it was me, and I was giving advice to the industry about getting products in, especially in your situation, I would call the district first, I would say "All right, I'm making entry in Los Angeles." I would call, find out who's most responsible and that’s on the website, there's a list of all IPMs, Input Program Managers, within all the districts, I would say "I am shipping products in for an exhibition, what is actually required?" you call my office and we're happy to facilitate that as well.

But I would call them in advance to make sure your products not going to get stopped. And if you submit a large quantity of something, you're going

to have a problem, I can tell you right off because it shouldn't be a large quantity that's going for sampling, or it should be a large quantity of anything that's going for research and development. So we would be concerned, we would look at that and say something just doesn't make sense here in terms of it, but that's what I would do if I was you.

Woman: Thanks.

Domenic Veneziano: Question?

Man: Good Morning. May I ask you especially when an exporter from foreign country is a small or medium enterprise, they usually have only little information about the whole import process and what happens. That they are gaining experience, they are getting more and more familiar but still, at the very beginning when they meet potential US clients, which might be actually importer would be filing information with you. They know very little.

Is there a chance, or is your information system should be the (WBE) or any other information. Can it also serve other information source, how to find what the history of US filers are with the FDA. Basically can it be used of some kind of source of information of track record of the company which is located in America and is discussing with foreign exporter about bringing their product.

Domenic Veneziano: So if I - make sure I get the question correctly. So you're looking for, is there additional information that can be utilized to understand the process of importation?

Man: Not really, what I was trying to ask was, does the filers, like US trading company, which are important products from abroad. They do have a

history with you. Either it's positive or negative, and sometimes, occasionally at the very beginning of the business negotiation, foreign exporters would like to know more about basically who is on the other side of the table.

And my question is whether the information you have, whether its, you know, online or any other way, whether its ant other way. Specifically to find out more about US company?

Domenic Veneziano: Yeah, so there is...

Sousan Altaie: Domenic, they're asking about whether you have information on the importers that they can leverage to use because sometimes you use information about the lots of very - including information, the history of that importer to prevent something from coming in. So he's asking if there's a database that they can go to figure out which one is a good one, which one is not.

Domenic Veneziano: All right

Domenic Veneziano: So there's different definitions. Before I answer that, I want to make sure we're clear on all the different roles and definitions. So you have the Manufacturer who manufactures a product. You have what we call an Importer of Record. That’s the person who's the most responsible at the time of entry. They are the individuals that would facilitate working with the manufacturer and what we call a broker or a filer.

The manufacturer has to have a US agent. If you're overseas, you have to have a US agent under the Bioterrorism Act in case there's an emergency where we need to contact somebody locally, we have that capability.

So when you register your company, you have to provide that US agent. US agents are often times a big company or a Filer, or a Broker. And you can use them as such. Our web, and then you have the import of record who works with a filer or broker a costume's broker.

They provide them with all of the data that's needed to submit. You can, it's part of our transparency, you can go online in our transparency website and it'll identify all of the Brokers that we did evaluations with and the status. Whether they're call is in compliance. It's called Compliance Action Plan or not. The ones that don't have a corrective action plan have been inspected and found to be in good work, in good compliance with us. So the information is there within our Website.

And also if you wanted to look at manufacturers themselves on inspections our transparency allows you to look up a company and find out if an inspection was done. So if an inspection as done of a facility, we would let you know what the status of that inspection was, whether it was violative non-violative or called OAI, which is an Official Action Indicated, meaning that it was a significant inspection where they issued a warning letter or some kind of action to that firm.

So everything is available online or should be available, that would be helpful. I will also let you know that the other thing you can look for is refusal data. So I think we're going to go through and we're going to go do some navigation.

Sousan Altaie: Yes

Domenic Veneziano: All right, so when we go through the navigation, you'll have capability of looking at all the import alerts, you'll also have the capability of looking at all the refusals that have taken place over the years, so on a monthly basis,

we post all our refusals, so you can take a look a that information. We post all of our refusals so you can take a look at that information and see what products and what manufacturers may have had issues or what products were refused.

Now I caution you to understand, we talked about the appearance standards. So when you look at those refusals it doesn't necessarily mean on all cases that there's a violation. It may be that somebody just decided not to submit anything and we refused it based on that appearance violation. So I just want to point that out, but a lot of that information is online.

Any other questions? Yes sir.

(Thomas Schmidt): My name is (Thomas Schmidt), I am from the embassy of Germany. And first of all I would like to thank you for this very informative lecture. I regret a little bit that I listened to that lecture in the second half of my term here. So it would be probably would have been better to have listened to it in the first. So maybe you can have such information meetings more often.

Yes. I have two questions. The first question relates to the import alert list. If a shipment is in violation with any rule here in the United States, who gets on the import alert list? The importer? Or the producer of the shipment?

Domenic Veneziano: So it can be any combination of it, usually it's the manufacturer. And the product. So we could link it to a shipper, or a manufacturer. We usually don't do the Shipper because it's not in violation. But if we're unsure of where the violation actually occurred, we could put the Shipper in there as well. But it's usually the product specific and we link it to the manufacturer.

(Thomas Schmidt): Yes, we had a problem with that because the Manufacturer of, produces not only for the US market but for other markets too and therefore he or she do not always meet the requirements of the United States. Especially if it's not produced for the United States an there might be somebody buying it and deciding to export that product to the United States and in that case, the producer faces problems getting in here without knowing about it.

Domenic Veneziano: So we call that grey market. If something is not intended to be manufactured for the United States and the manufacturer is aware of that - and let me just say first of all that one of the things that we're working on is notifying the Manufacturer that they've been placed on import alert. That currently doesn't happen right now and it takes a lot of resources in order to do that.

We actually increased our staffing a little bit and one of the things I've asked my staff to do is to create this procedure to afford or have the ability to issue letters to the manufacturer. Because they should know that they're being placed on import alert.

The grey market issue though, if somebody is claiming that they don't import into the United States. They should send me a letter, they should send a letter that we manufacture this product, it's not intended to the United States, and therefore it should not be allowed in, either way.

So there's a couple of issues associated, I'm not sure why you'd be registered with the Food and Drug Administration if you're not intending to import into the United States first of all, so that's one concern, so historically, now with the Food Safety Moderation Act there's a new biannual registration requirement, so if you are not intended, Tony Taube

would, during the import process, the first thing that do is under Prior Notice they would look for registration.

If its not there, they're going to refuse it before it even comes to the admissibility part of it as well. They would hold it out, allow you to make that correction before they would do their review.

Secondly, I think, if you sent a letter to us, we could say, "All right, we're going to target this". That means somebody is either providing false data in terms of who the manufacturer actually is, if they are claiming themselves as the manufacturer, and they're not, they're actually trying to get it in a different way. Do there's capabilities of doing it we just don't, its hard to determine unless somebody comes forward and lets us know that that's the case.

(Thomas Schmidt): Thank you. And the second question. Could we get access to the slides you showed here?

Domenic Veneziano: I believe that they're going to be posted.

Sousan Altaie: The slides will be posted on the web page but if you need them earlier, email me and I will send you the copy.

Domenic Veneziano: I can tell you that the presentation, the overall presentation, and it changes form time to time due to the new regulations, but if you Google it, you'll find them. I actually did some research last night and actually the slide came up. They were an older version of the slides but overall it should be ok. I will also say that one of the other initiatives that we have ongoing is an initiative called KISS, Keep It Simple and Straightforward.

I think that our Web site can be a lot better in terms of the different commodities and what's required to import products and where you can get information. It's really not easy to navigate the system, I think, at this current time but we are working on making it better and putting more information up that’s available and easily to be identified.

Right now you'll see that it's in a small area that’s hard to find. We want to make it more prevalent. We want to make it so its easy for you to understand what those requirements are when you're talking about exporting to the United States or importing to the United States.

(Tara Medling): My name is (Tara Medling) from the European Union Delegation, and first I wanted to thank you for your very interesting presentation. I have a question as regards import, the import alert system of FDA and especially how it is linked to other existing import alert systems. For example in Europe we have the Rapid Alert System or the WHO has the INFOSAN system. So how to deal with - how are you linked to them. And how do you deal with rapid alerts to other jurisdictions? Thank you.

Domenic Veneziano: So when you go online and you see the import alert system, you can ask, or you can subscribe to our import alert systems so you can be notified of all changes to import alerts. And you can, I believe you can break it up by food specific, or drug specific.

You can ask to receive all of those notifications every time there's a change or any update to import alert. We receive all of those information related to the INFOSAN and the EU notifications as well as Canada's import alert systems and we evaluate it.

So we would- if there was a concern about products that were on an import alert in Canada or in the EU through the RASIP System, we get

notified of it and we would do our research. We would search our database to determine if the product was coming into the United States and if it fails to meet our requirements.

And then we issue, or we work with our field and I would issue a bulletin or notification to our field to say, this is occurring in another part of the world. We want to be concerned and we want to see if the violation is also in the United States and fails to meet our requirements. The different between looking at them and why they can't be linked up is because the requirements for the EU and Canada and all the other countries are not exactly the same. The tolerances are different.

So what's violative in another country may not be violative within the United States. So we have to establish that violation. So we would go out, collect our own sample, test it, determine if it met our tolerances or was in violation of our laws and regulations before we implement an import alert or place them on an import alert.

Its a little different when you're looking at inspections, because the observations in the conference we have working with other countries can kind of dictate if we found that same observation, we found that same violation in terms of an inspection, we can come out with the same conclusion that says, yes, that would put this over the edge in the terms of Good Manufacturing Practices or being in insanitary conditions and take the appropriate action.

Any other questions? If not let me just say that I think, I agree Mr. Schmidt, I think this is a wonderful opportunity to have the embassies all come together. I think we need to do more of this. I know that Mr. Taube and I do a lot of outreach to embassies and everyone around the country

and in terms of getting the message of Import Operations but we really never had the opportunity to do it all at one time.

And I think this is a great opportunity to present it, although it's online, I think its best if you hear it and you have the opportunity to ask questions, real time, and you know where to go now, in terms of any questions that you do have.

And I hope the Office of International Programs will continue this type of event and provide us the opportunity to come here and speak to you again about importation of FDA regulated goods. So thank you very much for your time and patience and I wish you all the best and happy holidays to all of you.