

April 16, 2013

**FDA webpage Navigation for:**

**- Import program,**

**- Prior Notice**

**- Registration and listing programs**

**Anthony C. Taube, Director, Division of Food Defense Targeting**

**Andrew Seaborn, Office of Enforcement and Import Operations**

(Anthony Taube): Good afternoon, I was waiting for the high sign from the back that the recording is going so thank you for inviting me out to present today.

My name is (Tony Taube), I'm the director of the Food and Drug Administration's Division of Food Defense Targeting.

Some of you may have heard of our office by its old name, I think (AJ) mentioned the Prior Notice Center, has anyone ever heard that name before, recognize that?

Obviously he mentioned the prior list process which was promulgated out of the bioterrorism act of 2002 as (AJ) mentioned, which was enacted out of the results of the - events of September 11, 2001, the terrorist attacks.

So the bioterrorism act and the prior notice requirement came out of that act which was in an effort to better protect the food supply from terrorist attacks and other things that impact the public health.

And so the bioterrorism act is a huge act, has many different sections, but title three includes the prior notice of imported food and the registration of food facilities.

And those are our two sections that we also promulgated regulations that can be found in 21CFR part one and then there's sub part H which relates to the registration of food facilities and then sub part I which relates to the prior notice of imported foods.

So I just wanted to give those references out to you so that you had to refer to them. Primarily what I'm going to do is show you how to go about filing a prior notice of imported foods.

(AJ) mentioned that prior notice is required at port of arrival, actually it's required before the food arrives into the country at the port of arrival.

(AJ) mentioned the time frames, the two, four, eight hours depending on the mode of transportation but it actually can be filed well in advance, it can be filed up to 15 days in advance if you use the system that I'm going to show you, the prior notice system interface.

Or most shipments, most commercial shipments are filed through a customs broker using the automated broker interface through customs, using a customs broker and those get filed through a different system.

But I'm going to show you a way that anyone making a shipment or responsible for a shipment can file a prior notice on their own to FDA and again there's no charge to filing a prior notice.

This is the method that they can use to file that at no charge. So you've all seen the fda.gov, we're just at www.fda.gov and we're going to click on the food tab which is up here on the top.

And that will take us to the food specific screens and this you have to kind of watch because they've changed this from time to time where you find this next link.

But currently if you scroll down into the spotlight area there's a link that says prior notice of imported foods. So that's really the key link you're looking for, once you get to the food tab, you're looking for this link.

It used to be a little higher on the screen but now you've got to scroll down to get down to this prior notice of imported food link.

So we're going to go ahead and click on that and it takes us to this screen. This screen is packed with information. You know I mentioned you know being asked to present late but this is the most exciting stuff of the day, how to file a prior notice.

So put your seatbelts on, this is going to get fun, a lot of good information here. That was a little bit of a joke, no one laughed. So there's a lot of good information on this screen, there's information on the left hand side, what you need to know about prior notice, there's new features in the prior notice system interface.

Time saving tips and different things, there's a tutorial on the product code builder which I think (AJ) might run you through later on.

There's a link here as well and then under guidance documents there's all kinds of guidance documents that are also good links for you, including our compliance policy guide related to prior notice which is Section 110.310 of our compliance policy guide.

All good information, references for you to use if you're filing prior notice. There's also some instructional wizards here in the instructions area that you can use if you don't have a photographic memory and can't remember everything we're going to talk about in a minute.

So we're going to go ahead and go ahead and log in or hit this button here, this login create an account If you don't have an account you'd have to create a new account using the new user button.

And this is much like creating any account you would create if you're buying something on the web, you have to create an account in the FDA system. But in this case I have an account so I'm going to go ahead and log in.

Have to click the little I Understand button, I do understand. All right, so I click I Understand that I'm going to make accurate information to the government.

Hopefully it will log me in this time. So that takes you to this screen which depending on how you set up your account (AJ)'s going to talk about registration and listing.

Once you create an account it's going to ask you what kind of account do you want with the Agency? What are you going to do?

Are you going to file registrations? Are you going to file prior notices? and it gives you the opportunity to select those things that you're interested in doing.

In this particular case this account allows me to register a facility because I signed up that way and it also allows me to file a prior notice of imported food and this is the button I would click on, go through what we're going to do at this point.

So once I click on that button it takes me into what's called our prior notice system interface or PNSI and this is the site where actually you're going to file your prior notice.

Again there's more features in here to help get you started, talking about an overview, et cetera. But in order to start submitting a prior notice and this is not real intuitive, you have to read a little bit here.

But you have to create a web entry first. That's part of the shipment information or prior notice information so what we're going to do is click on this create new web entry.

And if you go through the tutorial it actually tells you this but I'm going to tell you that up front so that we can process. So in order to create a web entry the first thing it asks us is, do you have an entry number.

If you're using a customs broker, you might have one and you'd have to ask them what that number is to be able to follow your own prior notice.

In many cases folks going in and using this system don't have - excuse me I'm jumping ahead this is actually entry type. Going to get to the entry

number in a minute so I'm going to use this little drop down arrow here and it gives me a set of entry types to choose from.

Things like baggage, is this a baggage type entry, you know am I carrying this in with me as I'm flying into the country? Consumption entry which is a typical shipment coming in to the country, most are consumption entries.

But has other things like consumption express courier being shipped in through the UPS or FedEx you would want to choose that one.

And that has FTZ etcetera, there's mail, but in this case we're going to choose consumption, most entries coming into the country are consumption that's what we're going to choose.

We make that selection and we click the next button and then it takes us into the rest of the screen here's we're getting to that entry identifier, again if I have that information from my customs broker, I can enter it here.

If I don't know or I don't have one I can use this not known button and the system will generate an entry number for me.

All of the prior notices have to have an entry number so if you don't have one you just put the not known and the system will generate one for you as the little hint says here.

The next thing it says is how many prior notices do we want to enter or submit with this web entry, we're just going to choose one so we're going to enter one and then we're going to scroll down to the rest of the screen.

The next section is the port of arrival, where is this shipment going to arrive? So I'm going to choose a state, in this case I'm going to pick my beloved Michigan and I'm going to ask to find me a port code, what are the port codes in Michigan?

In this case I'll choose Detroit so that I can you know once I put the state in, it's going to give me a drop down and give me all the ports in Michigan.

I'm going to choose Detroit, then I can select the next button. Now I can scroll down, and it's really cool, the system if you forget to put something in it will tell you.

It will pop up and say hey you've got to go back, you need to enter this so it's real helpful that way.

Next thing is anticipated arrival date and again this is just as it says, it's anticipated, it doesn't have to be spot on accurate.

This is when you think it's expected to arrive into the country. So in this case we're going to say it's going to arrive this Thursday on the 18th, it also requires us to put a time to where we understand it's going to arrive at 9:00 am so we're just going to choose 9:00 am.

This is on a 24 hour clock so that's 9:00 am there.

Sema Hashemi: I just want to make sure is everyone following because (Tony) is going a little fast, so I just - is everyone okay?

(Anthony Taube): Yes, if you need me to slow down just go, because you're right I am going fast, it is a lot of stuff to get through.

But again in most cases if you have this information it's best to have the information in front of you when you start the process. So if you have it all in front of you the process is actually - can go very quickly.

If you're trying to figure it out as you go that's when it becomes difficult, it really dose. I had a question from the back. Yes? This is the initial port of arrival, the first port of arrival into the United States.

And I think (AJ) talked about how you can have a port of entry that differs so something might arrive say in Los Angeles but it's not going to make entry until it gets to St. Louis, it's going to be put on you know container is unloaded in Los Angeles and then that container is bound for St. Louis, say it's put on a train.

And then it makes entry in St. Louis where St. Louis becomes the port of entry. Prior notice of imported foods is required way back in Los Angeles, and so that's the port we're going to choose in that particular kind of case.

(Sousan Altaie): Tony you said that the expected date of entry is approximate, we all know approximate is after or before, which one would you prefer us to put in?

(Anthony Taube): It has to be a date in the future because you have to file prior notice in the future. So you're giving your best estimate of what date in the future the prior - or the shipment's going to arrive into the country.

All right, the submitter, and again you know if you can't see I know it's difficult to see but the system tells you the submitter is the person with the knowledge of the prior notice information.

Hopefully that's in this case someone directly involved in shipment and is often the person sitting here keying the information in.

So in this case it's actually are you the submitter for this web entry, I'm going to answer yes because I'm the person with the knowledge of the shipment but if it's different you can simply select no and enter the submitter using this button over here on the right part of the screen.

So in this case it then asks me who's the importer? Is the importer the same as the submitter, again I can say yes or no. in this case I'm going to say no and enter the importer so that you can see what that screen looks like.

So, I click on the importer button on the right hand portion and then it gives me a whole new set of information to enter.

I mentioned the food facility registration, if I have a food facility registration number for that importer, I can enter it in this field.

It also allows me to save favorites so if I have a common list of firms that I'm filing prior notices for I can actually save that name and address and registration number in my favorites and then select them very quickly.

That's again a nice feature for filing many prior notices. In this particular case I'm going to say I don't have a registration number for my importer so I can just enter a name, Joe Smith, and I am just going to give an address, and its going to asks me again for the state, put in a zip code and now here it asks me do I want to add it to my favorite list?

I can only add to my favorite list if I have a registration number. So because I don't have a registration number I cannot add it to my favorite list.

Now I'm going to go ahead and click save here. Then it takes me back to the last screen, you can see it adds my importer information to the screen.

The next is the carrier, that's who's actually carrying the shipment in, is it on a ship, on a truck, on an airplane, who is that carrier?

Is it United Airlines? Is it hot pod Lloyd? whatever, a ship company or is it on a truck line? In this case I'm going to say it's coming in on a truck because it's coming through Detroit.

Going to say land by truck, then I'm going to enter the carrier. Again it's going to ask me for information about the carrier. There's a code called a SCAC code, a Standard Carrier Alpha Code. If you have this you can enter it here.

If you're not sure if this particular carrier has a code you can say let me find a code. I'm going to say for a quick demo that my carrier is FedEx just to show you what would come up if you search for FedEx.

So you can see I can choose one of these FedEx carrier codes if I knew it was coming in on say FedEx ground, they would enter their carrier code.

So in this case I'm going to say cancel because this is coming in on a private truck line, again I'm just going to enter the carriers. It's AJ transportation and it's coming in on a vehicle and you can enter the license number.

And in this case we can say it's on a Canadian or an Ontario Canada truck. If I have a trip identifier I can add that, that's not a mandatory field and if I have a

bill of lading I can enter that again, not mandatory. And I entered the carrier and that information is entered.

Now once I get down and this is - I've now completed the web entry portion of my screen, I can hit save, if I've entered all the information to take me to the prior notice screen.

No! There we go, it says entry identifier is required, well I remember checking that not known button but it must have unchecked it on me.

So, I'm going to check that again, and now it's added it and it gave me an entry identifier you can see this entry identifier starts with pound, pound, pound and it gives me the rest of the entry identifier.

Now I have my web entry now you can see I have a button called create prior notice so now I'm going to create the actual prior notice.

Now I'm actually looking for the information about the product who manufactured it, and what's the product that's coming in? Okay so what's the country from which the article is shipped, again I can use the drop down list and any country that's in here.

I'm going to choose Canada since I'm coming from Canada, go down to the next, it's actually asking me for product information, if I have the product code and I know what it is I can type it right in.

Has anyone built a product code before? I know (AJ)'s going to show you but product codes are - FDA product codes are alpha numeric, seven digit characters that describe the product.

I'm not sure what it is, I'm going to use this little search button. In this case my product is beer. So I can put the product name in there and just going to put beer and hit the search.

And it gives me what it found for products that are describing beer, in this case I'm going to click the beer or lager. If I have root beer I could click on the root beer but in this case I have beer or lager.

So I'm going to do that, it's going to put in portions of the code, then it's going to ask me for the packaging method and the process applied.

So in this case I have bottled beer in a glass bottle so I'm going to choose glass and my process applied, this is where it gets tricky. And you know may not be a food science expert and know exactly how the product is processed.

But you know what we generally ask is that you do your best to figure it out, in this case it could be cultured or cured is probably the best one because beer goes through a fermentation process to make beer.

So cultured or cured would be the best one but you know would you be wrong if there's another choice in here called packaged food not commercially sterile you could put that on the technical right as well.

But in this case the best code is probably cultured or cured because it is - beer is made through a fermentation process.

Once I've selected those two I can click select and down at the bottom, it's now entered my FDA product code 32ACP04, that stands for beer in a glass bottle that's cultured or cured.

Now I'm going to put down my comment or name, in this case it's Northern Lager it's my brand name in this case. Now I've just described the product.

If I had a product identifier like a lot number or a batch code, I could use this product identifier, click add and enter an identifier. But in the most cases you may not have this so I'm just going to - it's not a mandatory item, you would add it if you had it.

And then I go down to quantity and packaging, again there's a descriptor here for prior notice purposes, quantity and packaging is an estimated quantity. You may think that you're going to have 100 cases shipped in but when the distributor sent it perhaps they only had 99.

If you put down 100 that's okay, it's an estimated quantity. You know, what we ask is that you're estimated as best you know at the time you're filing your prior notice.

But the way we do that is we start with the base unit, so that's the smallest unit of the packaging. So in this case the smallest unit is 12 and we're going to say ounces so again I'll put in 12 in the first block and then I'll choose fluid ounces because that's a 12 ounce bottle of beer in this case.

And then to put the rest of the packaging it says you start with the largest package to the smallest, so my next largest package is a case of beer or I can say 24 bottles, so I'm going to put 24 in the numbers column and then package type and here again we get a little confusing- there's a bunch of different bottles.

I'm going to say non-affected bulbous bottle. Again what if you guessed with one of the other ones, are you going to be wrong? You know we're not going

to you know knock you over the head for getting that kind of thing wrong, be in the ballpark in this case.

And then lastly I'm going to put in, we have 100 cases so I'm going to put 100 in the number column. And then I'm going to select cases in the drop down, then I can calculate my total quantity which in this case takes me to 28,800 ounces of product coming into the country.

So it calculates based on the units that I've entered, the next section is refusal information. This section was added as a result of the Food Safety Modernization Act which added this one element to the prior notice requirement that if the food in this particular shipment had ever been refused in any other country, you have to tell us what country that is.

And it's specifically related to the food in this shipment, in other words were these 100 cases of beer refused entry in a different country?

If it was I would have to enter that country. It's not whether Northern Lager had ever been refused in any other country, it's whether these 100 cases of Northern Lager had ever been refused entry into other countries.

So again this particular shipment was coming straight out of Canada, it's never been refused so I'm just going to leave it to no which is what the default is here in this case.

(Sousan Altaie): (Tony) I might be misunderstanding what's written there but as I read it says largest package to smallest, I would have intuitively put the 100 cases first and then I would put 24 bottles per case.

(Anthony Taube): You're right, I did that backwards. Thank you for - that's absolutely true.

Again I'm not looking down, I'm trying to - you're right though, I need to switch that around.

Thank you. Recalculate, thanks for pointing that out, that's a good catch.

(Sousan Altaie): Actually the calculation number was what triggered me but still the same, okay.

(Anthony Taube): Okay, so once I have that I'm going to hit save, now it takes me to the firms related to the shipment, in this case it starts out with who's the manufacturer for this product?

In this case the manufacturer's country of production is Canada, that's where the manufacturer is located so I'm going to select Canada.

Then I'm going to click on the enter the manufacturer button. In this case again if I have a favorite list, I knew that registration number I could enter it in this field or find it in my favorites.

In this case the only thing I have in my favorites is a company in Mexico so I'm going to click cancel here. I just wanted to show you how you could go in there.

So again I don't have a registration number and this is key, the original rule for prior notice required that every shipment had to state the registration number.

The final rule that was issued way back in 2005, it was about 2005, that's not right, 2009 was the final rule, took out the requirement to have a registration

number in the prior notice provided you tell us why you're not giving a registration number and you have to give us manufacturer's name and full address.

So if you don't know the registration number, that's okay but you have to tell us the manufacturer's name and full address. So in this case we're going to say it's Northern Brewery.

(Sousan Altaie): (Tony) the registration number is a required number, so is it going to return it back?

(Anthony Taube): Yes, Northern Brewery is required to be registered but the person filing the prior notice if they don't have it can still submit a prior notice. That's a good distinction.

Good question or point to bring up, it's required to be registered, so Northern Brewery has to be registered. But I'm not required as a file of prior notice to know what that registration is. I just have to again give the full address of the plant, I know it's that.

And I'm going to show you in a minute I have to tell the reason the registration number is not being provided. So in this case I'm going to say Toronto, so that's in Ontario and I'm not sure what their zip is, so I am going to skip it and it is one of the ones that is not required.

So in this case I can choose a manufacturer's not required to register or the registration is not known.

That is true, I don't know it, so now I can choose one of these reasons, why am I not providing the registration? There are a number of reasons.

Facility is out of business, it's a private residence, way at the bottom here there's a selection called unable to determine the registration number of the manufacturer.

And that's probably the most commonly used one since I just don't have it. We're requiring it, FDA is required to keep those registration numbers confidential.

So we can't give it out, if you call my office and said what's the registration number for Northern Brewery, my staff can't give that to you.

You can call Northern Brewery and say hey, what's your registration, your FDA registration number, they may give it to you, they may not.

They don't have to, that's up to them, but as long as you know their address you can still file prior notice for that shipment.

So I choose unable to determine, it also asks me should this facility be the default for any new prior notices for this web entry, it defaults to no.

Man: Why the registration number is secret or why they wouldn't give it to you, I mean if you have it, what happens?

(Anthony Taube): It's part of the bioterrorism act, we were required to keep those numbers confidential, that was one of the agreements with the trade is we would not share that information out.

This was a point of contention with the original interim final rule, you know there's a lot of folks who were filing or involved in shipments that didn't have the registration number.

Have you guys ever heard of the gray market or that term the gray market? So we might have a business who's their business model is they buy products from manufacturers and then they go seek a market for that product.

They may not have a business relationship, they may have bought that product from a distributor who was already a second party, but they could still - doesn't mean they can't ship to the United States.

It just means they're not going to have that registration number. Again it's up the firm, the firms can give it out all they want, they're not restricted.

But FDA was restricted from sharing that information. All right, so in this case I can't save it to my favorite list because I don't have a registration but I have all the other information so I'm going to click save.

And hopefully if it works right it's going to enter that information under the manufacturer. Here's a quick tip, I'm going to say the country is a shipper, is Canada, I'll click enter shipper and now I can say shipper is same facility as and I can say it's the same as the manufacturer.

Northern Brewery is not only the manufacturer but they're also the shipper, I can make the shortcut here, enter them as the same facility. I don't have to fill all the rest of the information out, I can just click save and it just says it's the same as the manufacturer.

The owner, again the owner's in the United States for this particular shipment, I'm going to say in this case the owner's the same as the importer to save time. But again this is a way that you can also file prior notices very quickly without having to reenter.

I'm going to say it's the same as the importer, in this case it's going to go there, and then the ultimate consignee is that's the physical location that the shipment's actually being delivered to.

In this case I can enter and say it's also going to the importer or if I wanted to enter a different location I could enter it as well, but in this case again to save time I'm going to say it is the same as the importer, click the save button, and it's going to save that as well.

Now the last piece of information that's on this screen before I submit the prior notice is enter a holding facility.

You might say what is a holding facility? Lot of folks misinterpret this as where the shipment's being held after it comes into the country. In this particular case a holding facility only has to be entered if once it arrives customs and FDA agree that the shipment can't come in and has to be directed to a facility not associated to the shipment.

So in most cases you're not going to enter a holding facility. You're only going to enter a holding facility if FDA contacts you and says hey we got that prior notice, you know that shipment cannot move past the port of arrival, we need you - or you need to tell us where it's going to be moved and in this case it has to be moved at the port to a facility that's not only customs bonded but also registered with FDA as facility that can hold the food.

So 99% of the time or more this is going to be left blank.

(Sousan Altaie): Would that be the case where we had noticed the hold on the country with papaya let's say and as a gentleman here said the shipment is on the road and is coming. Would that be the case where I'd put hold facility to tell them what to do with the papaya once it gets there?

(Anthony Taube): No that is not normally the case, not in the prior notice because remember prior notice is really separate from that admissibility stuff that (AJ) was talking. Prior notice is the first part of the process, where FDA is making a different decision, we're making a national security type decision on whether that shipment can proceed into the country.

I didn't mention that before prior notice, FDA often didn't get notified of food shipments until that food was well into the country. So in that example I gave earlier of that container that arrived in Los Angeles and it got put on to a train to go to St. Louis, we often didn't get notified until that shipment was in St. Louis.

So we had no ability to make a pre-arrival determination whether it was a national security risk. So the stuff that (AJ) was talking about, the import alert, once we make the national security risk technically those papayas unless there's some other reason they have to be held at the port of arrival are going to be well past the prior notice process.

And they have to be held intact say at the port of entry, which might be St. Louis. Again the prior notice is out of the picture already so again the holding facility here is only when you're directed by customs or FDA to declare a holding facility at the port of arrival.

It could be a customs bonded warehouse and generally that's just where it's at, so again in this case we don't have that, we haven't been told that yet so we're going to go ahead and submit and I promise I'm almost done - so I'm going to click submit prior notice.

It's going to give me a summary of all the information which I can double check, then once I say it's fine, it looks good to me, I can click yes.

I'm actually going to go ahead and submit this prior notice. Are you ready to complete your web entry, yes, it gives me a couple of opportunities to change my mind.

And actually here you can see it gives me a confirmation number. This is the number that actually signifies that I filed a prior notice for this particular shipment and if you then want to you know file your own prior notices and give it to a customs broker to use with the entry you can do that and this is the number you'd give them for that entry.

Again most customs brokers will offer this as a service and they'll file the prior notices for the trade person arranging for the shipment.

But again this system allows anyone to do it themselves, no charge. Usually brokers and filers charge you a fee for this particular service. Once I'm done I'll click yes here and I've effectively filed a prior notice for this shipment.

And it's just that easy. Wasn't that easy? I know it looks easier on TV than it does in real life but I'm going to give you a phone number for my office, again formerly known as the prior notice center, now known as the division of food defense targeting.

And that's 1-866-521-2297. We are - I have this office staffed 24/7, we're always there, someone always answers the phone.

We are there to help you through this process if necessary. We're not there to file it for you but if you get stuck we can help you figure it out how to get unstuck in this system.

That's what my staff is partly there for is to provide that assistance. Again that number is available 24/7.

Yeah, 1-866-521-2297. That's also on that website I showed you earlier, our number is listed right there on the website as well.

So I'm going to go ahead and log off, that should take me eventually back to that prior notice of imported food but I guess I have to clean the system.

Any other questions?

Man: This is kind of unrelated, but it has to do with food facility registration, I'm just bringing this up because I get this question a lot from the Malaysian exporters. When they register the facility, especially now with the modernization act that they have to reregister their facility before, well it was before the end of the last year, and they kept asking, what, I just wanted to clarify, because I've always been a little iffy, U.S. agents who can technically be put down as a U.S. agent?

Because I believe now it's mandatory that they have to designate the U.S. agent. Who can generally be classified as a U.S. agent that can be put down?

(Anthony Taube): You're absolutely right, there is a requirement for any foreign food facility that registers has to have a U.S. agent. There is no specific requirements but there comes with that a responsibility to be a U.S. agent, what you should be is have a business relationship or some kind of relationship with that facility.

You are then responsible to be a point of contact for that facility within the United States.

So in other words if FDA had an issue with a product and we needed to quickly get ahold of that facility and the number we tried to call in the foreign site is not answering, you've effectively got a hotline to the company.

You should be a quick communication link to that facility to be the U.S. agent. And you have to be a person within the United States and you have to have an email address.

Those are mandated but with the Food Safety Modernization Act that U.S. agent also has a new liability and that is if that facility was inspected and found to have violations, we -and FDA decided it needs to go back and do a reinspection, that U.S. agent now is going to get the bill for our inspection.

So that's created a little bit of added responsibility for the U.S. agent and some folks who were previously U.S. agents under the bioterrorism act of just being the communication link have decided hey look, I don't want that liability any more.

And so we had a lot of foreign facilities saying hey look, you know who can be my U.S. agent?

Man: That's why the confusion came, you know.

(Anthony Taube): There's no requirements other than to still be the communication link but recognize that you also have that responsibility and you will get a fee or a bill if we do a reinspection of that facility under the Food Safety Modernization Act requirement or the user fee.

And we haven't started billing for those yet, because there's a lot of guidance documents that are still in the works but if you want to read up on user fees and related to registration and reinspection there's information under the Food Safety Modernization Act link on our website that describe that.

But that's a great question because there has been a lot of controversy about that this year.

(Sousan Altaie): Actually the agent is only a person who's willing to have a relationship with the shipper, that's it. They're responsible for anything that FDA needs to ask or tell them.

Man: Once the money got involved in it then, you know, lots of exporters got to panic, and because the people that they were contacting and using as their agent kind of panicked and said that we don't what to do this anymore, you know if we end up getting slammed a 400 dollars or whatever your reinsertion fee is, so I just want to, you know clarify that, because I've gotten those questions. Especially when I told everyone hey the new registration is happening, and you have to do it by the end of the year, and they kept on asking me about the U.S. agent. And I was getting sort of back and forth so it could be anybody but it's still the same situation but they just have to be okay with they might get a bill every once in a while and they need to clear that up with the food facility.

(Sousan Altaie): I actually get this question often as well. My facility has failed the deadline of registration, what do I do now, how can I ship? The point is that you register any time you can to be able to ship.

So it doesn't matter if you miss the deadline, go ahead and register anyway.

(Tony): Yeah the key there is you know (Sousan) as you pointed out there was a renewal period so under again the Food Safety Modernization Act, the renewal period is even numbered years, so 2012 marks the first renewal period.

And it's typically from October 1 through the end of December, in this case in this year we actually extended it to the end of January because we got a late start with the system.

But once you miss the renewal period you can no longer renew an old registration the way the system works. So if you miss the renewal period what you have to do is create a new registration and you certainly can register - make a new registration any time as Sousan points out.

Man: Right now according to the FDA you know the FISMA the following facilities have to resist with FDA and also the U.S. agent. I know that right now there are companies that are doing such services for facility registration as well as U.S. agent for companies in my country of Viet Nam.

And they charge you know a fee. Some companies they have a name which is you know very confusing like FDA solutions. So people in Viet Nam they think that this belongs to FDA.

And when you know they advertise their services in Viet Nam they say that you know this is FDA and from FDA so people trust them and just pay them the money without thinking that this is just a service company.

And without knowing that they're even logging in the website by themselves and do it by themselves, so I think that is it by law that you know here in the U.S. those companies should not bear the name like FDA with them. Thank you.

(Anthony Taube): Yeah it is - as Sema just pointed out it is a common problem here in fact there was one company doing it quite extensively when the bioterrorism act rolled out.

And they've actually since taken FDA out of their name after we sent them I think a strongly worded letter but you're right that is an issue and you know we created somewhat of a cottage industry where companies are taking advantage of you know foreign facilities and saying hey we'll register you, be your U.S. agent.

And again it's not illegal to do, to offer that service to companies. But you know it is a little bit of a misnomer to add our - you know add FDA into their name and to represent themselves or misrepresent themselves as the case may be as being part of FDA.

But you're right, it is a problem and certainly communicate that out in your countries that it is a free process, there is no charge to register yourself. You do have to find a U.S. agent and you know again depending on you know you can set up a business relationship with someone to serve that role for you.

If they do it for free, great, you know if you can't find someone to do it for free and you want to use the service that is your option as a business to do so.

(Sousan Altaie) Literally that agent can be your cousin that lives in the United States.

(Anthony Taube): Thank you. Oh one more question?

Woman: Is this prior notice specific for food or if a company or a firm wants to file a prior notice for other medical products, like drugs or biologics, they have to go to different database?

(Anthony Taube): The prior notice requirement only applies to foods, the bioterrorism act of 2002 only said prior notice had to be filed for food so prior notice interface which I just demoed is just prior notice for foods.

So if it's a drug entries or drug shipment the only thing that they have to do is file entry, the stuff that (AJ) was talking about earlier so you would file entry, however it's done now through the normal process.

And that's the set of information has to be supplied. Just because that's what the law said, it only applies to food. Good question.

Man: My question to you, is it mandatory to have a custom broker to the release goods, imported goods from the customs authority, it is mandatory or the importer did it?

You know you should me how to make priorities without you know broker engagement but for releasing goods, I mean the importer can do it or is it mandatory?

(Anthony Taube): So again you know they have to meet what ever requirements are there for a shipment that enters the country. There's what's called informal shipment that are low value and customs, U.S. customs and border protection, you can have shipments up to I think \$1999 and that's an informal shipment.

And so customs, the customs requirements are less and it could be that perhaps an importer can meet all the customs requirements by themselves.

But again it depends on the commodity, it depends on you know the tariff codes and all that kind of stuff. And sometimes and often times it's easier to hire a broker to pay them a service to do that for you.

Again it's really situational dependent but it's not you know unthinkable that some importer couldn't do it themselves.

I think in 80% of the cases prior notices are filed by customs brokers as part of the service that they provide to their clients that handle the shipments. The other 20% are filed through this prior notices system interface.

So again it's possible but it's not as common as using a customs broker because they can take care of all the other duties and tariffs and all that kind of stuff that come in on the customs side.

Man: So FDA is not allowed to give registration code from the factory right, but can I get the name of the factory or something like that if I'm going to order or import the products from a specific country is there a company that I can safely order from?

(Anthony Taube): Yeah we don't do that again because that might imply that we're endorsing a particular company so that's really up to you as a business person to say who you want to order from.

So we don't give that kind of information out either.

Man: So I have to check with the company themselves that they allow to export to you.

(Anthony Taube): You know if they're interested or I mean if they want to sell you stuff then you can take care of the importing it or exporting it as the case may be into the United States.

(Sousan Altaie): You can always look at the import alert to make sure that the company you're having a business with can import.

(Sema Hashemi): Other questions? All right, thank you (Tony). So we'll have (AJ) present, thank you. We are going to have AJ present for the next maybe 15, 20 minutes and then we'll end up - we'll finish with our question and answer session.

(AJ Seaborn): Thank you but feel free to stop me again if you have questions. To follow up on the filer question, filers are licensed like customs, not us. I will show you, because FDA does have a filer evaluation program.

We do - we evaluate filers, do we need to put more scrutiny on our entries or not necessarily but any scrutiny on their entries depending on how well they file, the required elements for us.

But as (Tony) was saying the companies are paying filers to facilitate entries so it makes sense to take advantage of what they offer. Wanted to point that out.

But a good segue into registration and listing, we already talked about food facility registration, business center for drugs and the center for devices work more closely with device and drug registration than we do.

Drug and device registration is a requirement at the time of entry where as food facility registration is done prior notice side.

I don't have any dummy accounts set up for drug registration or device registration but I'll show you where you can find that information on the FDA.gov.

I prefer using the search function, the top right of the website but you could also go to the A to Z index and I'll define the registration information.

For drug registration we use the drug registration and listing system so a firm can both submit their registration and listing information through this portal.

I'm not that familiar with the system because we don't necessarily deal with it that often, ORA but it has instructions here, it has guidance for the electronic submission of the information.

So here's the site itself at the bottom here, you have the instructions again and again basically what it involves is it involves emailing the center for drugs, they'll set up an account for you.

It isn't necessarily as easy as food and facility registration, device registration is exactly the same way.

It would be obviously more consistent and helpful with all the same systems being the same, unfortunately it's not. The difference between drug and device and food facility registration though is that you can search firm on FDA website and find their registration information. I just search for (Hospira), find their establishment identifier as well as their address and their registration year for that firm.

Devices are the same way, as (Tony) was saying because of the bioterrorism act we don't share that information for food facilities.

Do you have any questions about drug and device registration?

Man: Are there any Bangladeshi pharmaceutical you know companies are right now registered, I mean any validation company? So is there any system to stats by country wise, you know, how many pharmaceutical companies in Bangladesh right now are registered?

(AJ Seaborn): Not that I'm aware of, but I'm sure that you could contact CEDR for that information, they probably have it on file somewhere.

(Sousan Altaie): You can actually pull reports off of this registration data information.

(AJ Seaborn): You could download this file, it is zipped as well it appears to contain all the registration information. I would imagine, let's see if it opens. Unfortunately this is in text not in Excel, it should be much easier to sort by country or some other filter, you said you can find that information (Sousan)?

(Sousan Altaie): Yes you can pull that form and you actually can do your own search and pull the information you want. But if you're interested send me an email and I will give you a list of Malaysian registered industries.

(AJ Seaborn): But normally whether it's registration issues or device issues, approval for their product, normally if you scroll down to the bottom right of each page at least on the bigger picture they have contact information within each center who basically their job whether it's industry outreach or small businesses, what not – you can ask them questions specific to their particular area of expertise.

Orange book search is also another good one for drugs, this is, allows you to search by the applicant holder for the drug or the drug itself. So if you have a specific questions about a particular drug you can go here as well.

But it all kind of leads back to the affirmation of compliance that I was talking about previously on the filer and importer, submit the information to FDA when they submit a formal entry.

This information tracks, allows us to expedite review of our entry. It's very important to submit the information to us, and submit it directly, its not always within the ability of the importer to make sure it's submitted correctly.

But once they're comfortable with their filer, the entry documentation, and what that looks like, it makes everyone's life a lot easier. I will talk about the imports page as well.

We have a – you can go to the A to Z index under I is the import page, our main page. We have a rather large project right now to revamp this page, it's been forgotten for many years I think.

If you look on the left hand side there's links to the same information multiple times so - but the one thing that we have added recently which is very helpful for industry as well for anybody who's trying to find information about a specific entry, as long as you know the port code, on the right hand side you can go to find an import office.

So it will bring up a map of the United States. Let's just say it's being imported through Los Angeles. And put that on that part of the map, it will bring up a PDF form and it will have a list of all of all of the ports that are covered by that district, as well as the responsible people for that district, their contact information both generally and foreign entry status.

So if there's any questions about an entry, you can use this page or this PDF to find out who is both responsible for that port and then it will give you a little peace of mind that you don't have to call around the agency to figure out who's going to deal with this entry.

But there's a separate resident post that deals with LAX, Long Beach, et cetera. I will not go through entire list but it's a valuable resource that probably was long overdue.

It's available for all of the regions. We talked about detention previously, once the entry has gone to a detention there will be a specific contact in the district to reach out to, so that will always be your point of contact.

But if it's general questions about an entry to a district, this is a very good resource. I talked about ITACS previously, this is the Import Trade Auxiliary Communication System, this interfaces with MARCS via the electronic document submission page.

I'll show you what it looks like quickly, it looks a lot like the pending system that (Tony) showed you earlier, you have to have the entry information, and be able to see the what they call the characters. And then type them in down here but it allows you to submit any number of entry documents against an entry line.

Talking about filer, I said I would show you - I told you about filer evaluation, it now falls under the scope of CBP so evaluate the filers as well for our entry data.

So if someone in your country or someone in the industry contacts you and you want to look and see for what ports that they're going to use, they want to find a good filer, quote unquote a good filer.

So as of last year we started posting the filer evaluation results so if you wanted to import into Laredo this is one of the brokers that you can use, you can last evaluation date, what their filer code is, what their address is, and what the evaluation result is.

On the previous page it explains what each evaluation result is, and the contact information, they can go to CBP's website. CBP has a running list for each port of the contact information, for each filer.

I talked about MARCS previously and may have heard of PREDICT, PREDICT really is just a function of MARCS, kind of like ITACS. PREDICT is our screening engine behind MARCS so as I was telling you it take into account general intelligence, previous sample analysis for the firm for different products, sectional results, et cetera.

PREDICT is really the screening engine behind - that's what drives MARCS, that's how we target the highest risk products, and distribute our resources accordingly.

Any questions up to this point?

Last thing I will go over is the product code builder. It looks very similar to what (Tony) showed you via PNSI, that at the request of someone in the room I will go through this because it really is more of an art form than a science to deal with the product code builder.

We struggle with inconsistency just because there are product codes that are similar and there could be more than one right product code, we are trying to develop a – those of you who are familiar with CRUS which is a Customs Ruling System, we are trying to develop something similar for FDA.

So you don't get told to use one product code in one port and then another product code in a different port, it happens more often than we'd like it to.

I won't go through the tutorial here but this is a tutorial for product code builder and it's the same builder that - same product coding that's done in PNSI so it's a very good resource if you're new to product code building.

I will go through the application though just to show you simply what it looks like. Again same product coding as via PNSI, there's many different ways that you can search for a product code.

I find it's easiest if you search by product name, let's say I want to find tongue depressors. The more general you are the easier it is to find product codes here

although it really depends on what your search is, that's why it's more of an art form.

You can see that there are at least five different industries; this is the first part of the alpha numeric code that involves tongues. You can see under industry 17 where the description is above the industry meat products and poultry, there are various animal tongues that have product codes for.

Under 37, there is Korean paste made from the starch of devil's tongue, 76, this is a dental device, industry, tongue scraper, other tongues, suspension system, that's not it. And then when we get to ear nose and throat we finally find what we're looking for, in this case, metal tongue depressor.

So I'm going to click this, devices are somewhat unique in that they have a different product coding nomenclature or structure than the other product codes do, I can never figured out why but that's how these product codes were designed.

So I'll hit next, you can tell in this case this product code is complete, there is no "sub class" which is typically the third box here, and no "PIC" which is process indicator which is the fourth box.

So in this case our device product code is complete- if you wanted to you could also search for partial product codes or verify product codes or you can go up here to industry, let's just say we're looking for a baby food product coming from somewhere overseas.

Can highlight this part of the search field, click next, it will take you and it will allow you to build a product code box by box, so we have the industry here, for a baby food product, you go to the second box.

And we're going to look for what type of product are we talking about. We're talking about barley cereal, so here it's filled in, the second box, and the product code at the end which is 01.

Once we put up the class and the product code now it's going to ask us because foods require a sub class, how was the product packaged? Typically packaged in glass jar.

And then we'll have to pick as well the process indicator. I would say more often than not these are commercially sterile. Again this information typically will change based on the firm and how their product was packaged and processed, where as the other three fields the 40s, the Bs and the 01 will stay the same for all barley cereal baby products.

And once you hit next it will give you a description of what your product code is, baby cereal in glass commercially sterile we know it's barley cereal.

Anybody have any questions or have they found any issues with that, hard to tackle over the here?

The more and more you use it like anything else the more comfortable you get with it, but like I said even those of us that have used it for a while, they add and they remove product codes all the time.

So what you may have used previously may not be the correct product code any more. It is just one of the extra I guess functions of the entry filer, the customs filer provides for you, they use this on a daily basis.

So they know ins and outs of product coding.

Ant other questions, concerns, comments?

There is lot of good information here both on the import side, each of these particular tabs here as well so whether it's drugs, devices, et cetera, they normally they have their own page about imports as well as specific to those products.

So there's a lot of good information here, obviously overwhelming at times but good idea for those industry folks who are new to FDA to browse the website in their product area.

Any other questions? All right, Thank you.

END