

Coordinator: Welcome and thank you for standing by. At this time all participants are in a listen-only mode until the question and answer session of today's conference. At that time you may press Star 1 on your phone to ask a question. I'd like to inform all parties that today's conference is being recorded. If you have any objections, you may disconnect at this time. I would know like to turn the conference over to Gary Norris. Thank you, you may begin.

Gary Norris: Good afternoon everyone and thank you for joining today's Stakeholder conference call. My name is Gary Norris, I am the Federal State Health Communication Program Manager in FDA's Office of Regulatory Affairs and will serve as the moderator for today's call.

The purpose of today's call is to discuss updates to the FDA Automated Commercial Environment Final Rule and the most common reasons for FDA entry rejections and shipment delays. We will also provide an overview of the use of the Supplemental Guide, provide answers to frequently asked questions, and disseminate contact information for FDA personnel working in import operations. Today's call is scheduled for one hour and 30 minutes with the first portion of the call dedicated to presentations. Following the presentations, we will open the phone lines and take questions from our callers during a question and answer session and end the call with closing remarks.

Joining us on today's call as speakers are Jessica Aranda, Program Analyst, Division of Special Initiatives and Coordination, Office of Information Systems Management, Office of Regulatory Affairs, or ORA, Lorraine Barnes, Program Analyst Division of Import Program Development, Office of Enforcement and Import Operations, ORA, and Brigitte Strelnik, Consumer Safety Officer, Division of Import Program Development, Office of Enforcement and Import Operations, ORA.

At this time I would like to turn the call over to our first speaker, Jessica Aranda.

Jessica Aranda: Good afternoon everyone. This is Jessica. So I'm going to open up the presentation and start with the basics of ACE and FDA's current status of where we are with our integration to ACE. So we're going to start with an overview of what is ACE, how ACE works for FDA, some of our common errors, and recent changes.

And then we're going to go into the specific information for all of the different products that FDA regulates and what are the requirements for those products. And then we're going to end with some helpful information and some resources so you can avoid delays, share your trends and incorrect information, resources for where you can go to query some of that information to ensure it's correct, and then give you some points of contact.

So starting out as brokers, filers, software vendors, you've been hearing about ACE for many years so you probably already know what it is, but we always like to start our presentation with the baseline of what is ACE? So ACE is the Automated Commercial Environment. It is a centralized system for all of the transactions related to imports and exports where filers can electronically submit all of the information related to their shipment and the government will then systematically process those transactions and send status updates.

Specifically for FDA, this slide here shows the ACE process. So if we start with number one at the very left of the slide, this is your position as the trade community as a filer you would access ACE through ABI, the Automated Broker Interface, and submit the requirements for CBP and whatever other

agency has jurisdiction over the product on that shipment, in this case FDA. And you would submit that information electronically to CBP.

Moving on to Number 2, once CBP receives that information there are two options for what can happen. The first option is that CBP conducts the syntax validation. They ensure that all of the information that is required is present. If everything is present, if everything is correct, then CBP would then pass that information to FDA. If some information was missing or something was in the incorrect format, the entry would be rejected and then sent back to you as the filer to make a correction.

Once you make the correction and CBP and CBP accepts your entry and that entry is on file, CBP then sends that information to FDA. Once your entry is on file and you get a message entry summary has been added the data is accepted, you usually get a message that says data under PGA review. I'd like to make a note that that message is an automated message data under PGA review. It doesn't - it's not a message that comes from FDA it's a message that comes from CBP. And it doesn't actually mean that CBP has sent the data to FDA - it just means that CBP will send the data and that PGA will respond.

So once FDA has received the information we process it with those database and screening tools that we've been using for many years. So on our side at the local FDA offices and from a systematic perspective, everything is the same business as usual as we've been doing for many years. If it's prior notice it goes into prior notice screening and returns a response. If it's an item that does not require prior notice, it goes straight into Oasis and is screened by our risk targeting tool PREDICT. And then from there FDA generates a message at the line level and sends those messages back to CBP. CBP sends it back to the filer.

If all of the information that is transmitted is correct, complete, and is able to be validated across our databases, there's a possibility that it would electronically receive an automatic automated message that may proceed, which means that no one at the port had to manually look at that information, or verify it or request any further documentation. That means that once it comes into FDA's system, if everything is correct and validated, then the message is almost instantaneously sent at the CBP and CBP sends it back to you as the filer.

So just to give you a little bit about where we are in our current status, many of you know FDA launched our eighth pilot in August 2015. And then the following June, June 2016, FDA and CBP required that ACE become the official system of record. FDA Final Rule, which mandated what must be transmitted in ACE, issued in November of 2016. And our current version of the Supplemental Guide, which outlines what data is required for every scenario, was published in February 2017.

We continue to work closely with our trade community that is software vendors, brokers, filers and importers to help ensure an understanding of this process. We are doing outreach across the US via webinar and in person outreach events to ensure that we're collaborating with the trades and ensuring that all of these processes that are new over the last couple of years are understood and so you can be in compliance with those processes.

FDA also continues to collaborate with Customs. We have weekly meetings with Customs to update or solve any business rule issues and other system issues request enhancements. At this point, we're at close to 10 million entries that have been filed in ACE, which equates to about 50 million lines. And we have 100% participation of all the filers that file FDA products.

One question that we get quite often is what are some of the benefits that FDA has seen? The President's Executive Order to streamline import processes was sort of the foundation of why the 48 government agencies came together to implement ACE, to streamline processes and make things more efficient. So again, the question we get is, are things more efficient and what type of observations does FDA have since your transition to ACE?

So one of the things that we have observed is that our automated may proceed, again that's transactions that are completely processed electronically by the system, have increased. So before our transition to ACE, only 26% of the lines were able to have an automated may proceed. And then in 2016 after the full implementation of ACE, after we started sending messages at the line level and updated many of our processing tools, now that number is 62%. So we've seen our automated may proceeds increase dramatically after all of the enhancements and work that we've done in the last few years.

Another observation that we have after looking at our data, we – and this was a goal that we had with ACE to request less documentation. So as you as filers and importers are aware, one of the statuses that FDA can send is a request for documentation. Perhaps when there is something that we need to obtain more information on in a shipment, or if information was transmitted and it wasn't correct, or if information just was not transmitted and we needed that information to make an admissibility decision. So as we've seen in 2014 3.13% of lines needed additional documentation from the filer to be uploaded to (iCAD). The number has gone down a bit. In 2016, that number is now at 2.59 lines needed additional documentation to be uploaded to (iCAD).

Some other questions that we have since our implementation to ACE are what are some of the lessons learned and the most common errors. So as you're aware , here are CBP rejects where CBP can reject your entry and there also

FDA rejects where once FDA receives the data, if something is not correct, we can also reject that and you would have the opportunity to make an update.

So some of the most common CBP rejects are missing or invalid Affirmations of Compliance. Not every FDA regulated product requires an Affirmation of Compliance, but many of them in most cases there's at least one that would need to be supplied. Another common reject for CBP is a missing or invalid entity.

So those are the parties that are associated with the transactions. That's normally the manufacturer, shipper, FDA importer, home delivered to party or ultimate consignee. If it's prior notice or a medical device or if it's a food that falls under FSVP there are additional entities that would need to be submitted. So ensuring that you know for each type of transaction what parties you need to transmit is very important.

Other common CBP rejects are submitting a product code that doesn't relate to the program code. So that was - an example of that would be trying to submit let's say a drug product code something that might be a dietary supplement under, you know, either a food or a drug incorrectly. You would need to pay attention to the product codes as well as the program code.

Other common rejects for CBP are not correctly transmitting the unit of measure. That is an optional data element but if you're transmitting a unit of measure you must ensure that you're properly submitting a container code and a base unit. And that the container code and base unit that you're using are applicable to the product at hand.

And also the source type code this relates to the country type. So depending on the type of products you may be giving us a country of production if it's a

processed food, or a processed product, or a country of source or a place of growth depending on the product type. And then also another common CBP reject that we see it and we hear a lot is for prior notice the party that's required is a UC and ultimate consignee. And then for all of our non-prior notice the parties that require is a deliver to party. So whether or not you're filing prior notice or you're not submitting a product that requires prior notice will determine which entity you're using.

If you're filing prior notice you need to use the ultimate consignee. If it's not prior notice you need to submit the deliver to party. So those are the CBP rejects. The rejects that would occur as soon as you transmit, your entry wouldn't even be on file, entry summary wouldn't be added it would immediately be rejected.

The next reject that we're going to talk about are more specific rejects. This is once CBP accepted your entry, your entry is on file CBP passes that on to FDA and FDA begins their validation. The top reasons for FDA rejects are invalid food facility registration number. That's a big one as well as a canceled food facility registration number. Many of you know that's not a number that you can go and publicly query that is a proprietary number that needs to be obtained from the party or facility that completed the registration with FDA.

Another common reject is an invalid product code. That would be using a product code that is maybe mistyped and just doesn't exist or a product code that has been outdated or end dated and is no longer valid. And then finally another common reason for a reject is that the party that you're transmitting as either the ultimate consignee or the deliver to party where the goods are going to be delivered to once that shipment comes into the US. That must be a US firm. It's and import. So that's coming to the US. Any foreign ultimate

consignee delivered to party would not be correct for an import and thus would be rejected once that entry comes to FDA.

Some additional areas of improvement is knowing the intended use for the product prior to transmitting the entry data. We see a lot of people that they don't know what the intended use is so they guess or they call us and they say what's the intended use? Intended use is something that the importer should be providing to the filer. It's not something that the filer should be guessing about or calling FDA. FDA doesn't determine the intended use.

The intended use is determined from the importer and how that product is actually going to be used once it is in the United States. Also know the required entities and Affirmation of Compliance, knowing what the correct affirmation and then not submitting it more than once. And then submitting the correct address and if you know the DUNS or an FEI submitting one of those.

Another common error we see a lot of times is with the intended use code for personal use. A lot of filers seem to be under the misunderstanding that if humans if people are going to use the product it's for personal use and that's not correct. Consumer use is the correct code for items that are going to be distributed, going to some type of distribution center or going to be sold in a store. Things for personal use would actually be for a personal shipment. So that's probably something with a very low quantity not, you know, a huge shipment of 1000 parts that are going to eventually be manufactured and sold for something else.

Moving on to the FD slide, as many of you are aware FD0 was eliminated once we transitioned to ACE. So the (sizes) are now FD1 through four indicating what type of data would be required if the item can be disclaimed,

if it's food that requires prior notice. One note that we want to make regarding the flags and the HTS codes even if the item does not flag for FDA but you know it's an FDA product you can still submit FDA data and you should still submit FDA data.

And then also we wanted to share many of you have read back in November, December our Final Rule was published which gave us the legal authority for exactly the data that we're collecting. So that can be viewed on the Federal Register by looking at the link that we'll include in this presentation.

Just to give you a quick overview of what changed line value was previously mandatory and it's now optional. The quantity and unit of measure for the items within each line was previously mandatory and now it's optional unless it's a radiation emitting product that's subject to a performance standard with a 2877 it would be optional. If it's a radiation product that is subject to a standard it would be required.

And then now one thing that was previously optional that is now mandatory is the contact information for the importer of record for all non-food lines you must give us the contact information for the importer of record. And I will make a note the line value and the quantity even though those are now optional if you have that information we encourage that you transmit it. Sometimes it is needed to make any admissibility decision so if you have it please transmit it.

Lorraine Barnes: Thank you Jessica. This is Lorraine Barnes. And the first commodity that we'll briefly review is biologics. Prior to submitting biologic entries in ACE it's important to know what is being imported. As a filer it's essential to correctly file an entry and as an importer knowing what you are importing and

the requirements will help you provide all the necessary information to your filer.

Step one in the process is determining that your product is a biologic as defined in the FDA statutes and regulations. Examples of biologic products include blood and blood products for transfusion and/or manufacturing into other products, allergenic extracts which are used in both diagnosis and treatment for example allergy shots, vaccines, gene therapies, cellular therapies and tests to screen potential blood donors or for infectious agents such as HIV.

Examples of human cells tissues that are cellular or tissue based products are bone, ligament, skin, dura matter, heart valves, cornea, stem cells derived from peripheral and (cores) led and semen or other reproductive tissue. Information needed for submission includes program and processing codes, product code, product description, packaging and condition, intended use code and Affirmation of Compliance. The origin and arrival information is mandatory as well as the various entities involved such as the manufacturer, shipper, FDA importer and the deliver to party. The filer broker point of contact is currently optional but highly encouraged.

Entry (view) processing delays occur when the importer and/or filer do not understand what is required to be submitted in ACE for each commodity type. If the required Affirmation and compliance codes transmitted are either not filed or incorrectly filed FDA will need to manually review the entry and will most likely ask for documents and for additional required data elements. For additional- and assistance you can always contact the ACE support or FDA imports inquiry.

Now moving on to cosmetics, again know what the product use that's being imported. Examples of cosmetics of course are product such as bath products, and makeup, hair coloring, manicure and shaving products and the ingredients to be used to manufacture these products. As with other commodities information needed for submission includes the program and product code, product description, entity information and origin and arrival information.

However there are no processing or intended use codes and Affirmation of Compliance's are optional. Again quantity and value are optional but highly encouraged. Jessica will now review submitting drug entries through ACE.

Jessica Aranda: So as Lorraine was stating for the other products it's very similar what's required for drugs is in the same format as all of the other commodities. First and foremost you must know the product that's being imported, what is the product, who's importing it what is the purpose that it's being imported for? You also need to know the information that's needed for submission? What type of application does the product have or other Affirmations of Compliance that are associated such as the registration and the listing?

You'll also need to know those entities that are required, the manufacturer, shipper, importer and deliver to party. Understanding the common reasons for delays in processing those type of products which could be submitting incorrect Affirmations of Compliance or incorrect intended use code, and knowing what resources are available online in order for you to look up that information or who you can reach out to if you have a question about submitting a product and whether or not it's a drug, or food or a combination product or something like that. So the different processing codes for a drug are prescription, over the counter, pharmaceutical necessity, research and development or investigational products. So you would need to determine this

in order to correctly file the product you need to determine the correct processing code.

You would also need to ensure that you are submitting the correct product code. As we reviewed in the earlier slides the product code and incorrect product code is one of the top reasons for an FDA reject. So for a drug you would need to ensure you are using the correct product code and industry code. And we've given you tips within our supplemental guide if it's prescription, over the counter, research and development, investigational drugs the product - the industry codes you use are listed here 54, 56, 60, 61, 62, 63, 64, 65 or 66. And if it's a pharmaceutical necessity one of the most common industry codes is 55 but there are various industry codes that could apply because of the range of items that a pharmaceutical necessity could be.

You would also need to ensure that you are aware of the correct intended use. Again this is not an answer that FDA can provide to you or that as a filer you should be guessing. This is something that the importer should communicate to the filer. If you need help narrowing it down but you can give us the intended use we will be happy to, you know, put you in touch with the correct contacts but you should have an idea and know the scenario for why the product is being imported.

So there's several choices for the drug product. Some of the most common is prescription product coming in for human use, consumer product, OCC products that are coming in for human use, active ingredients for additional processing into pharmaceutical products, active ingredients that are coming in for pharmacy compounding, drug components that are going to be used and regulated as a device under a premarket application. Also could be a scenario could also be importation for personal use.

Other intended use scenarios include drug products that would be used in a medical device under - as a drug device combination product under the center of medical devices, chemicals for research and development which are subject of an IND. This also includes placebos, chemicals for research and development that are for lab testing only and will not be used on human or animals, chemicals for research and development that will be used on animals.

And then the last couple of scenarios are finished drugs or APIs that are going to be used in in vivo bioequivalent - bioavailability study. And those would be products they qualified under 21 CFR 320.31 for those type of exemptions. Other scenarios are for US goods returns, drug products that are coming in as import or export. And then we also have the Code 980 if it's for other use. And that would be a product that doesn't meet any of the above scenarios and not elsewhere classified.

The entities that are required when you're submitting a drug product are the manufacturer, shipper, importer and deliver to party. For the importer you are required to also give the importer's contact information. The optional entities that are available to be transmitted for drugs are the filer broker's point of contact information, the sponsor if it's different from the importer and also the producer of the API. If you have that information again it is optional but it's encouraged if you can provide it. And with all of these entities the information that's required is the name and the address but if you have the DUNS number or the SEI we highly encourage you to provide it.

So the most common reasons for delays for processing drug entries are related to Affirmation of Compliance. And that could be because those codes are either not submitted or they're submitted but they're submitted incorrectly. Within this presentation for the different commodities we give you many resources to go and look up information where you can verify information.

So for drug – these all of the resources that are specific to drugs, for drug approvals, registration lookup, a DUNS number lookup, NDC lookup, NDA or ANDA lookup. These are all of those Affirmation of Compliance that we just mentioned where you can go and looked at information up to avoid getting a document request or avoid FDA having to manually verify what was present. And then we have some additional resources to look up IND, investigation only, labeling, information regarding OTC drugs and the labeling of those drug products and MDA applications, abbreviated MDA and prescription drug labeling information.

Lorraine Barnes: So moving on to human and animal foods. As with the previous commodities we'll go over knowing what the product is that is being imported, what information is needed prior to submission, some of the common reasons for food entry processing delays and then we've included some additional resources that we feel will be beneficial.

First we'll go over the program and processing codes. The program code for all food commodities is FOO. And the commodity subtype determines what the processing code will be. For example if a product just like fresh crated apples the commodity subtype is natural state foods, so the processing code would be NSF. But if the product was applesauce in jars the commodity subtype would be processed food. So the processing code would be PRO.

Something to note is that the program code and processing code need to match or you'll get a reject. For example if you use the program code FOO for a food product but then you use the OTC code with processing code which is for over the counter drug products your entry will be rejected by CBP.

Next the product code is mandatory. And for foods it's always seven characters. All food industry codes are shown here in the chart and can be found in the FDA supplemental guide. The supplemental guide also identifies the industry codes associated with the program and processing codes. The Process Indicator Code also known as the PIC could be one of many depending on how the food is processed.

Let's say you were importing canned garbanzo beans which were thermally processed. The industry code would be 24 and the PIC would be E for commercially sterile. This is very important since the PIC drives what Affirmations of Compliance will be required. The supplemental guide indicates that if the program code is FOO and the product is low acid canned food or an acidified food Affirmations of Compliance codes FCE and FID and container measurements or the volume Affirmation of Compliance code which is VOL must be provided. The Product Code Builder tool and tutorial can be used to build the product code but product code training is totally assessed for its curriculum from the ACS training. So you can always reach out to your local FDA office and request training.

Next the intended use codes are not required in foods, food contact services and prior notice. However they – there are three options depending on the import scenario. The research used as human food and for research used as animal food. These would be used for things like product testing for example manufacturer of infant formula in Canada sends a small shipment of – to the US for a nutrient content testing. And then none of the - and none of that product was going to be consumed. So - and just used for research. Then those codes would be appropriate the human - the research for human food code would be appropriate.

These intended use codes do not typically include samples say going for tradeshow as giveaways or for ordering purposes. The other possible intended use code is personal importation. And like Jessica said earlier there seems to be some confusion with the personal use and human food code. The FDA definition is a personal importation is a product not for further sale or distribution into the United States commerce.

These products may be carried in baggage, or shipped by courier or international mail. So the thing to note is that the foods intended use is to be consumed by the person importing not for commercial distribution. And remember the intended use code is not required for program F00 but there are several options applicable to the product that your being – you're importing.

Now the various entities, there are three ways to file food entries. Again the program code is F00. The first way is filing PM standalone. Secondly combined PN and 801A and when the entry is non-PN and the PN has - was previously met. This hasn't changed when transmitting or transitioning from ACE to ACE. It's just what was - is being required has changed.

So when you're completing your filing there is some additional elements that need to be incorporated that you didn't have to use for ACS. This chart depicts the various entity data requirements depending on which of the three ways you opt to file. As you can see most of the entities are mandatory PN standalone and PN and 801A entry filing.

As of May 30 the entity data requirement for the foreign supplier verification program importer is also mandatory. And the entity roll code for that is FSV. Although the broker/filer point of contact is optional again we highly

encourage transmitting this information so that FDA reviewers can expeditiously contact the filer to avoid processing delays.

As a reminder when importing human and animal food so the program code is FOO and the processing code is NFS, PRO, ADD, DSU or FEE And the industry code is anything besides 16 for seafood or 32 for alcohol. The following FSVP related details are mandatory.

The FSVP importer firm name. So that is the owner or cosigning of the article of food being offered for import or if there's no US owner cosigning at the time of entry then the US agent or representative of the foreign owner of cosigning as confirmed in a signed statement of consent. Also their address and the entity rule SSB and their email address. And the DUNS number is required or UNK is allowable for now.

As the only assessable Unique Facility Identifier also known as the UFI outlined in the guidance for industry based on the regulation. But the DUNS number may not always be the only acceptable UFI. If the line item is a food and the above items are not transmitted the entry will be rejected by CBP unless an Affirmation of Compliance exemption code is used. So if applicable there are two Affirmations of Compliance exemption codes. The first one is RNE for Research and Evaluation and then there's also FSX. And that's if the – it's FSVP exempt or it has a later compliance date.

We've included some (unintelligible) here that we think would be very helpful if you want to ask questions or get answers. And one of the links is for a CSMS message that was posted on May 31 of this year and it has a lot of really great information about FSVP and what is required at the time of filing. And contains links to various other resources available for additional information pertaining specifically to FSVP.

Moving on to Affirmations of Compliance, Affirmations of Compliance codes are used by FDA to determine product compliance. The top table is a list of required Affirmations of Compliance codes and if and when they are mandatory or conditional. And again depending on how you filed PN standalone, PN 801A, or non-PN or PN was previously met.

The bottom table provides a list of all the optional Affirmation in Compliance codes. Notice Affirmation of Compliance codes specific to low acid canned foods and acidified foods are conditional not optional as are the foreign supplier verification program codes FSX and RNE.

Again entry view processing delays occur when the importer and/or filer do not understand what is required to be submitted in ACE for each of the commodities. For example processors who manufacture, process or pack low acid and/or acidified foods are subject to registration requirements as well as processing filing requirements. They file with the FDA and provide information which includes the firm's principal place of business, each location in which the processing is carried out, the processing method and a list of the foods and containers dimensions processed in each of the locations.

When transmitting entry lines for these types of foods Affirmations of Compliance codes FCE, FID and the container dimensions and/or volume are required to be provided. And this information the filers need to obtain this from the importer of record prior to transmitting. Recently it's been determined that approximately 5-1/2% of all lines filed with transmission errors are low acid and acidified food lines and fail due to either they do not have Affirmation of Compliance codes FTE, FID and the container dimensions or volumes or what was transmitted is the incorrect firm or product.

And in the last slide we've got here for the food commodities is for additional resources. And I'll now turn the presentation over to Brigitte.

Brigitte Strelnik: Good afternoon. We're going to take a few minutes to briefly discuss medical device imports. We're going to discuss knowing the importance of knowing the product being imported. As we discussed with the other commodities knowing that you are importing a medical device is critical to providing FDA with complete and accurate information. Additionally we're going to discuss information needed for submission. And we're going to briefly discuss the intended use codes and the Affirmation of Compliance codes applicable to submitting medical device entries.

We're going to talk about common reasons for medical device entry processing delays to help prevent you from being victim to these common errors that cause delays when submitting an entry. And I'm also going to provide you with resources that you have available to you to help get your questions answered and obtain information for submitting medical device entries.

All right knowing the product being imported, a device is an instrument, apparatus, implement, machine, contrabands, implant, in vitro reagent or other similar related article including a component part or accessory which is recognized in the official National Formulary, or the United States Pharmacopeia or any supplement to them intended for the use and diagnosis of disease or other conditions or in the cure, mitigation, treatment or prevention of disease in man or animals. And intended to affect the structure or any function of the man or animal in which it does achieve its primary function through - does not achieve its primary function through chemical

action within the body of man or animals and which is not dependent upon being metabolized for the achievement of its primary intended purpose.

Medical devices range from simple devices to very complex devices such as tongue depressors, and bed pans, myocardial and epicardial leads, surgical lasers in vitro diagnostic test kits, reagents, diagnostic ultrasound products and x-ray machines. For medical devices it is important to know if the product being imported is a component or a finished device. This information affects the intended use codes and Affirmation of Compliance codes required for entry transmission.

For your reference I have put the component definition and finished device definition in the slide. Component means any raw material, substance, piece, part, software, firmware, labeling or assembly which is intended to be included as part of the finished package and labeled device. Finished device means any device or sensory to any device that is suitable for use or capable of functioning whether or not it is packaged, labeled or sterilized.

The program code for medical device commodities is DEV. The processing code is dependent on whether or not the medical device emits radiation. The processing code for radiation emitting devices is RED and the processing code for non-radiation emitting devices is NEV. The type displayed on the screen can be found on the supplemental guide and should be utilized to make sure you are using the appropriate processing code and your processing code matches the program code to help prevent rejections - prevent delays in your entries transmission.

As with the other commodities product code is mandatory. Please note that Industry Code 73 through 92 should be utilized for medical devices. As discussed previously you can utilize FDA's Product Code Builder for

assistance. Feel free to reach out to the local port of entry or FDA field staff to help you if you require assistance with the Product Code Builder or building your product code.

Intended use code is mandatory for medical devices. Filers and importers need to communicate starting early in the entry process regarding the intended use of their product because the intended use code you select drives the Affirmation of Compliance codes that you will need to submit. The chart here that is supplied in this slide and the following slides is also supplied in the supplemental guide. It is a list of the intended use codes with the import scenarios and the Affirmation of Compliance codes that are mandatory, conditional and optional.

Mandatory Affirmation of Compliance codes have to be given and the conditional ones should be given when their applicable. And optional Affirmation of Compliance codes are highly encouraged. I would like to note that intended use code if you use UNK that this - you will experience delays in your entry review processing as you will go to manual review. And the entry reviewer will be reaching out for the necessary information as the intended use code and Affirmations of Compliance that are asked to be supplied in the initial entry review process are required information to be verified upon importing an entry into the United States.

Some of the applicable intended use codes are a standard import device 081-001. And this is for your standard import of a device, accessory or components regulated as a finished device. An import of a reservice device or an import of a reprocess device. If you'd like to continue to read the list I'm going to move this slide to the next page. This continues the list of import scenarios with the applicable intended use codes and Affirmation of Compliance. I would like to make one note while you are reviewing the chart

on the screen currently which is talking about the intended use codes that this information is required at the time but it does not necessarily mean that you won't need to submit documents to FDA or further information at time of imports.

All right mandatory entities for submitted a medical device entry are the manufacturer, shipper, FDA importer, device initial importer in a delivered to party. It's important to note that the device initial importer was previously used outside of ACE as an Affirmation of Compliance. And hopefully everybody is aware that with the onset of ACE the device for initial importer is now a mandatory entity.

The filer or broker's point of contact is an optional entity that highly encouraged. This is because the filer is the one submitting the entry or the one that's tracking the entry. And you know where the entry is located in route you know the entry number. If you don't provide us with your information and you only provide us with the importer's information when we call to ask if the entry's available for a field exam, where it's located we're not going to get the same level of certainty as well as the same level of understanding the data requirements and the information that's needed and the location of the goods. So if there was an optional data element that should be input really the filer broker's point of contact information is very much encouraged. It will help prevent delays.

Additionally the DUNS number and SDI number are optional but also very highly encouraged data elements and they help us connect the firm that you are trying to transmit to make sure we have accurate firm information. Common reasons for medical device entry processing delays the required Affirmation of Compliance codes are not transmitted or they're incomplete or

they're inaccurate. The firm name does not match the Affirmation of Compliance.

The device initial importer entity is inaccurate or incomplete. The product code is incorrect. The country code is a US and transmitting UNK. On this slide we've provided resources to help you. There's a page on [fda.gov](http://fda.gov) for medical devices as well as examples of accessories of medical devices. There's device advice as well as CDRA to learn. Please make note of the device registration database which will be very helpful to filers, the pre-market approval database and the product classification database. Additionally the last link is who must register, list and pay the fee.

All right, I'm going to continue the conversation into tobacco. Submitting tobacco entries in ACE. The FDA regulates all tobacco products including hookah, electronic cigarettes, dissolvables and smokeless tobacco cigarettes or cigars, roll your own tobacco, pipe tobacco and future tobacco products that meet the statutory definition of a tobacco products.

Additionally the components and parts of these products regulated are regulated but not their accessories. It's important to know that intended use codes are conditional for tobacco imports and that the Affirmation of Compliance codes are optional. Please see the supplement guide for all intended use codes and Affirmation of Compliance codes. As with all commodities discussed optional data is encouraged as it helps expedite review of compliant trade.

Radiation emitting products. Submitting radiation emitting device entries in ACE once again we're going to start by talking about knowing the products being imported. Examples of radiation emitting products are diagnostic x-ray systems, (unintelligible) x-rays systems, microwaves ovens, laser products,

sunlamp products, high intensity discharge lamps and electronic ultrasonic therapy products. I do want to make one note that you can have radiation emitting products that are also medical devices. And these cases you want to make sure you submit all the elements required for radiation emitting products as well as all the data elements required for medical device products.

Sorry, okay. Commodity characteristic description is mandatory for radiation emitting products. And I did want to make note of this so that everybody knows. Additionally unlike many of the other commodities the trade name, brand name, quantity and packaging are also mandatory if the 2877 is required. And the PGA line value is optional but highly encouraged. The 2877 that's previously been filled out via paper form. The Affirmation of Compliance codes are all connected to that form. So if you are checking a box on the 2877 that information can now be electronically input into ACE as an Affirmation of Compliance code. For example if you would have marked RA5 on the 2877 you should be submitting RA5 as an Affirmation of Compliance code in ACE. By not submitting the information with the 2877 electronically in ACE you will cause delays. At this point I will be turning the presentation over to Jessica to discuss animal drugs and devices.

Jessica Armanda: Thank you Brigitte. So following the same format as all of the products and the requirements for importation animal drugs and devices it is critical to know the product being imported and the reason it's being imported and to also know what information is required so when you go to transmit your entry submit it to CDP and FDA. There aren't any rejections and we're also going to provide you with some resources.

So whether it's an animal drug or an animal device is the first item that you need to - the first decision that you need to make. Animal drug products will require and intended use code as well as an Affirmation of Compliance in

most cases. If it's an animal device doesn't require and intended use code. And at this time it does not require Affirmations of Compliance. If you have questions about animal drug versus animal device or what type of product code should be used, what type of affirmations are required you can reach out to ACE support or FDA import inquires in order to obtain information on how to correctly file these products.

Brigitte Strelnik: All right I'm going - this is Brigitte and I'm going to discuss information and resources for all FDA regulated products as well as I'm going to summarize what you've heard here to help you make decisions going forward as well as provide you with more resources available to you. Delays occur when inaccurate information such as incorrect product codes are submitted. Intended use code qualifier UNK will cause delays as your entry will go to manual review and it's information will be requested.

All information provided should be complete and accurate. Provide conditional data elements if applicable to your product being declared or your entry could be delayed. Produce optional data elements such as FEI and/or DUNS in quantity and unit of measure when known. We would like to stress the use of the supplemental guide. Start at the beginning of the appropriate section in the supplemental guide and go through that section of the supplemental guide when you are transmitting an entry. For example if you're submitting a biologics entry go to the biologic section and go through and utilize the charts that are available to you. The charts provided in this presentation came from the supplemental guide can be found there. And if you use those those will help provide you with the correct program codes, processing codes, intended use codes, Affirmation of Compliance so that you know all the data elements that you need to submit for the article that you are importing.

If you go through each of the PG records until all of the required information has been provided you will have all the information that you need to submit a complete and accurate entry. Each section identifies mandatory, optional, and conditional data elements, codes and code descriptions as well as the syntax for these codes and descriptions and data elements.

In summary know the product that's being imported and the associated requirements. Understand the data elements, provide correct and accurate information, give entry filers the information that they need as well as the entry filers need to obtain all necessary information from the importer. It's important to stress communication in this process because for many of the commodities the intended use code will drive your Affirmation of Compliance code and the intended use is going to need to be known.

FDA will not be able to process an entry without this information. You can help expedite FDA's review of your imported products by initially providing accurate and complete information and by responding quickly to requests for additional documents and information. I would like to take - go through some of the frequently asked questions that we get often enough that we felt you guys would benefit from hearing.

If I transmit an FDA entry does ACE allow me to correct the data if I realize I made a mistake? When CBP receives an entry it will automatically send the entry to FDA and to process in real-time if the entry is within five-days of arrival. Unless CBP or FDA rejected the entry no corrections can be made. If CBP or FDA did reject your entry work with your ABI representative to send a correction. This is very important information. There have been instances where the arrival date was put in as a typo. And instead of putting in June 29 of 2017 they put in June 29 of 2019. Therefore their entry was not sent to the

FDA because it wasn't within five-days. And at that point you could make a correction but you - because you're outside of that five-day window.

Once you're within the five-day window you cannot make a correction to your entry as they entry's been sent to FDA and we are not currently accepting corrections. This is the same process as ACF. When does FDA receive the entry data from CBP? I have had an FDA message for several days. This question is along the same lines. You have the five-day window. If you're outside the five-day window you can make corrections because FDA has not received your entry yet. If you're within the five-day window FDA has received your entry you cannot make corrections and at that point we can see the entry.

Now this is important to know when talking about when FDA receives your entry because when you transmit your entry you're going to get this data under PGA review message. This message is a message that's automatically populated when you transmitted an entry. So it does not actually mean that FDA is currently reviewing your entry. If you submit an entry ten days in advance you're going to get a message from CBP that says data under PGA.

The entry is not even sent to FDA for another five-days so FDA is not actually reviewing your entry. This is just a message from CBP letting you know that the entry's been received into their system. We will receive the entry within five-days of transmission. If it's within five-days of arrival and you've not received an FDA response within your usual turnaround time contact the FDA's ACE Help Desk at [acesupport.gov@fda.hhs.gov](mailto:acesupport.gov@fda.hhs.gov) and your CBP client - your client representative. It's important to make sure you contact ACE and the CBP client representative so that they can work together to help you figure out where your entry is and that everything's been transmitted correctly.

Is the drug registration number an FEI number? The drug registration number is the 9 digit DUNS number the firm (unintelligible) with the FDA Center for Drugs, Evaluation and Research and Drug Registration. Only those DUNS numbers on file with EDRLS are drug registration numbers. These can be found on the Drug Firm Registration Lookup page. The Web site has been provided for you and you can feel free to use this information.

Why can't I see the status of my entry in iText? Why does it say FDA Entry Status Information is not available pending receipt of conveyance or arrival notification when the shipment has arrived? CBP is not consistently sending arrival notifications to FDA upon arrival of a shipment. Without receipt of that notification iText will display the above message. This does not affect the filer's ability to submit documents, submit availability information or FDA's ability to review the entry or the entry documents submitted. FDA and CBP are currently working on the arrival notification issue and hopes to correct this message. But in the meantime you do need to be aware that if you receive the message FD entry status information is not available pending receipt of conveyance arrival notification that you can still submit your documents and you can still submit availability information as you should or you should expect to experience delays. CSMS message 16-001003 was sent out regarding this. And feel free to reference at CSMS message for further information.

We are frequently asked what are the lessons learned for how ACE changed filing for FDA. Communicate early and often about FDA requirements. This extends to the importer and a broker as well as sometimes the software vendor. Delays and rejects occur when inaccurate information's provided such as an invalid product code or unknown intended use code. Make sure you are using all resources available to you to prevent any inaccurate information being submitted that can be verified by other means.

Use FDA as a resource. Attend Webinars or request a training session. We are here to help. If you'd like to request a training session make sure you reach out to the ACE support email.

Is unknown still allowed as an intended use code? UNK is still allowed as an intended use code when intended use code is mandatory. If UNK is declared CBP will not reject the entry if the Affirmation of Compliance is not provided. FDA highly encourages the transmission of complete data including the correct intended use code and Affirmation of Compliances. Refer to FDA Supplemental Guide for a full list of requirements based on the import scenario. UNK should only be used if information is not able to be obtained. Utilizing this code may lead to a manual review and delayed processing by the FDA.

We've provided a chart for your FDA points of contact for imports. Make sure you use this chart. It'll tell you where is the best place to get an answer. So if you're having a technical issue related to the FDA's supplemental guide required data elements and general ACE submission questions including entry submissions rejected by FDA or request for ACE training and presentations you're going to want to reach out to the ACE support email.

If you have general questions regarding FDA import operations and policy including product classification, program, processing, product and HGS codes and declarations you're going to want to reach out to our FDA imports inquiry email.

First line support for product coding and entry specific questions including working through the FDA admissibility process, once the entry's successfully transmitted to FDA and accepted there's going to be your local FDA office.

And general questions regarding prior notice for food shipments should be referred to the prior notice email at the Division of Food Defense Targeting.

Additional resources are the TSMS messages provided. Multiple FDA lines are allowed on one tariff line. FDA A Centuries common errors and FDA ACE Reject document posted to FDA.gov. We've included the resources available online. Please see the FDA ACE information of Compliance and Information of Compliance Quick Reference Guide the FDA ACE ITS Web page including FDA's supplemental guide, the FDA's ITDS DUNS Portal for your DUNS lookup, the Product Code Builder Tool and tutorial Web site are available. There's information about FDA's import program. And you can also find information about ACE quantity data instructions to help you input your quantity correctly.

Once again we have the FDA Imports Inquiry Team available to help. And lastly the ACE support is available to help. They answer your technical questions related to the FDA Supplemental Guide, your required data elements, ACE entries, rejects and errors as well as if you have presentations that you would like done in your area. At this time I would like to turn the call back over to Gary who will open it up for questions and answers.

Gary Norris: Thank you. And I'd also like to thank all of the speakers, Jessica, Lorraine and Brigitte for that very informative presentation. We're running a little bit behind and so hopefully we'll - our colleagues will bear with us. We'll try to take as many questions as possible and may run over a little bit but hopefully we'll - we won't lose any of our callers. So I'll go ahead and ask the operator to open the lines and give instructions to our callers who have questions. Just a reminder to callers if you do have questions, please speak clearly, provide your name and your organization when you have a question. Operator?

Coordinator: Thank you. We will now begin the question and answer session. If you would like to ask a question please press Star 1, unmute your phone and record your name clearly. Your name is required to introduce your question. If you need to withdraw your question press Star 2. Again to ask a question please Press Star 1. It will take a few moments for the questions to come through. Please stand by. The first question comes from (Gus). Go ahead. Your line is open.

(Gus): I was wondering the seminar would be emailed to the community because we're unable to open the link to view the slides.

Gary Norris: I'm sorry could you repeat the question? This is the moderator...

(Gus): Yes the link for the MyMeeting Seminar was we were not able to connect. So I was wondering if that presentation would be emailed to everybody...

Gary Norris: Okay, I'm sorry to hear that. The slides - this is Gary the moderator -the slides will be available probably a couple of days from now. Tthe presentation will actually be downloadable so that you - everyone should be able get the recording of the call. So that will be available in the near future.

(Gus): Okay prefect. Thank you so much.

Gary Norris: You're welcome.

Coordinator: Our next question comes from (Lee Cosby). Go ahead your line is open.

(Lee Cosby): Hello. I was actually going to ask the same question. And he said it's going to be downloadable. Is that going to be from CPB's Web site or is that something you're going to send out?

Gary Norris: This s Gary the moderator again. So it will be at the FDA Web site. And I will actually send out an email message to all the callers, the participants to let them know when it is available.

(Lee Cosby): If I was not able to see that do you have my email address? I think I got it from higher management so is there a way for you to send it directly to me or you're to send it out to whom the initial message came out to and then we'll go from there?

Gary Norris: Yes or you can - can you give me your email address and we'll make sure we'll send it to you as well?

(Lee Cosby): Yes. That's lcosby like Larry, Cat, Oscar, Sam, Boy, Y @ups.gov.

Gary Norris: Okay thank you.

(Lee Cosby): Thank you.

Gary Norris: We'll get that out to you as well.

(Lee Cosby): Thank you.

Coordinator: Our next question comes from (Nancy Pello). Go ahead. Your line is open.

(Nancy Pello): Hi. I also was going to ask the same question as (Gus). But I had a second question concerning LED lightening strips. We use these in our manufacturing process for exhaust fans and rain charts for the lighting. And we've had a lot of the FDA requests for the Form 2877. And we are curious if we can get some kind of binding ruling or something that would allow us to get

permission without every entry getting caught with this FDA tag in our form trade zone operation.

Brigitte Strelnik: Hi. This is Brigitte Strelnik. I'll take a chance at that here. I did want to make you aware since you are dealing with a lot of the LED products that on June 6 2017 CSMS Message 17-000330 light-emitting diode reporting to FDA was issued where is discussed which - discusses LED transmission to the FDA. And as far as your question regarding binding ruling I do not know that there will be any binding rulings necessary in the near future. But the guidance on submitting LED products to FDA has been issued under the CSMS Message. And at some time in the future we will get out some work items regarding LEDs.

(Nancy Pello): Okay thank you Brigitte.

Brigitte Strelnik: You're welcome.

Coordinator: Our next question comes from (Alisha). Go ahead your line is open.

(Alisha): Yes I would like to ask for importing expired medications are coming back for destruction. What procedure to use? Do you need only registrations and things like that as far as FDA goes?

Brigitte Strelnik: Hi. This is Brigitte Strelnik. I'm going to take a stab at that one too. You have medications coming back for destruction only?

(Alisha): That's correct.

Brigitte Strelnik: And you're going to want to look at the intended use codes in the supplemental guide there. I thought there was one. I can't think of it off the top

of my head. Look at the chart in the intended use codes and see if you can find one applicable to your scenario. If you can't reach out to the FDA imports inquiry and we'll see if we can help you find the applicable intended use code that you should be using.

(Alisha): Okay thank you.

Brigitte Strelnik: You're welcome.

Coordinator: Again as a reminder please press Star 1 on your phone. Your next question is from (Curtis T.). Go ahead. Your line is open.

(Curtis T.): Thank you. This involves actually entries involving seafood which we haven't really covered today. But in particular the screening tool known as PREDICT how often is that PREDICT algorithm updated and is it updated with every current violation that FDA finds in the field during its course of operations?

Brigitte Strelnik: This is Brigitte Strelnik. I'm going to take that one too. The PREDICT tool is being updated routinely. I don't know that I'd reach out to say daily. I'd have to contact our IT people that work on the PREDICT team to know that. But it is done pretty routinely so and we are looking the PREDICT tool does go down to the firm level, the Product 2 level, the area level. So it's looking for multiple data elements on multiple different levels. But it is being updated to reflect the good field exams with the bad field exam and the good information with the bad information as well as how often things are looked at. So that is something that is updated an on a routine basis.

If you feel you're having an issue with some type of PREDICT screening there is a PREDICT email address. And I was trying to see if I could find it real quick. Reach out to the FDA imports inquiry and they'll get you that

PREDICT email address where you can reach out to. And the FDA imports inquiry might be able to help you as well. If you are having any kind of trouble that you feel you're being - there's a certain entry that's been flagged or not been flagged or something you feel is inappropriate but technically their PREDICT tool is updated routinely and it is working pretty well.

(Curtis T.): Okay thank you.

Jessica Armanda: And this is Jessica. I just wanted to go back to the previous question and I apologize for the delay but I was looking up a bit more information. This is regarding the drug that you mentioned were coming in to be destroyed. If they're coming back as US goods returned we have an intended use code for that that is 920.000. There's also the intended use code if it's not (L tracks) classified 980.000. You can send your question in that scenario and the information to ACE Support and we can help you determine if it falls under the US goods category.

Coordinator: Our next question is from (Michael). Go ahead. Your line is open. Hello (Michael)? Our next question comes from (Jacqueline). Go ahead. Your line is open.

(Jacqueline): Hi. Good afternoon. I have a question and actually Jessica, (Rand) and I have gone through this before. We have a foreign trades on our client that brings into a foreign trade zone. We do prior notice when it goes into the zone. It's withdrawn from the zone, moves in bond and goes into another port. At that other port we do a warehouse entry. And at the time we do a warehouse entry we need to do food and drugs. This is food stuff and liquor. And this cargo eventually is going to duty free shores so at some point it's withdrawn from the foreign trade zone as an IE. I think because it's a warehouse 21 food and

drug point that they were going to not require food and drug when it goes into the warehouse entry and I was wondering if any of that has changed?

Brigitte Strelnik: Hi. This is Brigitte Strelnik. Jessica's listening in as well. I wasn't previously in the conversation but you're going to a lot of different places in that one. So you're going to have to run that by me one more time and I'll see if I can get you a simple answer over the phone. But I suspect you're going to need a more in-depth review of your question.

(Jacqueline): Okay basically cargos imported into Miami is put into a foreign trade zone. At some given point the importer withdraws it from the foreign trade zone from transportation and moves on a 75-12 into another port. At that port it goes into a warehouse entry at 21. We submit the food and drugs for the liquor and the food stuff.

When it's being withdrawn from the foreign - or excuse me, when it's being withdrawn from the warehouse entry in that other port it's going to be withdrawn as an IE because it goes into a duty-free shop at the airport. So we're trying to figure out why we do Food & Drug prior notice when it gets to Miami before the importation and yet why we're doing food and drug on the warehouse entry. And I think at one point Food & Drug was going to relax the requirements on the warehouse entry and I was wondering if that was still in the pipeline?

Brigitte Strelnik: I am not aware that that has been relaxed and from my understanding it has not. What you can do is reach out to our FDA Imports inquiry with that and ask for foreign trade zone help. And you can even feel free to go ahead and CC me on the email and I'll reach out to some of our foreign trade zone experts as well as the ones talking warehouse and I'll see if there's any update

I can provide you on that. But from my understanding there's no change in your requirements to file and when you're required to file.

(Jacqueline): I think at one point Food & Drug was going to put an import for export as an intended use code on the Warehouse 21 entry.

Brigitte Strelnik: So what did you say the product was for this one?

(Jacqueline): Alcohol, chocolate...

((Crosstalk))

Brigitte Strelnik: So you're talking foods?

(Jacqueline): Yes food and alcohol.

Brigitte Strelnik: Okay. I would have to reach out and talk to not only DFTT as well as our foreign trade zone expert and our warehouse experts to make sure I get you the correct answer on that. So if you feel free to send it over to FDA Imports Inquiry with a - and let them know in the entry that this was a question brought up with Brigitte Strelnik on the ACE outreach we'll go ahead and try to get you an official answer on that but I don't want to misspeak and lead you down the wrong path.

(Jacqueline): Okay appreciate it. Thank you.

Brigitte Strelnik: You're welcome.

Coordinator: Our next question comes from (Michael Shackleford). Go ahead. Your line is open.

(Michael Shakleford): All right hi. My name is (Mike) and I - I'm a (Tuzi) operator. And I actually work with (Nancy Pello). We have the LED strips and a few of our entries we see they hold intact documents required for an 06 entries. And I was just wondering what documents are required exactly, the 2877 or do I have to submit invoice bill of lading -- that type of transport documents? And if - and I've also heard that it's a no performance standard RA2 affirmation code. And I'm not sure if I, you know, I'm just confused on what I need to send I guess.

Brigitte Strelnik: You want to make sure you do send in the 2877 but you also want to provide all - I'm sorry. This is Brigitte Strelnik answering again. You'll want to provide all entry documents that you typically provide for all entries including any kind of invoice or a bill of lading that you have -- anything of that nature, any documents that you have associated with the entry. And you want to make sure they have all the information that they need upfront when they're reviewing the entry.

So sometimes it's as simple as they want to do a field exam on an entry. And if you didn't provide quantity and value we have to insert quantity and value before we can set up the field exam. So sometimes things are as simple as we needed that optional data element and that's what we're after and sometimes they're looking for the 2877 because this is a radiation emitting product. In the case of if you're typically going through a local port of entry and they're requesting documents every single time reach out to that local port field staff and ask them why they are requesting documents every time. And they will talk to you and tell you what document is it that you need when you do this?

And they'll say oh we say that it's (sentry) and we're looking for quantity and value. If you input that up front we wouldn't even request documents. Or

they'll say we need to look at the 2877 for some reason in person. Granted, you should be providing that Affirmation of Compliance code electronically. But they'll let you know exactly what they need for your shipment. So questions about specific entries coming through a port of entry if you reach out to local field staff they will be able to help you and tell you why they're requesting documents.

(Michael Shakleford): And they did help me because it was - well four of our - four of my entries were held intact until I contacted Minnesota office and I spoke to a import director or what have you of the FDA. That is Center 2877 and everything went to a may proceed so that did help. Yes I think that answered my questions.

Brigitte Strelnik: Great. Thank you.

(Michael Shakleford): Thank you.

Coordinator: Our next question comes from (Colleen Miller). Go ahead. Your line's open.

(Colleen Miller): Hi. Yes. I was wondering if it's in the pipeline at all to begin working with carriers to notify them that a (sentry) is on hold due to FDA review or FDA hold or is it always going to relay upon the broker to make sure that the carrier doesn't somehow release the shipment to the trucker or the customer, the importer because it's FDA released?

(Elaine Barnes): This is (Elaine Barnes). Yes it is I'm afraid to tell you this but yes it is the broker's responsibility to let the carrier know. I'm not aware of anything in the pipeline to change that to be notifying the carrier.

Jessica Armanda: But this is Jessica. I don't know when you say pipeline if you mean like the ACE portal. This sounds like a question that you would want to ask CBP. They do send a one USG message which means every government agency that had jurisdiction over the shipment sent their release. And that message is, you know, a message for the carrier but whether the carriers have access to the portal and who's responsibility it is to communicate that that's a question for CBP.

(Colleen Miller): Thank you.

Coordinator: Our next question is from (John). Go ahead. Your line is open.

(John): Yes on the LEDs there was that letter from the FDA to the National Brokers Association and that said 2877s were not required for LEDs and no AOC was required either. So now I'm confused again. Thank you.

Brigitte Strelnik: This is Brigitte Strelnik. Give me one moment and I'm going to read you the guidance here. DA, I had the guidance in front of me, questions regarding. Are you looking at the CSMS message or are you looking at a different message?

(John): I'm referring to the letter the FDA sent to the National Brokers Association. And I'm also looking at a email I got back from (Denise Mackay) with the FDA confirming that no Affirmation compliance is required, no 2877.

Brigitte Strelnik: Okay give me one moment while we take the next question and I'll reach out and try to get an answer to your question because that'll be a quick one okay? All right.

Coordinator: We show no further questions at this time.

Jessica Armanda: Brigitte I think if they received instructions from the (Denise) who's the expert at CBRH and the letter then they should follow the instructions for that letter and...

Brigitte Strelnik: I just got my clarification, 2877 is not required. So if they're stopping you at the port for the earlier guide to look for 2877 they're - it's not required. And if you're submitting a 2877 Affirmation of Compliance when it's not required that may be why the entries are being stopped is they're confused to why you're supplying a 2877 Affirmation of Compliance for a product that does not require a 2877. So hopefully I cleared up my confusion there and hopefully answered an earlier question for our earlier caller. Did that answer your question if you're still on the line?

Gary Norris: I think they were disconnected.

Brigitte Strelnik: Okay.

Coordinator: We show no further questions at this time.

Gary Norris: Okay this is Gary Norris, the moderator. So we'll go ahead and do our closing remarks and I'll turn it over to Jessica.

Jessica Armanda: This is Jessica, just wanted to take a moment to thank everyone who joined the call today. Hopefully you found it helpful and informative. As Gary mentioned we will be sending out some communication as to where the content for this Webinar is available. If for some reason you aren't on the list or you're not getting any information and you want to make sure that you get the content you can always reach out to our help desk, [ace\\_support@fda.hhs.gov](mailto:ace_support@fda.hhs.gov). I know a couple people have already reached out to

request the information so you can reach out to that help desk if you want to ensure you get the email with the information. And you can always reach out to that help desk if you have any questions about FDA's ACE process or if you're getting any type of entry rejection.

Just want to reiterate if it is a real-time entry that you need assistance with please always email your client rep in conjunction with the FDA ACE support. There you'll get the quickest response. Sometimes it's a CBP and an FDA issue. If we're both on the email we can both resolve it as quickly as possible.

Today's call was recorded and according - recording of the call will be available on our Web site. It will probably take about two to three days. And we'll send out a message with the link when it's available. Again you can reach out to ACE support if you don't get that message. And at this time we're going to conclude the call. Thank you very much for joining us. Have a good afternoon.

Coordinator: That concludes today's conference. Thank you for participating. You may disconnect at this time.

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