

April 16, 2013

FDA Imports Program - An Overview

Andrew Seaborn, Office of Enforcement and Import Operations

(AJ Seaborn): Thank you all for coming. (Sema) thank you for the introduction. My name's (Andrew J Seaborn) or (AJ) as they all call me. Feel free to call me either one - whichever you prefer. I'm with the division of import operations. You may have heard the division of import operations and policy previously or DIOP. That was our old division. With a re-organization last year we switched over to this new acronym which is DIO. So it's getting used all around, not just from industry and trade but also internally as well.

So thanks again for coming. Feel free to ask questions at any point. Really that's why I'm here, to answer your questions. I'll give you a high overview of the imports and how we look at it from the regulatory side but really I'm here to answer any questions you have.

Here's a brief overview of the presentation. Looking at what we regulate. Look at import data from the past decade or so. A little bit about our law. I'm sure no one wants to hear about import of law for two hours. I know I wouldn't want to if I was sitting in your shoes. And then our process both from the food and feed side as well as the medical product side as well.

And then finally a little later in the agenda is the employed alert system that we have developed. It's been in existence for about 30 years or so. So I'm sure there's many constituents in your countries who have questions. We get a lot of questions from industry as well as from the government. So feel free to ask questions throughout the presentation there as well.

These are the products we regulate. I'm not going to read through the entire list but as you can see from the import side we have to be knowledgeable about any different products that FDA regulates, not just - we can't focus on foods. We have a staff of about 30 people or so in the division. So we kind of specialize in various industries but we have to know something - a little bit about everything whether it's cosmetics or animal feeds.

Recently it's tobacco - one of our new charges. So there's never a dull moment in import. There's always some little twist to a situation or some minor detail that changes our answer the way we look at this particular product or situation.

This is the organization of FDA for those of you who are unfamiliar. In each of the centers - which you can see at the bottom - they're the ones that are technical experts in the various products. So the Center for Drug Evaluation Research - they're the ones that do pre and post market surveillance. They're the ones that deal with the registration and listing of drugs. They're the ones that look for any security concerns when it comes to drugs. They have a counterterrorism office as well.

And then at the National Center for Toxicological Research. Along with the centers, they're the main research arm of the FDA. Then the Office of Regulatory Affairs. That's where my division resides and I like to say - since there's nobody from the center here - this is where the real work is done in FDA. These are the boots on the ground. These are the people in the field conducting the examinations, the sample collections, et cetera

Man: I understand it is scattered in Maryland even in DC. Is this true? I mean all the centers we have are located in different states?

(AJ Seaborn): They are. They are split out around Metro DC. There are a few in Virginia. Most are in Maryland. The Department of Health and Human Services which is where we reside under as an agency. They are located in DC. So based for the most part they are located in Maryland.

The National Center for Toxicological Research is in Arkansas I believe.

(Sema Hashemi) Yes it's in Arkansas. But (AJ)'s correct. I was just going to elaborate a little more just to give out specifics. So our Center for Food Safety and Applied Nutrition - CFSAN which most of you are frequent with - is in College Park.

CDER - our Center for Drugs - is mainly here at our White Oak campus where we reside right now. We do - our center for Biologics is currently between Rockville Pike in Rockville and NIH campus. And CDRH is here - our Center for Devices and Radiological Health. Our Center for Veterinary Medicine is also in Rockville Maryland. CTP is in Rockville Maryland but another side of Rockville almost near Gaithersburg. And as (AJ) said, NCTR is in Arkansas and our office of regulatory affairs - that's our inspectorate. So they're all around the globe - well not around the globe but around the US - the continent.

(AJ Seaborn): Thank you. I kid about ORA being the only office that does real work in FDA. And obviously the centers - they provide a valuable resource and they're the ones that are the experts. They're the ones that come up with new methodologies for things. So obviously they have a very important role to play as well.

Under the office of regulatory affairs, this is how it's broken down. We have what we call five different regions in the United States and there are district offices and resident posts that make up these regions as well.

Within DIO -- other than having specialties or specializing in certain areas whether it's food or drugs, we also oversee activities, we have what you call Regional Activities Managers (RAMs). I along with two of my other colleagues oversee - I import activities in the central region. So we have the most districts. We have six. So clearly what we're trying to do is we're trying to insure that things are as consistent as possible. That's really our task as a division and my task as one of the RAMs for the central regions.

As you can see our work has not gone down in the last decade or so, I started in 2002. As you can see where less than ten million lines per year being imported into the US. Now we project in 2013 almost five times that, up to 35 million lines. With that many more lines come that many more situations that need our involvement that we have to deal with whether it's questions from trade or freedom of information act request. Any number of issues that we would have to deal with on an entry. That means more work for our field staff as well.

So the investigations branches are conducting more examinations and sample collections or they have more lines to select from to do those examinations. The compliance branches have more enforcement or regulatory follow-up that has to be done. So obviously there's no shortage of work for us.

From last fiscal year 2012 this is a breakdown of what we've seen kind of in the little buckets of the types of product that we regulate. This is actually the first year that we've seen human foods fall from the number one spot as far as a percentage of lines and devices has taken that over.

Any other questions about the organization or import data?

Man: What do you mean by devices? Is it only imissionary equipment [radiation emitting devices] or other devices?

(AJ Seaborn): Devices is a rather large group. Really I think the reason why this is the case is how we started seeing medical kits being transmitted to us. We started seeing it as a different line for each different product. Medical devices encompasses a lot of different types of products.

(Sousan Altaie): Don't forget, the medical devices are anywhere from tongue depressors, gloves and small equipment all the way to radioactive and radiological logical equipment. So the number is too many because the range of devices are many.

Man: How do you classify this like human foods or housewares? Like we know that there is a harmonized tariff schema or something like that. How do you classify it?

(AJ Seaborn): For FDA what we do is for the harmonized tariff code which is really a function of Department of Commerce but also customs and border protection which I'll talk a little bit about later but that's how they classify products. And then for FDA purposes each of those tariff codes have what we call FD flags and that tells what we call the import filer or the filer if they have to transmit FDA data to us. And part of that FDA data is an FDA product code and that's how we distinguish between what each different type of product is.

So in addition to a description of the product, we have a product code that tells us okay so this is dietary supplement falls into human foods. So this is a dietary supplement coming from China and was manufactured by this firm, shipped by this firm and consigned by to this firm. So at the end of the year we'll pull all the data based on product code and that's what gives us this number or this pie chart of percentages by the number of lines.

Man: In the last slides about the office of regulatory affairs I see some abbreviation here. What OCI stands for - OCI of Field Offices, OCI Resident Offices and OCI's Domiciles?

(AJ Seaborn): That's our Office of Criminal Investigation. They are the ones without using criminal investigations and the definition of what they do - they're the ones that will work on the enforcement actions from the criminal side. So they're the ones that are going to work on smuggling issues or they're trying to clandestinely import something that we might regulate to evade customs for whatever reason so that we don't look at the product.

But really from the enforcement side that they work on - any of the criminal proceedings that we're going to take against the firm or an individual.

All right, moving on. The food, drug and cosmetics act of the - what I commonly refer to as the act - this is really where we draw most of our import authority from.

Customs and Border Protection - that really is the big dog at the border for imports. So they have their own set of laws and federal regulations that were codified as a result of that law. But chapter eight and section 801 of the act is really where we derive a lot of our authority and what a lot of our regulations are based off of.

And this is where we draw the appearance standard for imports as well. It appears from the examination of such samples or otherwise that one, the article has been manufactured, processed or packed under insanitary conditions. So this is when we're talking about conditions in a facility. We're talking about something being processed under these less than desirable conditions.

Or two, forbidden or restricted in sales in the country in which it was produced. So, that would be something that was produced in Indonesia that is forbidden or restricted for sale there which as you can imagine it's going to be difficult for us to prove as we don't have working knowledge of the Indonesian regulatory system, so we don't know their laws. So we would then rely very heavily on our office of chief council which is where a lot of our attorneys reside to go look at Indonesian law if we wanted to use that piece of 801.

Or three which is by far our most common use of section 801 and that is if the article is adulterated, misbranded, or in violation of section 505 for new drugs that didn't get approved. Everything that you would see in the food, drug and cosmetic act either makes it a dull trade, misbranded or unapproved for us to be able to take action in the import arena.

So if it's something that has salmonella and we've proved whether it's through a sample that we collected or a state collected or whatever - that makes the product dull traded under chapter four of the act. And then chapter eight and section 801 is what allows us to take action against that product on the import side.

And then such articles shall be refused admissions. That directs us what to do. So now we have the violation and we can refuse admission to the product. As I was saying, this part of the act gives us our appearance standard. This is our standard of approve for imports. So we can refuse entry to goods that appear to be misbranded or adulterated or unapproved. And then under the first bullet from the previous slide - that weren't manufactured in accordance with good manufacturing practices. This is different than our domestic standard as well as the criminal standard.

And the or otherwise part of that definition allows us to make our admissibility decision based on historical data. So that's previous sample collections, field examinations, et cetera Its inspection whether it's domestic or foreign inspections, information from other sources saying sample collections from a state or another government agency and then other evidence.

Again, we can all take that into consideration as we make our decision about the products. And as I was saying shall be refused admission - that directs our actions. So the intent is to deny the importation of violative articles. We expect the articles to be in compliance when they're offered for import.

If we do find violations after it's imported – let's say we just release the products - we still have the authority to take other enforcement actions such as seizure. We can injoin the firm. That's a different part of our law as such there are different conditions that are required to take that kind of enforcement action. Any questions about section 801 before I move on?

As I was saying, I'll talk about CBP later - Customs and Border Protection. These are different parts of the US code and the regulations that they work under. We talked about the harmonized tariff scheduled previously. That's what they use to classify their product. But they - I say gets the first cut at the product. They're the ones that entry is made to. So they get the initial cut or they have the initial authority for an imported product whether it is ours or whether it's a drug enforcement administration or DEA's product, et cetera

So the customs territory of the US which FDA also works in the 50 states, District of Columbia and Puerto Rico. All of our insular possessions are not included in the customs territory. So technically even though they're territories of the US, when something's imported from that country, it's effectively being imported into the US from that possession or that territory.

And I'll start a quick overview of the import process. Again, feel free to stop me if you have questions. So something is shipped from a foreign country to let's just say California. Upon arrival, entry is made through customs. And then if it's regulated by FDA, they forward that information over to us.

For food and feed only – So we're talking about animal feed. We're talking about dietary supplements. We're talking about your TV dinner, et cetera We require prior notice for FDA. Prior notice is required at the port of arrival. So while this may not be at the port of entry, prior notice is required at the time when it arrives in the US. And it doesn't matter whether it's going to be stored, distributed here, whether it's going to be transshipped through the US, whether it's going to be exported in the future.

The one caveat there being if it's exported immediately from that port out of the US but it's going to go to a foreign trade zone, et cetera And there are certain timeframes that have to be followed. So depending on the mode of transportation, it comes through via road normally via truck, it's two hours, via rail and air is four hours, and via sea, it's eight hours. For most modes of transportations, there's really no issue of meeting that timeframe if it's being shipped here from Southeast Asia. And obviously it takes more than a third of a day for it to transit the Pacific Ocean or the US.

So once the prior notice is filed and it's been satisfied on that side for food and feed or for every other product then the information comes through what we call the 801(a) admissibility as I was talking about previously in section 801. The entry is now live for the purposes of customs and FDA. If DBP has no reason to detain the articles or hold the articles. Then CBP will issue a conditional release for the products.

So there are times and depending on what time of day in the port that FDA will be there as well. So if we want to look at the product and we can immediately go walk over to the customs office and go examine or sample the product there.

But once this conditional release is issued by Customs and Border Protection - the product is technically allowed to go to destination. And so all the other agencies - whether it's us, fish and wildlife, whomever - make their admissibility decision as well. But it doesn't mean that the importer has been released from the conditions of their bond. So as part of each entry, the importer of record has to work with customs to set up a bond for that particular entry.

And without getting into too much customs and bond law, there are two different kinds. One being a bond for every shipment that they import over the year we call a continuous bond or a single transaction bond for that particular shipment.

So really what that is, is that's our hook or that's Customs and Border Protection's hook that if you want to take some kind of import action against the product and the product is no longer available, we can now go after that money or that bond, that's what the bond represents.

Some of you may have heard of our OASIS system in the past. On the entry admissibility side we don't use OASIS anymore. We use the MARCS system or MARCS Imports. So the information is sent from CBP electronically to FDA via Ace or ACS and we now have what the field calls or what we call the grab bag. So all the entries that are now made "maybe proceeded" by the system - they all show up in this grab bag in MARCS for the field to look at.

If it's not electronic which is very rare at this point - back when I started ten years ago it was much more common for the entries to be made via paper but not at this point. We have to hand carry documents or we have to go to customs to get the documents which obviously adds more time to the process. At this day and age with electronic submission and different portals, we don't see - we probably see a half a percent or less per year of entries that are made via paper and not electronically.

As I was saying earlier, the FDA information has to be submitted along with the customs information if it's something that has an FD flag which means that we want to look at it. So in addition to the importer consignee tariff information we're going to require our country of origin which may be different than customs, product code manufacturer, shipper, product description.

We don't require affirmations of compliance and quantity and value. We said that's subject to the discretion of the filer and the importer. But it's information that we can use to make our admissibility decision a little quicker. So if the companies - whether it's a filer or importer - can provide the information. It helps us do our job faster. It's the ultimate decision as a release or a may proceed if it'll get the importer a may proceed or a release quicker. It just eliminates steps that are otherwise unnecessary but it still is an optional field. So there are times we don't get that information.

I think a lot of them are self explanatory except for maybe the affirmations of compliance. We'll talk about registration or listing later. That's the field that the filer and the importer can transmit the registration or listing number, the approval number for a product, if it's been acidified or low acid canned food that's where they can transmit the food canning establishment number and the scheduled process identifier. Again, information to allow us to do our job more quickly and efficiently which in turn helps industry and trade as well.

So if this information - so if an entry where it isn't "may proceed" by the system, FDA has humans who - and in most ports it is their job to go in every day and look at these entries that got kicked out for whatever reason. They go in and look at biologics or the licensing of the product. We talked about drugs and devices and all of their requirements as well as low acid in acidified foods.

But then with in MARCS - It'll take into account many other kinds of information. So we're looking at inspectional information. We're looking at previous exams and samples. We're looking at general intelligence for that area whether it's - there was just a tsunami near Bangladesh. We may bump up the risk score for that type of product or certain products coming from Bangladesh.

All these types of products that are susceptible to water damage or if they lose power. Products have to be refrigerated for them to be - that's part of good manufacturing practices and good storage practices. And then from time to time the centers I talked about previously CFSAN, CDER et cetera will issue assignments because they want to gather more information about this product. So they'll issue an assignment, we enter criteria into our database, the database then flags those type of entries for the field to look at if it fits that criteria for the assignment.

There's a lot of information that goes into MARCS and into our entry review. Obviously I can't show you what it looks like because it is privileged enforcement information. But it is definitely a great step forward to what we had in OASIS. It provides us a lot of opportunity to look at additional types of information and pull it all together in one spot. We don't have to go look at it as an entry reviewer.

All right, moving onto drugs specifically. Again, as I was saying about the affirmations of compliance. In addition to what the system will tell us, it'll allow us to look up automatically our approval databases, or registration and listing databases. It'll look up those affirmations that are transmitted to us.

So again, not only is this optional information provided and we have it in front of us. Now the database looks it up directly for us. So that's why it's very important that the information's transmitted to us and transmitted to us correctly. So that database can do its job looking it up.

But drug products require approval except for investigational new drugs. Both the products and foreign source manufacturing site specific and it has to include the dosage form and strength. Again and similar to approval, the product has to be listed as well both product and manufacturing site specific and include the dosage form and strength. And those all have to be done by a registered drug facility which is a site specific.

However it does affect the listing of the drug. Our Center for Drug Evaluation and Research as well as the Center for Devices and Radiological Health have both said you can't have listed products from an unregistered facility. So if the - whether it's a foreign or domestic facility, if they let their registration expire, their listings expire as well.

Medical devices - there's a little bit more that goes on, on the approval side or a little I guess more of a less certainty when it comes to approval. Most class two devices and there's a select few class one devices (Sousan) was talking about previously. There's a whole wide range of what a device could include - a tongue depressor to a therapeutic massager to an x-ray cabinet. Obviously there's different - the different process of how they're manufactured as well as what they're intended to treat as well as how we approve the product.

Most class two devices and a few class ones require a cleared premarket identification before import and then most class three devices and a few class two must have an approved premarket application prior to importation. And the information 510K and 515A is where that part of our law is in the federal food, drug and cosmetic act.

This again is specific to a product. So and then similar to approval in drugs you have both registration and listing for medical devices as well. And I'll show you later where on FDA's website you can go to register and list these types of products as well as food facilities.

But as I was always saying if it is an unregistered facility it can't have a listed product. So it's very important - I think the takeaway message here is that it's important for products to keep up with their registration requirements for drugs and devices. And now with the food safety monitorization act, we now have a renewal requirement on food facilities as well.

So we just started implementing the food facility but re-registration or renewal requirement so I know (Tony's) shop has some issues there. So it's important that all parts of registration to be current. And on the biologic side we require licensing for the product which is very similar to approval for drugs and devices, both product and manufacturing site specific and then listing and facility registration again here as well.

Registration listing is though - is required for what we call HCTP's. Registration is only required for blood establishments. Otherwise we don't have a similar registration listing requirement for biologics. Questions? There was a quick overview there of drugs, devices and biologics.

But what the main point there again as well as it's become important for the foreign facility to know what their requirements are and for their products to

be in compliance at the time of importation. We get a very small window I'll talk about later after we detain a product before we refuse a product. So it's important for the regulated industries to know what their requirements are.

Al right, so we talked about tier one. We talked about what the requirements are for student fees on the prior notice side. We talked about what the entry reviewer does. So now this is the second tier - the admissibility decision. This is what we do with all the information we have in front of us.

Really it's limited to a couple of things. We're going to release the goods. We have all the information we need. It's a lower risk product. We don't have the resources to go look at it. We're going to release this shipment. Two we're going to detain the goods without examination. So whatever information was submitted to us, it matches probably an import alert and a product for whatever reason - let's just say we found pesticides previously. We're going to detain all future shipments of this product in this firm based on the previous violation we want more information.

And we're either going to request documents through MARCS or we're going to conduct an examination or sample collection.

The review of our documents will result in again release, detention or examination or sampling. You'll see that the path typically follows one of these scenarios. As far as FDA document reviews go, some of you may be aware of ITACS It's a relatively new system that works in conjunction with our MARCS system but it allows anyone with knowledge of the entry to submit documents to us electronically.

Previously it was always done via email, via fax, via paper. But again, this helps expedite the entire process along when we're talking about document review.

Hopefully if all the information's transmitted to us up front we don't have to request documents. But again there are times that we're going to have to look for documents because we want more information than what we can see directly in front of us. So then the process begins for each one.

We're talking about release - at this point now CBPs issued their conditional release. FDA's released it. The product can now be distributed but we do still have jurisdiction. So if we do find a problem or the state finds a problem after the fact, we can take additional enforcement actions. So at this point CBP and FDA - assuming there's no other agencies that have to review the entry - have released the product. It can now be distributed.

Examination and sample collection - we train both within the district they have their own training as well. We have a national training center. We train all of our field investigators in examination and sample collection techniques. So whether it's looking at a product for labeling, see if it's fits the requirements of our labeling laws and regulations or examining a can for potential food safety issues. They're trained in those aspects.

So obviously there's some things that you can't examine a product for. I don't know of anybody who can examine a product for microbiological concerns. If you know of anybody, let me know. We would like to clone that person. That would make our job a lot easier.

But most of our examinations again are done by the field staff that we've trained. Same with the samples - they're collected by FDA staff as well. And then they're also analyzed by FDA laboratories. Assuming that we haven't hit a capacity anywhere, there are specific analyses or assignments that may direct samples to a different laboratory outside of FDA. We do have what we call firm laboratories.

They're the ones that we looked at extensively. We've looked at their methodology, their analysts. We have confidence in them to conduct the analysis as our analysts would. So there are times that we will farm sample analysis to outside laboratories as well.

One thing that always comes up and this is where we tie the bond back into play is when articles are not made available to FDA for examination. Something that we're trying to work on with our import operations strategic plan is how we try to make the process more consistent across the board for issues like this when a firm or a consignee or an importer can't redeliver a product or can't make the product available for our examination.

Technically it's not a violation for us - for FDA. But we can ask CBP to issue a redelivery order, to redeliver the product from wherever it went to. So think back to our initial discussion about conditional release. CBP released it to the destination or wherever the shipper wants it to be sent to. CBP here can issue a redelivery order to bring it back to the port of entry. So this could be across town. This could be from a different state. This could be across the United States.

So for whatever reason the parties of the shipment didn't want to make it available for us to examine that we're asking for it to be brought back to the port of entry. And the employer has 30 days to comply with that. If not - if they can't - that's when we start looking at liquidated damages. That really is our penalty - the customs and border protection FDA penalty against bonds for that shipment. And we can go up to three times the value of that shipment against the bond.

So because we're \$10,000, we can submit a request to customs. Customs will take up to \$30,000 away from that bond that that import of record has. It is

always the import's records who holds the bond with customs and border protection – and typically it's a US firm - they obviously play a very important role or their pockets can be emptied rather quickly if they don't comply with the conditions of the bond.

We talked about the conditional release earlier and the fact that it's a 30 day window for FDA to take action. If we issue our notice of examination or sampling, it automatically extends it indefinitely with what's in the conditions of the bond. So it's important to keep in mind the conditional release period for each entry both from the industry side as well as ours. And again, it's something that we're trying to do with our IOSP - the import of strategic plans.

Look at how the field goes about doing their entry review, doing their field activities, to make it more consistent both on our side and for industry because obviously time is money, especially when the product is being held in a third party warehouse. That costs them thousands of dollars or can cost thousands of dollars per day to hold there. So the more information the industry can provide to us, the easier it makes our job.

So looking at our examinations and sample collections. Anything non-violative, we're going to release it. Again, if it's in domestic commerce. If it is violative this is when our detention and hearing process begins. I was talking about the small window between first us finding a violation or detaining it and the refusal. This is what the detention hearing process is. And this is a minimum of ten days. It's normally longer than that but it's always ten days at a minimum.

So whether we have the appearance of a violation – So this is the import alert side. This is where we have additional historic information or now we have a violative analysis or examination. We detain this product. The detention and

hearing process begins. All of the responsible parties have the minimum of ten days to give us evidence to refute this violation or tell us that they're going to bring the product into compliance.

So based on this evidence, the detention will understand that we're going to refuse it or it's going to be overturned and ultimately we'll release the product.

As I was saying, they can bring the product into compliance. Obviously it's only going to be applicable to certain situations. For example labeling - they could recondition the goods by putting a new label on the product. Let's just say it was missing some of the nutritional fact panel information. They could put a sticker on the product that provides all the correct nutritional facts. Now the label is in compliance so we'll release it.

There is a separate process for reconditioning and we won't get into too much detail but really what it involves is them petitioning us on FDA form 766 to local compliance, this is what we're going to do, this is how long it'll take and in the end it'll be in compliance with our laws and regulations - whatever the issue happened to be at first.

There are times that we'll audit sample some of the product or we'll go examine the product to make sure it is in compliance. And then if it is reconditioned successfully or partially successfully, we'll release that product that is in compliance.

This is one of my favorite slides. This is how easy I tell everybody the importation process is. Really this is much for your own information moving forward as it is for looking at right now but this is kind of a visual representation of what I just talked about. From when it is offered for import on the upper left hand side to requesting information - the prior notice

information which I just noticed the slide is out of date because it's no longer the prior notice center, now it is the division of food defense targeting and then all the way through our compliance and release or refusal at the bottom.

As you can see at the bottom, once we have refused it - assuming that there's been no mistakes made on our part - we will work with local customs and border protection and the responsible parties then have 90 days to either export or destroy the product. Once we refused it under 801 those are the only two options. It's got to be exported or destroyed. Any questions there up to this point?

This isn't part of my presentation on the overview but this is something I guess everybody wanted to hear about. This is export reform act is what amended 801(d) (3) of the act to allow certain articles that are otherwise don't meet our criteria. So we have said that they're not in compliance and would have been refused in our previous discussion.

So really what happens is they're going to be further processed or incorporated into other products and then exported out of the US. By law only components of drugs, devices, food additives, color additives, and dietary supplements are permissible for import for export. So you're bringing a finished food into the US. It's not permissible for import and for export. And this is under section 801 of the federal food, drug and cosmetic guide.

The other big piece that some missed is the fact that something has to be done to it. We talk about in some cases a de minimis activity. That is a rather gray area what de minimis activity is. But we expect it to at least be relabeled or some action to be taken against the product. It cannot be just stored here for an indefinite amount of time and then exported. You have to be doing something to it or further processing it somehow.

For food and feed products, prior notice is still required at the port of arrival unless one of the exemptions is met – there is a whole list of exemptions. If you go to the prior notice page on fda.gov it talks about when prior notice is not required but it's still required at the port of arrival though entry's not being made technically.

And for our purposes there's no limitation on the amount of time before the article must be furthered processed or destroyed - exported or destroyed. It's all about under the conditions of the bond which we've been talking about - what those timeframes are. Typically it's around 300 days. So it's a little less than a year.

Any questions about import for export?

Man Is the prior notice for foods and feeds only?

AJ Seaborn It is, Drugs and devices, tobacco products, have no requirement to prior notice at this point.

Man Is the prior notice just a notice or is it like the approval proposes? And what are the requirements for that?

AJ Seaborn Prior notice is brought about under the bioterrorism act in 2002. But it's kind of like our admissibility process for each product. We're not approving the product purse but if we go back to my slide here, it has to be satisfied at the top right before that food or feed can move into our normal admissibility process.

Woman: It is simply a notice that the product is entering the country. (Tony) will describe how you go about doing it live on the webpage. We'll go through the process itself.

(AJ Seaborn): Any other questions? That wraps it up this portion.

(AJ Seaborn): Import alert-this is always a topic of much interest. I was saying earlier this is where we have information. And whatever this evidence may entail - whether it's analyses that we've conducted, whether we have information from states or other government agencies - we have evidence to say that we can detain future products based on the appearance.

So we've done a facility inspection and if they don't follow the good manufacturing practices, we will put this firm on an employed alert. And now depending on what that inspection covered. Either all of their products or a subset are subject to detention without physical examinations.

So you hear me call it the DWPE which is what we call it. Really it means that we don't have to examine the products to detain it- make the responsible parties provide evidence to us so that it is in compliance with our laws and regulations. So what it does is allows us to focus our limited resources on other products and other companies.

I talked about chapter eight previously about the act. With sufficient evidence which my division always reviews before a product and firm is put on DWPE. That forms a basis for import alerts and the entire system that we work on. I've included the link here which is - which lists all of our import alerts as well as the guidance that we've given for this import alert and all of the firms and manufacturers or firms and their products that are on or subject to this import alert.

We have about 275 or so and it's obviously a major task for us as we have field staff and other information coming in. We have to evaluate it to see does

this fit our standard and our evidentiary requirement for future detention of these products or this product from this firm.

So as I was saying it frees up our resources to examine or sample other things - theoretically it provides uniform coverage across the country. We talked about accurate data previously. That's very, very important on the FDA product code side. That's how we target firms and products on import alerts. So it's very important that we get accurate information both up front as well as for future shipments from firms.

Really what it does is as I was saying it places a responsibility back on the responsible parties or the importer and the consignee normally. So as I was saying we want all the products that are imported to be in compliance when they're offered for import. We don't expect products to come in to not be in compliance and then for the consignee or other party to bring them in to compliance after they've already been offered for import.

Import alerts do not create new requirements. They already existed - as I was saying - in the act which defines what adulterated and misbranded mean but it simply serves as a repository for firms and products.

If you want to go look at the criteria that we use for detention without physical exam, you can go look at our regulatory procedures manual. We have an entire chapter which is chapter nine devoted to imports. That talks about both addition and removal from detention with out physical exam.

One of my favorite slides - the one I use in almost every presentation when I talk about import alerts - they are not subject to DWPE because they're on an import alert. They're on an import alert normally because they're subject to DWPE.

It isn't the import alert that we say is what causes it to be detained. It's the fact that we have the evidence previously to show that this firm and this product are not in compliance or they appear to not be in compliance.

Okay, I'll go over adding up a firm's products or importer potentially without physical exam typically based on our field office's information from a foreign inspections under the food safety monitorization act. We're performing more foreign inspections than we ever did previously. So we'll see more and more firms and products being put on those types of import alerts for GMP's, or foreign governments, states, other federal agencies here in the US.

We're going to still require the same evidentiary information that we didn't even –for our work or our field examinations and sample collections. So it isn't a new standard because another agency gave us the information. It still has to be collected properly. It still has to be analyzed properly, et cetera.

There are really three different types of import alerts. Most of them are product and firm specific and most of the time it's the manufacturers who are put on the import alerts or subject to DWPE. These most often will contain what we call the red list and some of the more common examples are 45-02, 16-81, and 99-08 which deal with unapproved or non-declared color additives, salmonella in seafood and pesticide in food products respectively.

Product general import alerts - so these are products that are inherently problematic. They often contain a green list or none - for example 21-07 and 61-07. 2107 is Tamarind products for fill. I don't remember what 61-07 is.

But again, it's products that over time the center for food safety and ORA have gotten together and said these are problematic for this reason and Tamarind for filth for whatever reason they decided that it was inheritably problematic. And then country or area-wide import alerts - these are specific

to a country or normally a country again may contain a green list or none at all.

This is 02-01 which deals with rice products from India I believe. 16-131 is various seafood products from China, and 99-30 is melamin and food products from China as well. So these are specific to a country for a specific problem.

We talked a little bit earlier about the detention process, the detaining without exam process is no different. We still give the responsible firms the detention and hearing period - so in the minimum of ten days the importer and other responsible parties have the right to give us evidence to refute the appearance of a violation.

If they submit the evidence after the ten day period or after this detention hearing period expires, there's no or- there's rarely consideration given to that evidence. It depends what the evidence is that was given to us. It depends if we've already refused the product or not. As we were saying earlier, the detention will stand until it's refused or overturned and its released.

Not all charges are the same thus you can't provide the same evidence for every charge to overcome the violation, typically its a private lab analysis done to show the product doesn't contain pesticides, product is not contaminated with salmonella, et cetera. However, not every detention need a private lab test such as when we're talking about inspectional issues or GMP issues. We always say you can't test good manufacturing practices into a product. You can't overcome GMP issues or processing issues with a private lab test.

We talked about reconditioning previously as well. Whether it's relabeling a product, sterilizing a product, rinsing a product - whatever's going to overcome that potential violation or apparent violation, the firm has to submit

to us what their plan is and we may audit the final result and whether we're going to approve the reconditioning or deny the reconditioning.

Any questions about additions to import alerts to DWPE?

And on the removal side this is where it definitely varies by import alert. For the most part we're going to look for what we call five clean shipments as well as what did the firm do to take care of the issue and what was their investigation into the cause of the issue. Those five clean shipments are evidence to us that whatever was done testing the issue and correcting the issue was sufficient to overcome that particular violation or problem.

So if you have pesticides in your product, we want to find out that oh, one of your growers that you source from uses this pesticide and it's in their shed. You educated the grower. You saw that the pesticide was removed. Again, if the pesticide was removed, the five clean shipments show that that was the case. We'll now remove the firm from detention without physical exam. So the remedial actions, the verification through actual entries assures their consistent compliance.

Again, this is another function of our division. With 275 import alerts, there are obviously firms that want to come off import alerts every day. We get dozens of petitions per week that we have to review as well as dozens of cases where - based on other evidence - we want to add firms.

So we process our cases as we receive them first in first out much like firms do with their product. So whether it's an additional or removal case, whatever's next in line - those 30 or so people who work in our division will process those cases as we receive them.

It doesn't have to be submitted - the petition doesn't have to be submitted by the firm itself. It could be submitted by their importer which is probably the case half the time or other representatives that they have which is normally an attorney or other consultant here in the US.

Once the industry submits the petition and we review it, here is the information for submitting petitions to us if you get questions from your industry. I would say probably now we get 75% of ours submitted electronically because it's easier. No one wants to pay to ship it here from whether it's in the US or outside of the US to our office. That's another issue we're no longer - as I was saying earlier - the division of import operations and policy - we're just the division of import operations but they'll still get here if you send it that way as well.

Most of the time the petitions include a cover letter as well as their remedial actions. But all of our - all petitions that we receive whether hard copy or electronically - we'll send an acknowledgement back in kind. It'll tell the petitioner what the case number is, who the person it was assigned to and what their contact information is.

We typically will not - as I was saying - rearrange the order of petitions without a good reason. And there are times that we will. If someone says that we put them on an import alert or subjected them to DWPE erroneously, we'll go look at the reason for the addition to a DWPE and then process the case accordingly.

Some reviews can take two to three months to process - as I was saying - just based on the sheer volume of work that we have. It may take that long but I think anecdotally it probably takes more in the order of a month or so to get it processed by the time we get to that case in the queue.

So as we get more and more people - as we try and bring them up to speed - hopefully we get that timeframe down even further. And then a decision letter - once we made our decision - is send back to the petitioner. And if they want it sent to somebody else, we'll include them as well.

Typically if there's a denial letter - well always if there's a denial letter, it will include an explanation as to why we're denying it. Most of the time it's going to be based on the shipments that were submitted as evidence because there may have been one or two that were spread out between those five that were refused for whatever reason or for whatever the reason was and that pretention was submitted.

So if it wasn't the pesticide case, you know, even though you may have had what we call five clean shipments in let's just say a three month timeframe. You may have had one or two other shipments that were refused because they did have the pesticide in there.

So we're going to look at what was the last date that we refused an entry for that reason and that's now the new starting date for this petition and any other. So we're going to say alright, whatever your remedial actions were - they obviously didn't work - why does this product still have this pesticide in the product? So what is your remedial action for this? What your investigation have done for that and then we're going to look for five clean shipments after that fact.

All of our denials go through our management just to make sure that we're on sound footing. Assuming that we approve the petition, it still will go through a QA process, just not through our management. But the letter will get sent back to the petitioner and we'll also include the notice to our filed staff to alert them that we approved the removal of this firm and product.

And then once the decision letter is sent out, that effectively closes the case. And if we do happen to deny the case, any future submissions would be a new case.

I talked a little bit previously about what to submit in a petition. We are looking in to the investigation for the cause. The actions that were taken to prevent future violations. Any import alert specific information. So it's very important for the firms to review the import alert to see in the guidance section if they're requesting something else. Typically with GMP or processing issues, we're going to be looking for an inspection of the firm to remove them from the import alert and then all of the entry documentation for those five entries or however many you want to send typically you will send just five but you could send ten - whatever you want to send to us to make your case for us to remove the firm. Here it lists out the different entry documentation that we're looking for. This is the same entry documentation that we have in our cases that we build in the field. We want to be able to link the entry number to the product that was offered for import.

One note and again, if the petitioner wants to submit the private laboratory results, they're more than welcome to but we don't request them because all the private laboratory results for a given entry - one of these five or any other entry that was detained without physical exam by us - is reviewed by the district and the FDA lab at the time of entry. So we don't review it again here.

That being said, we are going to go look at the shipment history for the firm is being petitioned to come off the import alert. And we're going to see what other types of products they import. Are we seeing similar violations for those products? Are we seeing - as I talked about earlier - are we seeing violations and refusals for the same reason for this product or if other products - it's rather I guess subjective review. We try and be as sensitive as we can but I'm

not sure in my five years with DIO that I've ever seen two cases that are exactly the same based on sectional history, shipment history, et cetera.

As far as remedial actions, basically we're looking for assurance that the violation has been corrected. If it is Inadequate for whatever reason - that's another reason we will deny the case as a petition and we'll look at the shipment history for each product.

If the petitioner doesn't submit information that we request otherwise, we'll also deny the case for that. That being said, if something's missing, we always go back to the petitioner and give them at least two weeks probably on average to submit the information but if they don't then we will deny the case.

And again - as I was saying - the petitioner is free to submit another case to remove the firm and product but that's a new case. It goes back in the queue at whatever point it was submitted to us. So really it behooves the petitioner to have all their ducks in a row before they submit the case to us.

We have a list of the common reasons for denial which I've already gone over. I would say probably the most common other than product failures is not submitting all the entry documentation to us, I provided a list on the previous slide. I was saying we want to be able to connect the entry number to the product with those entry documents.

The staging of shipments - I don't see it that often anymore. It probably does happen. We talk about it in our regulatory procedures manual what staging shipments means but really it means we need the evidence. We need these five clean shipments to show over a reasonable time period that whatever the violation was, was corrected.

The firm couldn't just split up what used to be one shipment. So let's say 5000 pounds of product into five different containers. They send those five entries to us all in the same day and expect those to be their five clean shipments. It doesn't show up the consistent pattern of compliance.

There are exceptions. I mean if it's a formulation issue - let's just say that there were unapproved color additives in a product if you can show us you change the formulation after - maybe you only have four shipments. It's rather obvious that the firm's not going to re-change their formulation after the petition was sent to us and we removed the firm and product. We'll take that into consideration that this is a formulation issue versus a processing issue whether we approve or deny the case.

Any question about addition or removal from DWPE?

Man: So just to have a better idea on the ground really could you give us some statistics on for example in the last one year, how many, you know, petitions FDA received and how many of them denied and how many accepted - just an idea?

(AJ Seaborn): I wouldn't have that information off the top of my head. But probably anecdotally I'd say we probably approve 90% of the petitions that are sent to us just because once we get the petition, we want to work with the firm if they want to come off the import which obviously they do. It costs them time and money if we detain their product. We'll work with them. If they have the information available, we'll wait until they submit the information to us. So then we'll have the entire picture to make our decision.

And it doesn't help us any either to just keep trading cases and perpetuity for us to review. It takes time away from our administrative staff. They have to figure out if somebody else has submitted a petition or if they submitted a

petition previously because obviously the person who reviews the petition first has the working knowledge of that product and that firm in the case history.

We have an electronic case processing system which anybody can go in and look at on the FDA side but if I work with firm A for a month to get their petition to where it needs to be for me to review it properly then any future cases will be sent to me because I have that working knowledge. So we'll help people who want to be helped to submit their decision but at some point we're not going to wait around for forever to review a case. But that's probably 90% of the petitions that we're going to approve.

Any other questions? I will show you an import alert.

So this is fda.gov. This is our homepage. You'll see more of it later when we go through the prior notice demonstration. I'll show you registration, listing, et cetera. But it lists of all 275ish import alerts can be found on our website. They're organized by any number of ways that you may want to go find it - typically by numbers is how I'm going to go find the import alerts because I know what I'm looking for. You can go to other parts or other was of searching it as well.

This is a good example this is 21-17 which is a countrywide alert for us for all papaya from Mexico. So it'll go through with the number, when it was published. This is the last publish date which really means when we last added or removed a firm from this import alert, what the type is. So whether it's - and typically all of them are detention without physical exam, we do a few surveillance alerts. But I think at this point most of them are DWPE.

The name, the reason for the alert - you can see under the reason for the alert it talks about - can everybody read that or do you want me to make it bigger? Little bigger? Alright.

Under the reasons for the alert it talks about any revisions that we've done to the alert whether it's a guidance section. These are all revisions to this particular - the text of this alert. We're not talking about firms adding and being removed here. In this case it talks about why this import alert as well was created for papayas from Mexico based on outbreak data.

The guidance is where you're going to find a lot of the information. If there's information specific to this alert about removal from or addition to, it'll be in the guidance section as well as releasing individual shipments.

Typically here you'll see in the third sentence it talks about submitting a private laboratory analysis to show that there is no salmonella in the papaya. So for a particular entry - as you think about the entry being released after it was a physical exam, they're going to send us private lab analysis showing a representative sample was tested by a qualified individuals in a private lab. There's no salmonella. If they agree, they'll release the shipment. We release the shipment.

And then further on down it talks about removal from potential physical exams as well in this case in addition to the five clean shipments and the investigation and the remedial less corrective actions. It talks about the fact that we're going to, I take that back, I wanted 21-01. Very similar - this is cantaloupes from Mexico. Again, it talks about outbreak data being the reason why we created this import alert.

So in addition to the five clean shipments and the corrective action investigation we're going to be looking for information from the firm about these various areas as part of their process - so water quality, worker health hygiene, their sanitation facilities, et cetera.

Man: Say for example, you know, I am an importer of papaya from Mexico, yes it is in the pipeline and suddenly I see the importer alert on the FDA site. So as an importer of papaya because my imported good, my consignments it's into the ocean, it's coming. So as the importer, what should be the best approach to deal with this sort of scenario?

(AJ Seaborn): Hopefully you're not importing papaya via the ocean otherwise hopefully you're not selling it fresh because you have little hope of selling it fresh. But there are two issues - there's the entry itself. They're showing FDA that the product is free of salmonella - this particular product. Then there's the removal from the detention with out physical exam part.

So they kind of are tied together but they're also separate functions of FDA. So the best case scenario is if a - I guess in your scenario with the papaya coming in from Mexico - if it's not on the green list of this alert, we're going to detain that product without physical exam. So they'll be given the option to test the product and show it's in compliance. If it is then we'll release it. If it's not then we're going to refuse the product if they can't bring it into compliance somehow.

But then on the removal from DWPE side, that release feeds back into the five clean shipments or that refusal is noncompliant. When we look at the shipment history, if the petitioner doesn't send us that entry to look at up front. It's going to raise a flag in our mind. It really depends on which side of the fence we are taking, and what the outcome of that one shipment in the context of all their shipments does really look like.

Man: that is not described in that list.

(AJ Seaborn): Another country you mean?

Man: In Mexico.

(AJ Seaborn): Okay. We don't take into considerations provinces or states or counties of various countries. This is dependent upon physical exam of all papayas from all of Mexico.

I would say other countries we would look at differently depending on we have other employees set up for that product and country. But when I get down to the green list, I'll talk more about what the green list means.

(Sousan Altaie): AJ you mentioned that they have to agree to these samples to say it's Salmonella free so it would be released. They, the importer should arrange for that or the FDA does that on their own?

(AJ Seaborn): That's a good question. As far as a product that we detain without physical exam, it's up to the importer or the responsible parties as a whole because typically the importer won't be the one who has the product in their possession. They have to coordinate sample collection and analysis with a private lab. FDA has the authority to audit their samples if we so choose but the onus once we detained it's always on the importer to overcome the violation.

(Sousan Altaie): And so they do their own testing and you examine the test results.

(AJ Seaborn): We have the ability to. It doesn't happen 100% of the time.

(Sousan Altaie): Okay.

(Sema Hashemi): Who bears the cost of the examination?

(AJ Seaborn): What about the examination?

(Sema Hashemi): Who bears the cost?

(AJ Seaborn): It's always the importer once we've detained the product. Products that are offered for import just as us collecting surveillance samples or examinations, we bear the cost. Or really the U.S. taxpayer bears the cost because they pay our salaries. But once we detain it then all of the costs are barred by the responsible parties and it depends on their business relationship it could be that all of the cost of importation will be deferred back to the manufacturer.

Some importers just build that cost into their prices. So it really depends what kind of relationship the importer and the manufacturer have.

Man: Yes, could you – we're confused by the example you are providing here. Papayas and cantaloupes- doesn't that fall under the USDA APHIS people? And second - if this is a countrywide determination that anything from this country has to be shot down then isn't that more of the matter of say the Mexican Department of Agriculture has to lobby with the FDA, the USDA to straighten everything out as opposed to this one importer?

(AJ Seaborn): On the first one, USDA is involved. They have a different mission than we do though. They're looking for pests, diseases et cetera. So this is one of or a type of product that we have joint jurisdiction on.

Just like – I have recently dealt with the dietary supplements that contained dried shark fins - Fish and Wildlife also has a great interest in something like that because they want to know when certain species are imported into the U.S. or products made from those species. And then from the...

Man: I'm sorry. So just like - so for example like after the pest assessment were done the USDA AFIS will say any papaya coming from Mexico are okay then

it becomes the jurisdiction of the FDA to say it is not like, you know, dirty or filthy or anything like that? So they pass the buck up to you guys then after the initial okay?

(AJ Seaborn) Exactly

Man: So, all right, sorry go ahead.

(AJ Seaborn): but it also ties back into our conditional release discussion previously, the customs has release it. A product like this - the USDA hasn't released it yet nor has the FDA. So until it's released - until the bond is what we call is liquidated, I was talking about liquidated damages earlier - damages against the bond before it is liquidated. The entry will not be closed on the customs side until all the agencies have released it or made some kind of admissibility decision against that entry.

So in this case until FDA and USDA have released it, customs still leaves that entry open.

Man: Right but if you have like a – if you are saying there is a country wide like anything coming from Mexico like the papaya can't be allowed into the country?

(AJ Seaborn): From FDA's perspective?

Man: The FDA's perspective. So who makes the lobbying, you know, that sounds more like a deal for the Department of Agriculture from Mexico would have to lobby to make sure, you know, that the processes that they do are acceptable to the USDA and to the U.S. government. So like, you know, if I'm importing papayas and you have a country-wide ban on it, and it's coming

from Mexico, it's probably nothing I can do right? because that's more country to country.

(AJ Seaborn): There is on the entry side - something that the importer can do. They can show us that the product is free - in this case - of salmonella by testing it in a private lab. Obviously SENASICA who handles agriculture from Mexico is very interested in something like this. Because it makes their job more difficult I'm sure, obviously from a country to country perspective. It's obviously a business issue as well.

So SENASICA is very interested in things like this. They aren't necessarily petitioning with us on a case by case basis though. That's more of an upper-level discussion. Maybe at the department level or agency to agency level.

Man: Right, that's what I meant.

(AJ Seaborn): Why is this happening? What caused this to happen? Should it still be happening? What can we do to alleviate concerns, et cetera? It's much more a political issue than this your product in compliance.

Man: So country wide would have to be done government to government - like you said - the higher ups. But the import is still on a case by case has to lobby to get the product in even though there is a country wide stop on the product.

(AJ Seaborn): Correct.

Man: Okay

(AJ Seaborn): Okay cool, some people like to or some people say and we hear erroneously that FDA's banned this product. FDA hasn't banned it. We've detained it and without us looking at it until you show us that it's in compliance.

Any questions before I continue? All right,

So the cantaloupe import alert talks about - look at paragraph that says October 26th 2005. It talks about SENASICA and the MOU that we signed with them regarding Mexican cantaloupe being imported into the U.S. as part of the MOU, they identified to us cantaloupe firms that they see as being in compliance with Good Agricultural Practices from Mexico similar to our - what we call gaps - which at this point I don't think they have the full effect of law and regulation.

Something that we take into consideration as we look at firms on the manufacturing side or the growing side. In this case we have both a yellow list and a green list. Once we have the documentation from SENASICA saying that they basically certify that the member is in compliance with the gaps on their side, we'll add them to the yellow list.

At that point they can then petition us with the five clean shipments to be put on the green list. So at that point they're exempt from this import alert. We will not detain their product without physical examination but we can still conduct surveillance on it.

So it isn't like there's no possibility of every having papaya or cantaloupe being imported to the U.S. without it being detained first but you have to show us that you can produce compliant products - in this case it's by SENASICA telling us that you're manufacturing or growing products under Good AG Practices and then the five clean shipments are evidence that that is the case.

Going down it talks about - this is the green list. You can go to both the yellow and the green list. This is the yellow list. So these are the firms that SENASICA provided us gap information on, based on their inspection and

then there's going to be a green list as well. So there's another set of firms that have shown us SENASICA's been there. Your firm is in compliance with their laws and regulations for agricultural practices. Plus you've positioned us, we have looked into your shipment history, it's okay, and now you're on the green list. You can import papaya or cantaloupe freely into the U.S. as any other importer would.

If you look through here you can see the type of information that we put on here. We'll typically have notes saying - every import alert is different. That's why I say that the petitioner should look and see what is their specific import alert that they're on ask for in the guidance section before you petition us.

Or if you have questions, call our division and we'd be happy to discuss with you whatever questions you may have before you submit it. Again it helps everybody out in the long run and less time consuming for you and us if you know what we're looking for.

Anybody else? All right, thank you.

END