

FDA Webinar for Trade
Jan 31, 2017

All right. We will take it from the top and I will make it brief so we can get to the meat of the presentation. How we got here the final rule from FDA we were to collaboration with CAT and the Department of treasury to establish this role early of December 20 early of December 2016 for implementation towards the early part of January 2017. That is really what the supplemental guide which Frank referred to earlier is based out of. The premise of the role is to facilitate compliance within FDA. There were reviews on our side that lead to that facilitation. A lot of us focused on limited resources on those regulated products that present the greatest public health risk to us. Largely the final goal outlined for various products but it also includes a technical revisions of various sections of FDA's regulations.

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Sorry. One more time. People are saying you were starting to cut out and now there is no sound. Maybe we should wait for the call in numbers.

I guess that's the best.

Some people are saying they can hear and others are saying they can hear. Some people are saying they did hear and then you cut out.

I was wondering if this was a policy test to see if you've got it right.

[Laughter]

Are just a test for AJ's patience.

Hopefully we passed both of them. [Laughter] >>

[Technical difficulties] >>

For those of you that can hear just know that we are not talking. We are waiting for the phone line so you should not be hearing anything now. Please give us a couple more minutes and sorry about this

I am going to be adding some Colin lines to the chat box. Everyone should be able to see some lines that they can call into to listen to the presentation. >> Let's give everyone a minute to call in and then hopefully we can get started for the last time. >> It looks like some users still have audio to their computers. If you want to continue listening in there that is fine just make sure to mute your computer in case you're getting feedback or if you call-in. >> I think everyone has had enough time to call back in. From the top again. I will make it short and sweet. Were talking about how we got here to the new supplemental guide/implementation guide for FDA. FDA did publish a final rule in December 2016 which was then effective 30 days after the

publication date in the Federal Register. This is in part required the submission of certain data elements in a commercial environment for FDI -- FDA that were transmitted electronically for FDA products. In addition to the various data element requirements for FDA the importation, it also provides various sections of FDA regulations. One being the clarification on the owner or [Indiscernible] portion. Within 21 CFR and the second dealing with notices of action within the [Indiscernible]. And it allows us to reject entries that are incomplete and or and accurate at the time of submission to FDA. I do want to take those -- thank those who participated in the pilot. In the middle of 2016 on July 23. We strongly encourage CDC and [Indiscernible] to continue certifying their systems and processes for a more orderly and effective and efficient transmission of entry information to the various government agencies. We do see and have seen historically [Indiscernible] rollout. Many benefits in trade. If nothing else requiring accurate and complete information upfront means that it is less that FDA has to do and/or less time it takes FDA to clear compliance of the various requirements. Like I said, we do very much appreciate the effort and collaboration in moving forward we are transitioning from a facilitation all ready in place, a system of record to how can we make this a better experience for everyone? To that end there will be continued outreach from the FDA perspective that we are putting together both for our own field staff as well as for trade. I think that is probably enough from me at this time. I will be on the line and working with Jessica and I will turn it over to her and answer questions as well . Thank you.

Good afternoon, everyone. I apologize for the technical difficulties getting this up and running. Despite the delays, hopefully we can give you some good information that's going to help you over the next couple of weeks when you -- when the new requirements are deployed so you can avoid getting rejects and continue on with this new transition. First and foremost we will get started with our regular status update. Since August 2015 we have processed almost 7 million entries and 34 million lines. The purpose of the webinar today is to review the changes to our supplemental guide which will be deployed on February 9 which is next Thursday between 6 AM and 7 AM. We will answer your questions about the things that will be deployed and provide any other clarity on requirements.

Before we jump into the specifics, some changes that impact multiple commodities of multiple products. The first one, the importer of record -- record contact information. For all FDA lines except for items that require prior notice the importer contact information is required. Email and a phone number for the importer of record will be required for the FDA line unless it is food, processed food, beef, anything [Indiscernible] those are exempt from these requirements. Another big change in the next two things are going to talk about are for the software vendors and how they sent certain codes. Basically when you are sending contact information into PG 19 and PG 21 records contact information is mandatory to PG 19 and PG 21 codes must match. We can review some examples of that at the end of this presentation. Basically for something like the importer of record would you are required to give contact information for PG 19 and the PG 21 must also have the

same code. If you are sending the contact information with the prior notice of measure the codes in both of those records must match. PG 19 and PG 21 must have a [Indiscernible] when you're sending them. If you are a software vendor hopefully you have adjusted accordingly. We were made aware that a certain environment has a [Indiscernible] so if you were sending it the old way maybe a prior notice submitter and a PG 19 record but you are sending a PK and PG record and is not rejecting, that is something they are working on and we will try to update you. I have some examples we will go through at the end of the presentation.

And then we discussed those mandatory contact information. Import of wrecker, there is an optional contact information so we are highly encouraging you to put the code PK for the software vendors. If you are a file or

the recent FDA is asking for the file or contact information is because if you gift the import of record or the manufacturers contact information we may not be able to get a quick answer on something that could help expedite us processing the entry. That is why we are asking for file or contact information.

Moving into the specific requirements for different products. First we will review changes for Biologics. If you are filing that type of product the product code the first two numbers must start with 57. Any biologic files must start with product code 57. Next, previously in our supplemental guide there was a processing code for regulated devices. They may have been a medical device and they may have had IGE the investigational device or the premarket information. All of that information has been taken out of the biologic section. It can no longer be filed under PIO. It should be filed under the medical device chapter. Because that was change there were some codes for the biologic devices that have been removed.

Another clarification that a software vendor brought in last week this is something new. I'm not sure if it is clear in the change log or if we had a question from vendors that were testing this last week. For the biologic code if you were looking at that in the supplemental guide it will be Pro seven and wrote eight. We have a processing code for HCT and the intended use code 082.000. It appears that there is two contradictory requirements. For this processing code and continued use code either HCT is required or HRN. For this intended use code there is two separate scenarios. If you were programming this is a software vendor just know you need to send either or. Make either or mandatory so that you either send one or the other. >> That's the changes for Biologics. Moving onto the next chapter is cosmetics. There weren't any major changes to cosmetics but just for clarification purposes if you are -- it must start with 50 or 53. Of your filing a cosmetic there are no applicable [Indiscernible] codes. You can leave that field blank. Intended use is not required for cosmetics. Just another point of clarification we have seen some filers that are attempting to file drug products or medical device products as a cause major. If it has a drug listing number or any affirmation that would indicate it is a medical device that means it is not a cosmetic. Only file cosmetics using the 50 or 53.

Moving on, requirements for human drugs. Similarly to the other products we have restrictions based on the type of drug product that it is. Or the product code. The industry code which is applicable. Brand name is becoming optional but we encourage you that if you know the brand name give us that information. The biggest change for human drugs is update to the intended use code. If you use a filing prescription human drug product the code that you probably use all of the time is 080.000 which was prescription. That code is gone. The first code that was replaced this year is 080.012 which is for prescription. They are the subject of an approved drug application, abbreviated MVA or Biologics license application. Anything circled in red is new. If you are and importer of drug products pay attention to these intended use codes. We also have the last one for other use. If you are filing a drug product and nothing really seems to fit, you can definitely reach out to the FDA for clarification. This code 980.000 was added if the scenario that you're importing is classified into any one of these codes. The center for drugs highly encourages that you take the time to select the appropriate intended use code. They have laid out a scenario for each import scenario and they even give you this for other use. If you're not seeing the exact scenario rather than providing an unknown into the code, they encourage you to look to this list. Talk with your importer and determine which would be the correct intended use code.

And then appoint on those changes, because the actual code changed that means what would be required also changed. So before you were using an old code and that triggered the drug registration and drug listing and drug application. If you are filing a prescription product it will be required but just because of the new number code, it would be a trigger for what it is asking you to transmit.

I see a lot of questions coming in. I will try to work with AJ after I go through the slides to revisit the question. If you have a question about a specific slide put that in your question number and then I can go back and revisit that slide.

Moving on to food. Any of the prior notice requirements remain unchanged by the ACE final rule. You won't see those changes in the section. We did clearly annotate the product code, industry code or the different types of food. When you register for the webinar we saw tons of question come in about what intended use code am I supposed to use for food. Intended use code is optional for food. There are only three choices. What if it is for research, what if it is for research animal feed and one if it is for personal use. So if it applies to any of that, you can select it but if it does not supply if it is commercial food going to some type of distributor, and it's not going to a person's home is a small personal shipment, you don't need to fill out the intended use code. Again, commercial shipments no intended use code is required.

Moving on to the next commodity type, tobacco. For tobacco the product code must start with industry code 98. Previously the brand name was required for most tobacco. Now the tobacco brand name is only required if it is for consumer use. You would tell us that by selecting the consumer use code. Apart from all of the regular data, the information

and product code etc. affirmations of compliance are optional. There is not much additional data that is required for tobacco.

Moving on to medical devices. The product code must start with an industry code within the range of 73-92. One change for the chapter previously if you were submitting you in K unknown as an intended use code it disrupted the logic of what affirmations would be required the system did not require any affirmation. If you select you in K starting February 9 have the device registration number and device listing number has to wait -- that is a way for us to encourage you for the correct intended use code. Please work with the importer to obtain this information. If they don't have a device registration it may be because they fall into a different import scenario. Again, take a look at the correct intended use and import scenario and choose appropriately. We discourage you from using a blanket element.

Next requirements for radiation emitting products. There were not many changes for this. The product code must start with industry code 94-97 for any type of product

Next commodity types in animal drugs. Previously animal drug chapters did not have a lot of mandatory invitation -- information. It was not clear what affirmation of compliance were required for animal drugs versus animal devices. Specifically for animal drugs we followed the same as human drugs. We tell you what products are allowed. We have an appropriate situation, import scenario for each that you will be bringing it in. Intended use is required for animal drugs and based on the intended use code, you can see what affirmations are required. >>

Similar to human drugs because the intended use codes were updated the affirmation were also updated. And animal drug does truck that required an application and maybe a different intended use code from the software vendors because they had that type of validation you would know which affirmation to enforce.

And then requirements for animal devices. The main requirement for devices is the product code that starts with industry code 68. Intended use codes and affirmations of compliance at this time are not required for animal devices.

So now I have two slides for the software vendors. This is basically how that data is sent. If you are a Filer and you're wondering about these codes, don't worry about it. The first slide shows a sample a layman's terms sample. A quick sample of how the PG 19 mpg 21 contact information should be sent. This is a sample for bio medics. Here are the seven entities. The only PG 21 that are required for the prior notice submitter and the prior notice translator. As I mentioned the Fpl import of record contact information is only required for non-prior notice programs. If you wanted to send one you could but it is not a requirement. What's reflected on this slide covers a mandatory requirement and how the information should be sent. As I mentioned there isn't issue and they are testing this. They are testing with the PK right now it's not rejecting. That is going to be fixed. If you're sending multiple PKs or if you are sending something that doesn't match

that's mandatory, you will get a reject. We're trying to get that fixed as soon as possible. Hopefully by next week.

I also have a quick sample of how data should be sent for non-prior notice. For most other commodities there are for entities that are required and delivered to party. For these entities the only one that has the mandatory contact information is the FD one. And so when you send that the PG 19 in the PG 21 code must both say FD one. No other code is excepted. After you send the FD 1 you at least have to have the FD 1 there. So talking about PK which is the bio contact information. You have two options for how you send that. If you want to send her under the deliver to party you can do that. You can send the PG 19, PG 20 and PG 21 with the code PK. That is up to you. That is just a sample. We have requested this get fixed as soon as possible.

And then moving on to some of the questions that you all sent when you registered for the webinar. One frequently asked question is the topic of DUNS versus FBI numbers. Which numbers do they want? As you will know what is mandatory for the entities his name and address. And then you have an option to either submit a DUNS or FBI. You can send whatever you want. The instructions from FDA and the preferences that if it is a medical device or biologic those types of products most of them have a registration number that is a FDI. They encourage you to send an F encourage you to send an FDI number. That is the one they assigned which is probably correct and that may help expedite your entry and just reviewing that. If it is a drug product, they encourage DUNS numbers and if it is any other type of product like food, tobacco etc., we encourage DUNS numbers because we have a portal you can go to look up the DUNS numbers for each site.

The next question that came in when you guys registered the import of record contact information can we list the general email and phone number or does it have to be for one specific individual? The importer of record can either be a person or a can be a corporation. You can list the general email for your office, a general phone number but please don't make it spam email. The electronic name that no one notices make sure that whatever you give us is what we will contact you on so make sure it's a valid email and multiple people can check regularly.

The next question, we got a bunch of questions about device for an exporter. If you have additional questions that we are not covering I know this is a popular topic, email me and we will loop you in and try to get a specific answer for your question. These are two questions we received. Either exceptions for the device for an exporter when a foreign manufactured device is sent to the US for recycling or reprocessing? If it's specifically coming in for reprocessing either a single use device or multi use device we do have intended use codes for that. That scenario would not require [Indiscernible]. If you're not sure about the scenario or if it's coming in for reprocessing or repair, or you're not sure, try to get as much information from the importer and email us. Our division of import alteration will try to determine what the current does correct scenario is and what the requirement would be for that scenario.

Is the device for an exporter required for US goods returned? When US goods are returned for refund/overstock to manufacture DFE is not required. If the original manufacturer is not a US firm, this is not US goods returned and the device for an exporter would be required to register and that scenario. I know a lot of these questions are complex and they relate to a very specific situation for your firm and your supply chain. If you are not totally sure, reach out and we will link you with new medical devices to try to determine the requirements for your specific scenario.

The next question that we had that we receive somewhat frequently when you're transmitting the manufacturer address are we supposed to revise -- provide corporate headquarter information for the company or are we supposed to provide the exact physical location of where the product was produced? FDA defines a manufacturer as a site-specific location where it is manufactured. We would be looking for the site-specific location.

Next we had a couple of questions that came in regarding quantity and how that should be submitted. Even though quantity is optional, we still encourage you to transmit that information because it helps us review process. Each level of processing should be transmitted largest to smallest. Each product type has their own specific units of measure. Something like a medical device will have fluoride ounces and so make sure for whatever commodity that you are filing you know exactly what units of measure are applicable. And then here are a few examples for medical devices. 200 cartons, six boxes in each carton eight pieces in each box. You go from largest to smallest. 200 cartons, six boxes, eight pieces in each box. The last unit is a base unit. Only one base unit is allowed. Some people think only one unit of measure is allowed. There is a difference between base unit and unit of measure. Base unit is that last level. We wouldn't want you to give us pieces and then pieces again. We just want the base unit. An example for food, 100 cases of let's say mineral water. 24 in each box. 16 ounces in each bottle. So 100 cases, 24 bottles, 16 ounces.

Another frequently asked question is is UNK still allowed. It is still allowed but it is not allowed for other data elements. Before you could put UNK for the brand name you don't need to do that anymore. Before you could use UNK 's son affirmation of compliance but you can't do that anymore. UNK is only allowed for [Indiscernible]. You can use it for any type of [Indiscernible] but we highly discourage you from using this. Most of the logic for our requirement is based on a use code so if you were choosing an intended use code and giving us incorrect information we know what affirmation of compliance are required so the person at the port is looking at that information and they say okay I can see why they sent this and they are able to make their decision.

A couple of resources. We talked about DUNS number. We talked about resident FEI numbers. If you would like to get a DUNS number for free or look up a DUNS number to see if you have one, the website is www.FDA number to see if you have one, the website is

www.FDADUNSLookup.com. In for the medical devices they have a registration and listing database where you can click on the link listed here. You can either type in the firm's registration number or the firm's name or a couple other variables. Once you type that in you can see the firm's information and the firm's FEI number. If you're filing medical devices that is a very helpful link so you can submit the correct FEI number. And then lastly hopefully most of you are familiar with these resources. If you have a question about the specific ACE entry, if you are having a reject or you're getting a reject from CVP and you need help we have a 24/7 helpdesk. There is the toll-free phone number. If you just have some general questions about the FDA or things like temporary [Indiscernible] canopy disclaim, HTS codes and stuff like that, you can contact our division www.FDA import inquiry at [www.FDA import inquiry@FDA.HHS.gov](mailto:www.FDA_import_inquiry@FDA.HHS.gov). You can reach out to those email addresses as well to request them for their outreach or to request a small webinar or a specific group of people and we will try to accommodate that as best we can. That is the information. I tried to extract from the supplemental guide and put it in a couple of slides so it is easier for everyone. If anyone has specific questions, I can pull that guide open. At this time, maybe we can start going through the questions and making sure we provide a clarification or answer anything else you may have. >> I've been trying to answer your questions throughout your presentation. I don't think I got into too much trouble. If you have additional questions, please feel free to put them in the chat box. We've gotten a lot of questions about is a copy of the presentation on a viable. It is available on the left-hand side of your screen. There is a pod that says today's presentation. There are at least a handful of files there that can be downloaded.

The supplemental link and guide is also provided. >> I saw a question and it disappeared. It was asking about if numbers are more than nine characters. It is okay if they are FEI numbers in there longer than nine characters. DUNS numbers are the number that is only nine characters. If it is a FEI number, I believe we have it listed and I am double checking here. It can be between four and 10 numbers. If you are experiencing something less than that are greater than that, let us know. ACE's beef -- is between 4 and 10 date.

What should we do about emailed addresses that are too long for the field? We have a record called [Indiscernible] and it is basically a carryover of any data element that you don't have enough room for. So for like email addresses or an address you don't have enough room hopefully that is something your software vendor has programmed or is currently working on. They can transmit the full email address to us. >> We have a couple of questions related to value. I presume that this is are the articles more likely to be held? If the value was not reported in the answer is no not necessarily. There are many risk factors taking into determination whether to have a system related problem or force the manual review. FDA value is not -- not in the final rule as such. I will say that FDA may have questions about the value throughout the entire visibility process. We might want to conduct further examination of the product and so we need to value prior to setting up work on that line electronically. It's one of our

system rules. While we do encourage the transmission of optional data, it is not a required field and it does not cause the product to be held any more often than not. >> Sunglasses are a medical device and based on what type of product it is doesn't tell me the intended use. Sunglasses could be coming in for anything. They could be coming in for import or export. You would need to talk to your importer about what the scenario is. So if it is a distributor to be sold then the appropriate [Indiscernible] would be 081.001. That's a medical device for consumer use.

Other people are asking where we can get the supplemental guide. It is on the website. Just Google FDA supplemental guide and it should come up. You can email support and ask for the document version which is easier to read in PDF. If you don't have a copy, we can get you a copy.

It is available on the left-hand side in today's presentation pod. There are many places you can get to that.

Someone is asking if they have a line where the packaging is completely different like they have boxes that are all different sizes and they need to break it up in several lines, or should they just pick one of the sizes and submit that for quantity?

AJ?

Sorry who is looking at a different question.

If they have a line that has different types of processing quantities they are asking if they should just pick one quantity and submit that or do they need to break it into separate lines?

That would equate to multiple lines being transmitted for that product.

Someone's asking about the medical device and if that's the same number. Often times they are the same number but not always.

We've gotten a couple of questions about specific care codes and [Indiscernible] associated with that. There a function of CDC and not FDA. That being said I'm going to request the FDA to look at a change for an active code. I will provide the email address in the chat box here. For those individual who deal with such submissions for request for change.

There was a follow-up question about the sunglasses. FDA does not tell you what the intended uses. You have to talk to your importer and asked them what the intended uses and who was going to. If it is going for distribution and consumer use it would be 081.001. A medical device for consumer use. Someone is asking what is the intended use for green coffee beans. Food does not require an intended use code. If it's a special situation when it's something for research you can let us know that but otherwise you don't need an intended use code for green coffee beans.

People are also asking what is the FEI number. It means firm establishment ID number. That is something that for certain products FDA assigns. >> I'm not sure if you can help me with this one. That says medical device prototypes subject to FDA.

Probably not. We would have to send it over to our subject matter device experts. I do not know at what point it officially becomes an article under our jurisdiction.

Other people are asking where can we find an updated list of intended use codes. The tenor supplemental guide. Each chapter. When they're talking about one list we can send one out after the December webinar. >> Here's a question leading into the webinar as well as here about the recordkeeping requirements for the importer. The importer of record who distributes various products. Not being the recordkeeping expert for FDA I would suggest going on to FDA.golf and looking at the recordkeeping requirements for the facility. I know they have their own requirements and there are various recordkeeping requirements for FDA depending on the [Indiscernible]. >> Someone called me out for having an incorrect sample for quantity for food. Yes I have some typos. It's 100 cases, 24 bottles, 16 ounces. I accidentally had the word carton in their. I will update the presentation before I send it out. >> Someone followed up with sunglasses. Are sunglasses a medical device? Yes.

I saw the question before. Is a chart or other document showing the codes with updated FDA slides. Yes I believe that is kept by CDC. We can certainly find the appropriate follow-up for a contact within CDC. However they keep the active list of codes with all of these partner government agencies. >>

Someone is asking about the PK. The supplemental guide shows PK for into line with the presentation says there is only one PK per of the line which is correct. The supplemental guide is that the FDA line level. All of FDA's instructions are at the FD line level. There is only one file or contact information allowed for the FDA line. >> I am still seeing a ton of questions about different sunglass scenarios. Whether it's for research, a lot of sunglass situations. Email us and we will work with you but most likely they are going to require FDA.

Someone else's asking for a support showing going to go back to that slide. ACE support .HHS.gov. >> We've gotten questions about product code assistance for FDA product codes. Those of you working in the agency doing product coding, if you need assistance with your product code feel free to reach out to local FDA. All of that information can be found on FDA.gov as you search for imports. We have a newly redesigned import page that has a link to the various contacts within the district we are importing through. If they cannot be of assistance or if there's disagreement between the various districts, you may email the division of import operations at www.FDA import inquiry all one word at FDA.HHS.GOP.

Someone is asking , they were a broker and had to enter an FDA number for each entry is that correct? Are we required to have a FEI. FEI is

not mandatory. That is optional data. They are not required for a broker. You're not required to put that as an entity. We asked for your contact information but FEI number is not required. Other people are asking about the supplemental guide. The title page says November 30 which was the original day we published it. The save document says November 28 -- I'm sorry December 28 which is the right version. We made some edits to the change log. The title page says November 30.

Someone is asking for the [Indiscernible] using the PK. Additional entity be added to the all ready required entity or will it replace one of the existing ones? I'm not sure I understand the question. You can add a PK to something that is required. You could have to PG 20 wants for that are under optional entity put it. If you email me I can work with you and create a sample of how it should be sent. >> Some people are asking what to do if you don't know the facility registration number and can you put unknown for that. You cannot put the code unknown for that number. If you talk to your software vendor and referred to our supplemental guide there are some different scenarios. If you're unable to obtain the registration you can select the specific code. Talk to your software vendor or email support if you were not sure what code you can use if you cannot obtain the registration number or it is unknown. >> I have a question related to the and minimus number for filing. -- The minimus number for filing. The minimus number for filing. It hasn't been updated. There is technically no value for filing and they will rely on the requirements for CDC. We encourage the electronic filing of entry for faster and more efficient process for FDA. We will be coming out with new section 321 guidance for the future.

Someone asked is the role of PK mandatory or optional. It is optional but we highly encourage it. PK men's -- major sending me the broker information. We can answer your questions faster if you give us a number to call or somewhere to email. It is optional but we ask that you send it.

Someone ask and we look up or verify registration numbers.

No. Those numbers are proprietary and you can query them. CB Mac --

Someone says went is the Duns number or FEI required. It is not required.

I have a question here about what does the specific [Indiscernible] mean. If you go to the same website and search for the imports page there is a sub page that talks about watch -- what each flag means. SC 1 a product not of food but may or may not be FDA regulated. 2 means is out of food but it is FDA regulated. 3 means it might might not be a product and 4 means that it is a food.

Someone asked why FDA did away with [Indiscernible] through ADI. The reason we did away with that query is because of the budget in real time. We are working on an API that would interface the actual food to your software. If we delete product code and add a product code everything would be in real time and that's something we have in the

pipeline. The reason we deleted it was because the product code builder right now [Indiscernible -- audio cutting out] >> Someone asks what is the process for updating or correcting FDA product codes. I'm not sure exactly what you mean but if you have a reject, and FDA reject that says invalid product code you would need to work with your Representative and send the corrected version of the entry. If you get an FDA reject you can send the corrected version.

If you ever get an FDA reject you should contact support and we can help you determine why it was rejected and what exactly was wrong about the product code and help you transmit the right information.

Did you say it is being [Indiscernible]? >> There's a question on here about the Filer having access to all the appropriate information. The expectation in the reason were doing the outreach is known as of the communication does not exist or need to be enhanced where the importer provides the correct and accurate information for the products for the file or that way we help to assist in open that line of communication. The expectation I would expect is that when the entry is transmitted it would be accurate information. >> There is a question you may be able to help with. Are you able to confirm that a formal entry is required regardless of value when it's in FDA regulated product.

The answer to that one is no. CDC determines the [Indiscernible] type and category that is required. FDA can request through CDC based on our plans regulatory follow-up. However, there is no requirement that they are formal entries.

Someone else's asking in a case for an affirmation of compliance is mandatory and they just don't have it. What happens if your importer does not have the affirmation but there is other lines of unregulated FDA product. Will it hold the entire shipment and I'm not able to transmit the entry at all. For FDA you have to have , to be able to transmit electronically you have to have everything that is mandatory. If your importer does not have a [Indiscernible] it could be possible that a falls under a different import scenario. If not you should contact us and we can try to work with you but to file electronically you must have all of the mandatory data elements. >> Someone is asking about the requirements for tanning beds. I am not sure about your question. What would be required in addition to the [Indiscernible] number. Send that to ACE support and I will link you up to try to get a response.

Another question here, is FDA data available to other agencies with respect to [Indiscernible]. That would depend on whether the other government agency has a regulatory requirement to have that data and or two if FDA has an information sharing agreement with the other agency.

One of the benefits of ACE's so that entry data that is similar across partner government agencies is submitted only once.

Another question that I see, something about the raw material for pharmaceuticals. Something that would be a pharmaceutical necessity.

Pharmaceutical necessities do not require an intended use code.

Someone also asked us to provide unique ID number with ACE expedite FDA review. If you were talking about a FEI number or a Duns number if you're providing one that's correct it has a possibility to expedite our review and may also help you get an automatic proceed.

A lot of people are still asking about getting a copy of the webinar. We will be sending out the information of how to access the recorded webinar. >> Given the technical issues that we had, we will look at the video and the recording to make sure that it's acceptable quality. We have also caption the webinar as well so that should be available. The other question here, what happens if sunglasses actually coded as a drug but the information needs to be updated to correctly code the device I see Jessica scrolling through the slides here. Presumably if you have a medical device input as a drug you would not be able to submit all of the acquired data elements for that product and that she would get a reject back from CDC and or FDA indicating that the required information was not submitted. You would be able to retransmit with the correct information.

I am saying questions asking when exactly are these things going to be in effect. The updated intended use code and all the changes that we reviewed, those will be in effect beginning February 9. It is usually complete around 7 AM. So between 5 and 6 AM. If you get to work after any time you get to work after 7 AM Eastern time these will all ready be in effect.

At one point I did not mention, someone did send a question, who was the [Indiscernible] our software. So probably because they have new intended use codes King in the number code are choosing from a drop-down the number code for intended use code, those will be different. If you are choosing a certain one or if they are auto populated and you have the same entry and nothing changes but his prescription drug that number will change so you need to talk to your software vendor and you will need to key it in and change it. If they updated on the backend. Make sure for all of these changes we discussed today you are in contact with your software vendor and you are aware if there are any changes and you know what to expect. You are prepared for February 9. Communication with your software vendor is key. If your software vendor has questions they can reach out and we will work with you together to make sure we can help you be prepared as much as possible.

Someone is asking is you and Kay allowed as a qualifier for listing numbers. If you don't know the device listing number can I put unknown. No. After February 9 at 7 AM that is no longer accepted. You can only use you in K as an intended use code.

Product codes are popular topic today. Talking about the fact that many products are [Indiscernible]. Our subject matter experts routinely look a product codes under their purview to make sure that they have what they need from a data collection perspective. That information is

given to our import clients who then work with CDC to make sure all of the new product codes are updated and are available for you.

As well as in our product code builder on our site.

What about issues where an incorrect product code is discovered during an audit but it was not rejected during the entry transition process to FDA. At this time there is no ability to repair those codes. If there was an issue of concern where the entry needed to be updated, whether it was via product code or some other reason at this point if it is between five days in the time of arrival that information cannot be updated. Of the entry was transmitted five days or sooner, five days or later, then arrival entry changes can be made up until that five day window. FDA is looking at the ability to make changes later in the entry process even when accepted by FDA however that is still under discussion internal to the agency and will then have to be taken to CDC as well for the appropriate changes.

Someone is asking for the importer of record do I just give the phone number or do I need to give the email? Name, email and phone number for the importer. >> I have a question here on notices of action and whether or not they will be available on the ACE portal at some point. That's an excellent suggestion. At this point that is not an enhancement we are addressing right now. However we are looking at using FDA's

ACE to send notices to the affected parties. At this point it's only a pilot but were looking at ramping that up in the very near future.

You can find more information at the same website You can find more information@thesamewebsiteFDA.gov and search for it look for the main import page and you can find it from there or just query that.

Someone is asking is there a way that we as brokers can see our score so we can improve our entries? Know. The score is something that is proprietary to FDA and how we assess risk. If you're interested us a filer or an importer on how your filer can improve the data that you send, you can discuss that with your district during a valuation about things you can do to improve our things that were transmitted that were incorrect. We do not disclose information about protect. Someone else's asking if they can confirm the changes have gone into effect. We are working to make sure that everything about the deployment is communicated they usually send out a CSM's that they're having an outage due to the deployment. When they confirmed they are backup the make sure these changes are in place.

Someone else's asking for medical device initial importer. Some device initial importers have registration numbers. DII is not currently listed as an option. How do we report the registration? If the DI I that is registered, when you sent the PG 19 you can send that number and use that link that I used in the presentation of how you can query the FBI number for medical devices. You don't need to send it if it's not a registration number. >> Are you going to be able to transmit

documents to FDA through DIS. You have to transmit through I check which is FDA system for now.

Someone is pointing out the import trade ancillary communication system. Thank you. Much appreciated.

We're getting a couple of questions about LED lights and whether they are and FD a product or not. Yes they are. Based on the product we need more discussion on what exactly it would be. And/or a medical device but yes LED lights are at least radiation products.

That would require FDA data.

Someone is asking about the status of corrections and how can this data be revised after it's been submitted to FDA. We don't have any mechanism where you can call FDA. If you notice something is wrong and it if they have the entry you will have to cancel it and refile it. If it is something small AB you can contact your port and updated. If you file did as [Indiscernible] and -- and FDA regulated problem we have no mechanism for fixing that and you would have to cancel and refile it.

Someone asked can you please reiterate about the PK and when it has to be used. Is up for all FDA entries. PK stands for the file or contact information. We encourage you to send it to us. It is not mandatory. The reason we encourage you to send it to us is because if there is a problem with the entry and as we all know everyone is in a hurry. The quickest way we can reach out to you and the quickest way we respond as if you give us a phone number or email that we can say this is wrong when you upload your document picture this is what you sent. It is not mandatory but it is optional if you can send it we ask you send the filers information.

A question about who to make contact about [Indiscernible]. Any rejects or system only and we cannot manually reset entries after the fact. That is undiscovered is under discussion for future functionality within FDA. >> We are on track for implementing the rest of these changes on February 9.

Another question does the current notice flag?[MUSIC]

The FD flag whether it's three or four indicating it may require NSC three or does require prior to Ancey for is based on the code. If you have questions about the codes and the flags associated with it I will be providing the contact information within the division of import operations.

There's a couple of questions about the manufacturer. The site-specific location the last substantial change of the product. There's a couple of questions as to if it's a legal manufacturer or the actual manufacturing site where the operations occur?

Within FDA we always talk about the smokestack locations for the products. If there was an issue where would we go to find what happened

with that product. In the example just given that would be the actual location where it was produced. >>

Looking to see if there were any other questions we haven't gotten to yet

there's a question related to win reporting values for FDA said that value take into account additional consideration such as any deductions for insurance. For the purpose of the transmitting values to FDA it is acceptable to transmit the value which was submitted to CDC given any allowances to the various charges. That being said FDA prefers the values declared for the purposes of FDA entry data. The one issue is that based on our discussions with CDC the line values may not exceed the entry value.

Another question we -- you may be able to help with. As you're familiar with the final rule made import of record contact information mandatory and it can be a person or corporation. We have a couple question saying can the broker put their name email and phone number in that field instead of the import -- importer of record.

It's for FDA to get the contact information of the most responsible party. Certainly the filer could also be the importer of record. However FDA's expectation would be is the contact information for the importer of record? >> I'm checking to see if there's any other questions that we can get to. We have a couple of more coming in. >> Just so everyone's clear there was a, to please confirm the timeframe for FDA changes. That is up until five days prior to arrival for the article. Anytime after five days the entry maybe only changed if the liner entry has been rejected by FDA. Like I said earlier we are considering moving that timeframe closer to and or/post arrival. However at that time that would not be accepted by FDA. Unless the entry is rejected changes may only be made up until that five day window prior to arrival.

Someone is writing in about an intended use code 180.014. Import of a device for nonclinical use bench testing. It says they are being asked for an ALC code. I am not sure who is asking. If it's either your software that's triggering it incorrectly or if you just mean that someone at the port is asking for it. I'm not sure what you mean. Systematically it is not requiring anything. If you send us an email you may have to provide documentation showing is for clinical research or for nonclinical use bench testing so they know that they don't need to ask you for that.

If you're sending the documentation saying for bench testing and they are asking you for something you don't have, send an email to imports inquiry and we can make the port aware and they need to see the documentation again that it's going for bench testing. When you file that type of entry you could put product for bench testing or customer evaluation and you can go ahead and up -- upload and show so they know. >> When we pull the contact information we are going to look for a PK if it's not there but it's transmitted, we will try to use that information. We would have access to the prior notice transmitter information to submit a PK. We would use that as the contact information.

other people are asking are you going to post these Q&A's? We will try to provide Q&A once we can write all the questions and answers.

AJ we have a question about broker only.

Historically the expectation for now is that FDA will continue to send the notices of action to the importer. Historically FDA has sent the notice to the company and file or given the language in the final rule FDA requirement is ascended to the importer of record. We will consider sending to the filer in the future as well. However the importer of record does record is the most responsible party and should be able to provide that information as well. >> A couple of people are asking if the device listing number is query able. Now, that is proprietary and you would need to work with your importer to obtain that information. That is not something FDA has publicly available.

A question I know we've seen this before what is the procedure to clear [Indiscernible] the cannot be transmitted. Do we need to have proof? >> I would have to look at more of the specifics. I am not aware of their status if they cannot be submitted electronically like any shipment of expect local CDC to provide that information to local FDA and make a determination

Someone is asking how do we determine if a party is considered natural state or process food. We have a definition we can send you. We can send you the definition. Send us a product in question and we can help you determine if it is natural state or prior notice -- sorry process. Usually natural state means however it is found in nature. No, or minimal processing.

We can send you the definition if you contact support. A lot of people are asking , you guys are writing in the questions and they want to be able to ask the question and have a conversation. There is a weekly trade call at 2:00 every Thursday. FDA does join the call so if you have FDA questions that is more of a forum for questions. You can always email or call our support and hopefully they can put you in contact with someone if you want to have a conversation about a specific scenario are asked a couple of questions it was Seder that stated earlier that prototypes may not require [Indiscernible]. Who would recontact? At think what you heard was I asked AJ if you can help me if this will require FDA and he said it may not he may not be able to answer not that they may not require FDA. If you contact import inquiry I will go back to that slide and show it now. There is documentation on whatever prototype you're asking about we will work with the center for medical devices to determine if it is regulated by FDA and requires to be filed or not one more slide. FDA inquiry for medical devices the model has to be provided. That is not mandatory data. How do we register for the weekly trade call. We just send an invite. If you were not on that it is hosted and will get you the information and forward you the number. >>

Someone asked was intended use code removed?

Yes. >> What is the most common rejection for medical devices?

One is the missing entities because you have to give five entities you also have to give the device initial importer and select the correct intended use and based on the intended use their shoes the affirmations required. You would have to submit the affirmation and submit them in the correct format. Those are the common areas we see rejection questions about for medical devices. >> I'm repeating it because someone sent me the information. We have the number for the CBP Thursday call. Thank you for sending this. The trade call number is 877. The trade call number is 877336. The trade call number is 877-336-1828. Again 877-336-18 877-336-1828. The access code is 612. The access code is 612421 4. The trade call is hosted every Thursday at 2 PM Eastern time. Again, one more time the number is 877-336-1828. Access code, 612421, 61242114. That is at 2 PM Eastern time every Thursday and it usually lasts about one hour. If you're having any issues this is specifically for ACE or any of the PGA usually a representative from each PGA is on and you can ask your questions. It is East Coast time at 2 PM.

I see a couple of questions about whether or not obstacles might require FDA. The answer is yes. As a laser containing product even though it's not a medical device, --. >> Someone is asking is there some type of field to annotate SPV withdrawal. Items that are going into a you submit the private or -- prior notice when you're going in. When is coming out you don't need to provide your prior notice information. The way that you do that you would have to talk at the person asking is a filer or software vendor. If it's a type XXVI, that information is obtained from entry-level if it is a 21 withdrawal you need to work with their software vendor and the record is called PG 30. The way to annotate the code and that's how we would know not to require the prior notice. If you are withdrawing from a [Indiscernible] talk to your software vendor and ask if you need to send the firm's code.

Someone also asked why is FTE firms code now within all of the chapters that used to only be in food and now it's another chapters. It's an other chapters so FDA gets that as an entry type XXI and that's the reason we have that. It is a way to tell us even if it's not prior notice is telling us is an entry type XXI and gives us the code. >> Someone is telling me that I may have transposed the numbers for the access code.

I'm opening up the official invite. Again the phone number is 877-336-1828. The password is access code 612421 4.

If you can get in just email support and we will get you the right number and forward you the invite. >> Someone is asking when you're correcting an FDA entry and you add additional lines, you have to talk to your client Representative about this. They know more about the functionality than I do. If you don't get a specific answer I can get you another client Representative that works with us in the business office. I believe we send a correction, you have to send every line under that line. If you were putting additional lines under that I think that would be allowed. Please confirm with your client Representative on the correction functionality. >>

We would need to meet more about the product itself and what it is being used for. There have been some rather interesting uses for similar products in the past. It may or may not be an article of food. It may be another [Indiscernible] regulated by FDA or it might be good FDA regulated product at all. Give us the information presented here it is most likely a food product and as FD three and would require prior notice and if -- entry data. If you would like to discuss more does specifically we have that at the email address up here. >> Someone is asking can you send a correction if you put the wrong shipper for your entity for FDA. It depends on how much an impact. If it's a 100 line entry and you put on the wrong if it's just one line you could call the report and see if they would make the update for you otherwise you would have to cancel and refile.

I'm going to put on if type XXI [Indiscernible -- audio cutting out] There are different types for warehouse entry. The type XXI is for general warehouse where those coming from foreign trade zones or type XXVI which I believe Jessica referenced earlier. >> Someone is asking are the appendix coats good for all FDA programs I am trying to remember what that appendixes. A lot of the appendixes like appendix R and other appendixes that have affirmation of compliance, those are getting updated. For the most accurate and recent information for the FDA it is always in our supplemental guide. If you see an affirmation of compliance listed or some other code listed in another document but not in our guide, always go with our guide for the latest information. The latest units of measure, I'm not sure what day they updated it. I will have to check the date and if it's after the date we published it is probably not in seeing. I know we gave them something soon .

Someone says do you have an updated tips for importing FDA products?

We are trying to get that posted this week. I have one correction to make to the slide that I share today. Once I make the correction and send it to CBP I will send that so they can post it or send it so everyone can have access to that. >> Is [Indiscernible] always required for sunglasses or any medical device.

Yes. It is not an affirmation.

It would always be required for medical devices. >> We are up to our 3:00 window. I will look at one more.

There is some sort of database that shows FDA ruling. The answer at this point is no. We have talked about for a long time developing some sort of system that memorializes our decisions or determinations on various issues however based on competing priorities, that has not happened yet.

We hope to in the future at some point. Jessica, anything else on your end?

I have two things. I've got an email from a client Representative regarding ring [Indiscernible] whether it is to a bond warehouse if their specific codes specific from and not go to a warehouse. It

reflects the firm's code. I'm not sure if that answered your question if not email me it's been a while since I worked on that stuff. I'm having a hard time remembering on the spot but I can try to get you an answer to your question.

The last one that I will answer is something I just saw the came in. The question is for medical device or the device initial importer why that's a mandatory into Tory for medical devices if every medical device may not have a [Indiscernible]. They actually put a note for that. It says it's in our supplemental guide. It's on page 238. Under PG 19 for medical devices 2.5. If there is no DII that must register the name and address of the [Indiscernible] good news required if you have a question email -- email me and I can send you the link. Enter the name of the US firm receiving the goods in the DI I field. >> I'm still seeing a lot more stuff for sunglasses. Please email support on the same email if you have questions about what is required for sunglasses or if sunglasses are subject to FDA or components of sunglasses. Either the manufacturer of the lens, email us and we will help you with those specific scenarios. Always email us if you have a question. Or call us if you are not getting answers to your questions. Email us again. You can email me or email FDA and we will try to get you the help that you need.

I don't have anything. AJ, anything else from you?

I want to thank everyone for their time and participation here today. We look forward to continue our collaboration. As we transition to making a better product for everyone across the board. I want to thank Frank and Peggy for all of your assistance throughout the project.

Thank you all.

Thanks, everyone. Have a great day.

[Event concluded]