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DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

"WHAT YOU NEED TO KNOW TO ENSURE COMPLIANCE WITH
THE NEW FDA BIOTERRORISM ACT REGISTRATION AND PRIOR
NOTICE INTERIM FINAL RULES"

Thursday, March 18, 2004

New Orleans, Louisiana

[TRANSCRIPT PREPARED FROM A TAPE RECORDING.]

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02N-0276

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P R O C E E D I N G S

MR. FRAZIER: I would like to introduce all the panelists up here this morning that will be responding to your questions.

On my far right, Mr. Mark Hackman. He's a compliance officer with FDA's Center for Veterinary Medicine; of course, Mr. Howard Hodes, here, with Customs and Border Protection; Bob Lake, again, from the Center for Food Safety and Applied Nutrition; and we have Mike Marley, here. Mike is with our Information Technology group for Import Operations; and, again, Mr. Ray Russo.

So if you have questions now, I would ask that you stand up--if you would, come up to the microphone there--regarding food registration and we'll take your questions and respond accordingly.

Questions on food registration.

I have one person coming.

I would also like to acknowledge that we do have local Louisiana State regulatory folks here, as well, and you might take an opportunity, for those of you who don't know them, to greet and

meet them as well. They will be your local contacts here.

Would you introduce yourself, and state your question, please.

MS. KOTCH: My name is Katherine Kotch. Is this thing on?

MR. FRAZIER: No, it's not. Could you--

MS. KOTCH: My name is Katherine Kotch. I work for Sazarak Company. I've asked this question once before.

My company has multiple trade names; way more than the form allows for on the internet. How am I supposed to handle that?

MR. : Yes, that's a good question. Yes, this has come up. I guess that's one thing I should have mentioned--can you hear me? Okay.

Yes, there's only a spot for four trade names on that. Again, I remember hearing from a bunch of alcoholic beverage companies, for example, that they had hundreds of trade names.

There's no way to put it into the system.

I think we've telling them just to put the top four that you can put in. There's just no way to do it.

MS. KOTCH: Yes, that's what I did.

MR. [PANELIST]: Yeah.

MS. KOTCH: Okay. So there's no form, or additional information that--

MR. [PANELIST]: Not at this time. We would have to modify that to add additional fields on that. It does allow a maximum of four at this time.

MS. KOTCH: Okay. Thank you.

MR. [PANELIST]: Just to clarify, though--I mean, you've done what you can do and what the system allows, so you should feel comfortable with that. We will be comfortable with it.

MR. [PANELIST]: I guess we can take that question back as a potential area for technology review as to expanding it, if necessary.

MR: : Well, there's also an issue on the paper form, too, because they would then have to modify that to add additional space to

do it, too. But, yes.

MR. FRAZIER: Other questions on the food registration system?

MS. ADAMSON: Hi. My name is Barbara Adamson. I'm with UPS Supply Chain Solutions, from Dallas, Texas. I've come here from Dallas.

MR. FRAZIER: Welcome.

MS. ADAMSON: Thanks. I have a few questions.

First of all, I know there's registration required for foreign producers for admissibility purposes, and I'm wondering if you can elaborate a little bit: what is the difference between registration for admissibility, versus prior notice. I think some of our clients have been a little confused about--you know, we ask for a prior notice registration number. They want to give us the admissibility registration number. And I think that's been an area of confusion from importers.

Do you want all my questions at once, or do you want me to--

MR. FRAZIER: Why don't we take them one

at a time.

MR: : Again, the prior notice requirement is separate from the registration requirement. But, as I indicated earlier, our way of enforcing the registration requirement with regard to imported foods is to, as part of prior notice, ask for the registration--the number for the manufacturer. So if the manufactured food comes to the U.S., prior notice is submitted, and there's a blank where it says, you know--requests the information for the registration for the manufacturer, then that would be a basis for refusing entry.

So--but that's--it's actually the registration requirement that I talked about that's being enforced. It's simply that the mechanism for doing that for the imported product is when the prior notice is being submitted.

Now, I guess the other thing--you use a term--you used the term "admissibility." That is actually a separate concept, at least in the way we at FDA look at these things. There's the

registration requirement, there's the prior notice requirement.

The issue of admissibility is broader than either of those. I mean, somebody can submit a prior notice that is complete, including with the information on the registration number for the foreign manufacturer, but if we decide that that's one of the foods that we want to test, to look at, and when we examine it--take a sample, take it back to the lab and find out it's got pathogens in it--then the admissibility determination will be it's not going to be admitted into the U.S. It will be, you know, rejected--but for a substantive reason, which has always been there.

So we have to remember--or everybody needs to remember--that all of the reasons for either letting something in or not letting any in, with regard to safety or other requirements out of the Food, Drug and Cosmetic Act, those exist, they're unchanged. This is another layer on top of that that's simply requiring that we get, for imported products, information about those products sooner

than we previously got it, as well as requiring some information that heretofore has not been required.

So, I hope that helps.

MS. ADAMSON: Was there a difference in format between the admissibility registration number and the prior notice number? Is one, like, 12 characters long and another is 10? Or--is there an easy way for a broker or an importer to understand the difference in registration number from admissibility to prior notice?

MR. [PANELIST]: I'm not sure if I understand. There is no registration number for admissibility, other than perhaps for canned food. You're taking about FCE numbers.

MS. ADAMSON: Right.

MR. [PANELIST]: Ahh.

MR. [PANELIST]: Okay. That's part of the [technical difficulty]--and that is something that we are, long range, are trying to unify those two systems.

MS. ADAMSON: Okay.

MR. [PANELIST]: Okay. One was a pre-existing requirement, and--

MS. ADAMSON: Yes, that's what I--

MR. [PANELIST]: It was specific to the processed food, and there you have a two-part number anyway. One is the facility registration, which at some point will probably get integrated into the master food registration system; and the other is a specific process--you know, this is the process for this size of canned peas.

MS. ADAMSON: Mm-hmm.

MR: : That will go away.

MS. ADAMSON: Right. Okay. Thanks.

MR: : Yes, and let me just elaborate on that a little bit, too. Okay? I didn't understand where you were going, either.

There has long been a requirement that low-end canned foods be registered because of the potential for botulism in those products if they're not processed properly--both domestic and foreign. And that's a requirement that's been there going back into the '70s. It still exists. It is--you

know, this again is something on top of that.

We do, ultimately, envision trying to join these registration systems together. But yes, for now, that's an existing requirement that remains in place.

MR. [PANELIST]: Yes, let me elaborate on that a little bit.

I mean, if you--because I've been talking with the CIFSAN people about, in fact, integrating LACF registration system with the general food registration system. And, in fact, if you go into the system and look, it has grayed back--that it's sort of coming the LACF component of it will be there. It's not there yet, but I think, you know, we're looking at a reasonably soon future to have that integrated so that the two systems will talk to one another, and the information can be shared and not have to be re-entered between the two. And it will be done through this system.

It's called--that's the reason the system is called FURLS--for "FDA Unified Registration and Listing System"--because the strategic intention is

to unify the registration and listing systems in that one way to go in.

MS. ADAMSON: Okay.

MR: : But thank you for your question.

MS. ADAMSON: Thank you. I have one more question, actually.

when we talked about the PIN number for the registration account, exactly what information would be shared, if somebody were to pass on their PIN number to another person, they could log in. What information would they be able to see? What is the purpose of sharing that data?

MR: : They would have full access to the registration--

MR: : Okay--quick question on that. Let me just add to that. Is this a view only? Or would this give them the capacity to augment, annotate, or whatever.

MR: : This is complete, equal access. If you share the PIN and registration number with someone, they can set up an account,

and they have full complete access to it.

So, if you don't want that, do not share that PIN with them.

MR: : And the other words of advice--words of wisdom--do not lose your PIN.

Other questions on food registration?

[No response.]

Okay, hopefully we've answered those fully for you.

You do have information. You have all the slides from the presentation for food registration and prior notice in your pamphlets that you picked up when you came in.

For food--we'll go into prior notice after the intermission. You can take your notes on those slides, and you can be prepared to ask us questions when we have a Q&A session for prior notice.

So, for right now, let's take about a 15 minute break. At that time, you can walk down to the Rampart Room, if you wish; stretch your legs. There's coffee and water outside here, and juice, as well. And we'll be back here promptly in about

15 minutes.

Thank you very much.

[Taping stopped; taping resumed.]

MS. POLLACK: --you have type ingredient but sometimes this particular item may not be used for a food.

I'm just trying to find out if on this tariff number, is there something in the PN system that allows you to either--to submit it, although maybe it doesn't require PN, or would the system reject it? Are there actually.

MR: : No, the only thing--when we get this worked out, the technical details, the only thing we're going to end up rejecting are the few FD-0s, where we've said in advance we don't want it.

MS. POLLACK: Okay. So you will, if someone wants to do PN just to cover themselves and be sure--

MR: : Right.

MS. POLLACK: --your system will accept it.

MR: : I mean, one of the things that came across my desk the other day--Customs brought it to us--was gaseous hydrogen--you know? It was being used to hydrogenate vegetable oils--

MS. POLLACK: Sure.

MR: : --now then it becomes a PN submission.

MS. POLLACK: In today's environment, right now, if someone would attempt to do PN on something that they think, that it--

MR: : You mean a totally unflagged [technical difficulty]--

MS. POLLACK: --PN or will you reject it?

MR: : I think you're probably still going to be in a reject mode right now.

MS. POLLACK: Okay. Do we have a timeframe on this?

MR. [PANELIST]: [inaudible].

MS. POLLACK: And the only reason I'm asking is we have several very large customers that are very insistent about this. And they want PN done, and we can't do it.

MR: : Umm--yeah. Until it's resolved, then you've got to just go the route of the submitting on the web.

MS. POLLACK: Okay. Okay, thank you. And I apologize. I'm Faith Pollack. I'm with Federal Express.

Thank you.

MR. FRAZIER: Okay.

All right. Okay--

MS. POSADES: I'm Ruth Posades of Mississippi. we are here to represent some of our dealers who cannot come, with regard to imports. We deal with seafood sanitation inspection for the state, but some of our dealers have imports, especially shrimp.

So I'm just going--some of this I don't quite really understand the depth, but I can see it's really a lot of work. I would like only to deal with the shrimp that they import.

You say that you have--they have to do prior notice. If they import these shrimp--some of them comes from Asia--different countries of Asia.

For every order that they have, they have to register the prior notice? Or can they do register ahead of time, or something like that? What do they do?

MR: : Let me speak to that.

What you're asking--let me see if I'm understanding your question correctly--is whether, for each import shipment they have to submit a prior notice?

MS. POSADES: Yes.

MR: : And the answer to that question is yes. Each time it comes in, even though it's a repetitious thing, the prior notice is required by statute to be submitted.

MR: : In addition to that could you address whether shrimp from Indonesia versus whatever [technical difficulty].

MR: : Well, again, for prior notice purposes, it doesn't matter where it comes from. I'm not sure I--

MR: : If there's one shipment with shrimp from two different growing areas, that

would be separate prior notice.

MR. [PANELIST]: Yes, each line item requires prior notice. Yes. All right.

MR. [PANELIST]: Each food product, not a category.

MR. [PANELIST]: Right. Right.

MR. [PANELIST]: There's been a question that's come up about when you have a shipment of mixed commodities, where you have some that--for example, I'll use your example of shrimp, but there are also, in that same container, may have non-FDA-regulated products.

Our advice is to try and separate those things in the future. It's just--it's going to make it a paperwork burden for the importer to put in prior notice for certain line items which are FDA-regulated, and then the products that are not following under the prior notice registration. You know, it's going to lead to a question of what else is in that container?

So if you can try and ship all food commodities in the same container, regardless if

they're from multi-countries, each line--as Mr. Lake has stated--requires prior notice.

The firms that are sending in the shrimp--each individual firm--is required to have their own registration.

MR. FRAZIER: Any more?

[No response.]

Okay.

PANELIST HODES: This is just going to lead into the enforcement phases of the Act. It was--as everybody knows, it was implemented on December 12th, and enforcement of the requirements of the BTA are going to be phased over an eight-month period. Unless a threat is identified and FDA, working in conjunction with us at the National Targeting Center, which Mr. Frazier alluded to, orders a hold on this merchandize, then enforcement actions are gong to be taken based on the following schedule.

Okay. Phase I has already passed. Just a few days ago, if you noticed a change in the weather, or whatever, it was because we went into

Phase II. I didn't even realize it, to be honest with you. But anyhow, March 13th through May 12th, no shipment would be stopped for administrative failures. So, in other words, you know, unless there was--once again, similar to the first phase, unless there was a hold for bioterrorism, shipments would not be stopped. However, penalties against violators who had been counseled--in other words, even though we weren't stopping anything, we were taking notice. And if there were a pattern of non-submission of prior notice, or whatever, and it's considered egregious--and most of the brokers here know what "egregious"--you know, the broker law is similar to that in the wording--you know this phase is basically to just sort of ease into the enforcement process.

Let's see. There we go.

[Slide.]

Phase III begins May 13th--about two months from now--through August 12th. And during that phase, failure to provide prior notice will result in refusal of the shipment and/or penalty.

This refusal results in merchandise being held at the port of arrival, sent to a secure facility, as determined by the CBP port director, or exported under CBP supervision.

Now, one thing I noticed in this presentation as it was sent out: it's saying "failure to provide prior notice." They don't say failure to provide "adequate" prior notice. And I think this is what differentiates Phase III from Phase IV. And if I'm wrong, correct me.

But if a refusal results in merchandise being held at the port of arrival, it will be sent to a secure facility. My understanding is--and correct me, once again, if I'm wrong--that if a shipment comes in during this phase, and there is no prior notice--okay--not inadequate prior notice, but no prior notice given, then it will result the shipment being refused.

Is that correct?

MR. [PANELIST]: Yes.

PANELIST HODES: Okay. So, am I making myself--does anybody have any questions about that?

Until August 12th, you know, you're required to submit prior notice, but if there is an inadequacy, once again, it will be tracked or whatever, but you will still receive your merchandise.

If there is no prior notice submitted during that period, then the refusal will result in merchandise being held at the port of arrival.

Okay.

Now, I don't want to get into definitions of secure facility or anything that--because that's going to come down later--unless somebody has a specific question that--in this regard. Okay. And we'll just go further and we'll get into the facility definitions and all that.

Okay. In Phase IV and thereafter, it is my understanding that this will be the full enforcement phase. Failure to provide prior notice will result in refusal of that shipment. That's it, pure and simple. If there's--you know, whether it's adequate or inadequate--in other words--well, if it's adequate prior notice, obviously, it's not going to be refused.

But any prior notice that's not provided, or inadequate prior notice, will be refused. And it will be an FDA determination that prior notice data is either incomplete or inadequate, and it will also result in the refusal of the merchandise.

[Slide.]

Okay. All right. I think a lot of this is stuff that we've already gone over in previous sessions, but there is a memorandum of understanding between FDA and CBP that in the absence of FDA performing prior notice-initiated examinations and/or sampling, we will--Customs officers, or CBP officers--I keep making that mistake--are commissioned to do these examinations. And there's a 24/7 800 number that's going to assist both the trade and CBP, and that's the number three. And obviously you don't have to write it down because you have this information.

In New Orleans, there is core-hour coverage, I understand, of the port, which is 8:00 to 4:30, I believe. All that means is that during the normal working hours of the New Orleans port,

there will be somebody made available from FDA to do examinations that are required. However, after those hours, if necessary--and if we can't get an FDA person in there, then we will be commissioned--provided it's not a bioterrorism thing. In those cases, all that Customs and Border Protection is going to do is to put it aside and wait for the--isolate it according to our hazmat procedures, and call in the FDA on those.

Let's see.

[Slide.]

Okay--submitting prior notice. We've gone over that--via ABI, ACS, or through the prior notice system interface--FDA's OASIS system, right?

[Slide.]

Question? Yes?

MS. : Regarding the two systems that you just mentioned, could you just share, maybe, one or two details regarding the WP application? Number one, is the WP functional and working today? Successfully?

PANELIST HODES: Umm--

MS. : Or is it still--

MR. [PANELIST]: I don't believe it is.

MR. [PANELIST]: We've gotten about
30--last I spoke to John Ogliori, who's the CBP
client rep--

MR. [PANELIST]: Yeah, we should have--

MR. [PANELIST]: --there are about 34
filers who have successfully done WPs.

The biggest problem we've been having with
the WP filers is they're not giving us
the--essentially, the IRS number, even though
they're giving us the clear text. And [technical
difficulty] takes that IRS number. We don't
get--we get it scrambled. We get encrypted IRS
number.

And without that IRS number--without that
encrypted number, we can't process the shipment.

MS. : Furthermore, on the WPs,
the need for the IRS or the EIN number has been
removed from foreign-to-foreign shipments--is that
correct?

PANELIST HODES: You're talking for--

MS. : T&E's.

PANELIST HODES: I believe so.

MS. : Okay. And one other question, specific to the in-bonds, the in-transits or the T&Es: is there anything in the WP system that would prevent, as far as the Customs' identifier number, could you use the house or the master airway bill, or do you have to use the T&E in-bond number? Or a different type Customs' entry number.

MR. : I believe the house and airway bill number is one of the identifiers.

MR. [PANELIST]: Right. It is [technical difficulty]--is coming up.

MS. : Okay. I'll just wait.

PANELIST HODES: I think we're going to come to that. So--

MS. : Okay. Thank you.

PANELIST HODES: If it's not answered through these next few slides, we'll--

MR. FRAZIER: It looks like you have somebody else.

PANELIST HODES: Okay.

MS. JOHN: Hi. I'm Lauresa John, and I'm with Sazarak.

MR: : Yes.

MS. JOHN: We're the importer of record. My brokers do my prior notices.

MR: : Okay.

MS. JOHN: You were talking about penalties if they had been canceled, or--basically, my question is, as the importer of record, is there some way I know there's going to be a problem if my broker doesn't volunteer it? I mean, if you're counseling them, or the prior notice hasn't been filed, would we be notified? Because we're not directly doing the prior notice.

PANELIST HODES: If you're the importer of record, unless your broker is listed as the importer of record, you're the--it's under your bond, right?

MS. JOHN: Right.

PANELIST HODES: So, you know, your broker will be notified of a refusal. As far as the

penalties--you know, there isn't a firm penalty situation set up yet. We already have established liquidated damages type things for, you know, missing information and that kind of thing, but I know of no penalty situation.

But your question is, if your broker doesn't give you the information--

MS. JOHN: Would I know?

PANELIST HODES: I'd get a new broker.

[Laughs.]

MS. JOHN: No. Well, you know, most of my brokers are great, but some of them--

PANELIST HODES: There's actually nothing we could do in that situation, other than--in other words, that's something between you and your broker. They should be providing you with that information. But if you call us and you need to know what the situation is, if you're the importer of record, we can provide you with that information. Just because you have a broker doesn't mean you have to use the broker for all situations.

MS. JOHN: Right. I mean, I guess that was basically my question. As importer of record, is there some way I would be notified if there was a problem? And I think the answer is "no."

MR. [PANELIST]: The problem is the importer of record isn't a liable party for prior notices. It's the submitter, who often is the same person--

PANELIST HODES: Right.

MR. [PANELIST]: It's the submitter, under prior notice, is the person who has provided the information for prior notice--

MR. [PANELIST]: And that's the importer, in 99 percent--

MR. [PANELIST]: --which is typically the importer, but can be the overseas--you know. It depends on how the business arrangement is set up.

PANELIST HODES: Right.

MR. [PANELIST]: I mean, I'm just thinking, if I were a foreign shipper, and especially with the concerns on the registration, I may choose to--I know there are some foreign firms

they're going via the web, and they're just going, "Broker, here's the confirmation number you're going to put on this line item." You know, that way, they don't have to give their registration number out, because once they hand it to a third party, you know--yes, it shouldn't go any further, but they may have concerns about that.

MS. JOHN: Okay. Thank you.

MR. FRAZIER: I hope that answers your question.

MR: : Just a point of clarification--and I want to jump in here. I saw Bob moving there when you were asking about failure to provide prior notice.

That is a prohibited act. And FDA can take an action against--

MR. [PANELIST]: Okay. But I think they were talking about Customs, what--

PANELIST HODES: Oh, I'm sorry. And, of course, we would have--All right.

[Slide.]

Submitting prior notice--okay, once again,

we've gone over this. CBP's ASC to FDA's OASIS system has been enhanced to support the prior notice. The software changes were required to support prior notice information. The ABI software changes--I'm assuming all of you are working with your client rep and your software people to get this all done.

The new ABI/ACS OASIS interface, known as WP, modeled after the existing process, is available to submit prior notice for entering the United States as an automated in-bond.

[Slide.]

Prior notice information supplied along with the ABI entry data--80 percent of the entries are, you know--are going to be processed that way, according to our projections. FDA provides the prior notice confirmation number electronically to CBP, and CBP advises the filer.

Prior notice results are matched to the ABI entry, and then electronically provided to the CBP officer for release.

Submitting prior notice via ACS--no entry,

which is, once again, known as WP. The electronic information through ACS--no consumption entry information; required information is: in-bond number, complete airway bill, master airway bill, bill of lading number--and we're working on a bar coding on the FDA prior notice form.

So does that answer the question about the--

MS. POLLACK: I guess my specific question is: do you need all those data elements, or can you use the house airway bill, or the master airway bill, in lieu of the in-bond number--

PANELIST HODES: Right.

MS. POLLACK: --for the Customs--

PANELIST HODES: That's my understanding. In other words, any one of those numbers can be used for tracking. You don't have--

MR. [PANELIST]: The bill of lading has to be a complete bill of lading, with the SCAT code on the front of it.

MS. POLLACK: Okay. Okay. Thank you.

MR. [PANELIST]: Because otherwise it's

not a unique number.

MS. POLLACK: Right. Absolutely. Thanks.

PANELIST HODES: And I'm sure that FedEx is probably going to use the airway bill number. Is that--that's what you intend to do, I would assume?

MS. POLLACK: [Off mike.] Well, we're--[inaudible]--because we have different type of transactions.

PANELIST HODES: Well, just let us know.
[Laughs.]

Ahh, let's see.

[Slide.]

Any transaction involving human or animal food subject to prior notice requirements can be input through FDA, the prior notice system interface--PNSI. Non automated and/or paper entries--mail, foreign trade zone admissions, in-bonds--unable to be filed through ACS/ABI.

[Slide.]

Submitting prior notice via FDA Prior Notice System Interface: the filer submits the

prior notice information via the system interface and receives a confirmation number, which the filer then adds to the paper entry submissions. CBP officers will need to query the new database file for PN results, and we might require you, for release, a paper copy of the prior notice--if requested by us.

[Slide.]

Let's see--and once, again, that's the web site.

[Slide.]

Submitting prior notice--alternative methods. How to submit a prior notice when the PN system interface is unavailable--which it was about a few days ago, huh? You use the alternative methods listed below to submit prior notice. However these are to be determined--FAX number to be determined.

[Laughter.]

MR. [PANELIST]: Well, what happened, I think, when the system was unavailable, I think it was Monday afternoon, I think it was. If it's

going to be down for more than two hours, I think it is--which is the smallest lead time for the prior notice, right?--the "System Unavailable" message will then supply the fax number by which you can fax it in. Otherwise, you know, we get it fixed [inaudible].

PANELIST HODES: Because somebody mentioned it to me, but we had--

MR. [PANELIST]: Well, we just--we don't want people faxing stuff in unless they have to.

PANELIST HODES: Right. That makes sense.

Merchandise with inadequate or no prior notice is subject to refusal. At the CBP port director's discretion, in consultation with FDA, and based on availability of storage and resources, merchandise subject to refusal may be held at the port. For seaports, airports and courier hubs, the terminal facility of the arriving carrier is considered to be within the port of arrival, and may be directed to a secure facility, under bond, or exported.

[Slide.]

The status of merchandise with no prior notice--the legal status is considered to be "GO"--general order merchandise. If the carrier has a terminal facility, it will be held in constructive general order at the facility under final disposition--which would, of course, be either an entry, an export, or a sale for export only, or destruction.

So, in other words, if this merchandise is sold and it has no prior notice, it only can be sold for export. Does everybody understand that? It's the only sale that can take place. And it's got to be immediately exported on an IE, or destroyed. And, in any case, it will be under our--CBP--supervision.

[Slide.]

If there's no terminal facility available, the port director may send it to the nearest GO warehouse or suitable facility, which may be inside or outside the port limits.

That's more for a border situation. I think here we don't really have that type of

problem. But if anybody has a question about it--

The port director will make an operational decision if and when a GO number should be assigned to the shipment--okay. And we're going to attempt to not do that. That's my understanding--although we haven't had the situation occur.

[Slide.]

Procedures for movement of goods to a facility not within the port of arrival--I'll go over this quickly. The documentation that is required: it requires the appropriate CBP control documentation, either a 6043 [technical difficulty] transfer for movements within CBP limits; a CBP 7512 "Restricted In-Bond" for movements outside of port entities; and, of course, no documents are needed for movement of merchandise to a terminal facility of a carrier within the port of arrival.

Procedures for merchandise held in a secure facility. Once again, merchandise is held under GO procedures for each port. Perishable shipments, or where there's no suitable GO facility, it will be held under constructive GO, or

directed by the port director to a suitable facility, and will be destroyed or sold--once again--for export after three days' public notice.

The carrier will assume the cost of destruction and the storage costs would be between the carrier and the importer.

[Slide.]

The definition of a secure facility. I'm still not sure that I'm totally clear on this, but I'll try to be. What is a secure facility? A bonded facility designated by the CBP port director may include GO warehouses or other suitable facilities. Facilities must be registered with FDA--just like we discussed earlier.

Facilities may be outside the immediate vicinity of the port if suitable for the storage of food. They may not be--and this is important--may not be the importer's, owner's or consignee's facility. And the merchandise may be sent to a suitable facility in another port if no other options exist.

Merchandise under constructive GO will

stay at the carrier's facility until final disposition of the merchandise which, once again, is either make an entry or export it--sell it for export--or destroy it. If eventually sold--once again--it will be for export only--prior notice obviously not required--and shipped directly on an immediate-export out of the port in which it is being held.

[Slide.]

Okay. This is a registration issue here: which facilities must register? All facilities that hold food for consumption in the United States must be registered with the FDA. And this includes terminal facilities, container freight stations, bonded warehouses, CES--centralized examination stations--GO warehouses, and Customs-approved storage rooms.

MR. [PANELIST]: [Off mike.] Howard?

PANELIST HODES: Yes?

MR. : [Off mike.] Didn't they say earlier that a lot of those are just transiting and didn't have to be registered?

MR. [PANELIST]: They would have to be registered if they're going to hold things that are under refusal.

PANELIST HODES: Right.

MR. [PANELIST]: So, if the stuff is under refusal--yeah, if it's just--

PANELIST HODES: If it's just transferring the merchandise for--you know, to move it, that's different.

MR: : It depends what function they're going to do.

PANELIST HODES: Right.

MR: : But if they're going to be holding stuff that has been, you know, held for lack of prior notice, now they're a holding facility, and therefore they have to register.

MR. [PANELIST]: That's correct.

[Slide.]

PANELIST HODES: Procedures for export: the shipper or the importer or the carrier may decide to export with our concurrence. It should be under physical control and custody of CBP, and

may be documented using an IE.

[Slide.]

Procedures for abandoned goods. Foods that are abandoned, refused for no or inadequate prior notice, treated the same as if no prior notice, will be considered general order merchandise and will follow the normal GO guidelines.

[Slide.]

Procedures for segregation of BTA-refused foods. For foods that are refused under 801(m) that are comingled shipments, either within the same container or truck, where you have foods that have satisfied the prior notice, and not satisfied the prior notice, these goods may be segregated in accordance with local procedures, and in coordination with the facility and carrier, so that the satisfied goods may enter.

Food that is not satisfied is treated as refused, and subject to being held at the port, moved to the secure facility, or exported--like we just discussed. The carrier, in this case, must

bear all costs.

[Slide.]

These are all the entry types that are impacted, most of which we don't deal with. BRASS is a border program. I don't believe--does anybody here deal with BRASS?

[Slide.]

Permit ports: they now can run selectivity at these--as of December 12th.

[Slide.]

ABI, ACS, Customs form 3461--I know you all use that--[technical difficulty] requirements must be satisfied for merchandise to be released from CBP custody and entered into the commerce of the United States.

[Slide.]

In-bond filing trade requirements. Prior notice submission through ABI, or the PNSI, must include the in-bond number and the bill number if applicable. Prior notice must be submitted for IT in-bond shipments, however absent an identified threat, they will be allowed to travel to the port

of entry for satisfaction of prior notice.

So, that's a case where the port of arrival--it would be allowed to go to the port of entry to satisfy the prior notice, but it wouldn't go any further than that. And the entry must be made before.

MR. : Maybe I'm reading that wrong. I thought that if you're doing an IT, you still have to file that--prior notice has to be filed before it crosses the border.

PANELIST HODES: It has to be filed, but it doesn't have to be satisfied.

MR. : Satisfied. Okay.

PANELIST HODES: So, that's why a lot of this--you know, "adequate," "satis--"--you know, there's nuances here. So you've got to sort of consider that aspect of it.

[Slide.]

Prior notice requirements must be satisfied at the port of arrival for merchandise to be released from CBP custody, and have a transportation and export entry processed. This

will allow merchandise to be trans-shipped through the United States. So if it's only moving through the United States, and going to be exported out of the United States, then you do have to satisfy--actually satisfy--the prior notice requirement at the port of arrival. Is that clear to everybody? In other words, if the stuff is going to move through the country, but not offered for import in the United States--it's going to go to Canada or wherever--then you do have to satisfy the prior notice at the port of arrival.

Yes?

MS. POLLACK: [Off mike.] I had one question with regard to that.

PANELIST HODES: Okay.

MS. POLLACK: [Off mike.] At one point in time there were one or two ABI admin messages, they had a Q&A section on it. And within, there was a very specific question that gave an example of aircraft [inaudible] region which was destined actually to Seattle, but it made it's way--a preliminary stop in Anchorage, only to either

refuel or add domestic freight to it. Nothing is removed on the international side.

My question would be: what is the port of arrival for PN purposes, because the admin message said "Seattle, not Anchorage."

MR. [PANELIST]: I believe that's still the position.

PANELIST HODES: I would think the port of arrival would still be Seattle, but--

MS. POLLACK: [Off mike.] Port of arrival for PN purposes.

PANELIST HODES: Yes, it would have to be satisfied at Seattle, because you're saying that it's not entering the commerce of the United States, right? It's just being--goes to Anchorage; it makes a stop and--

MS. POLLACK: [Off mike.] Stop and either gas and go, or on-load domestic.

PANELIST HODES: Yes, that's what I would think, because there's no intent to import.

MS. POLLACK: [Off mike.] Just--could I--just to touch base on that a little further,

because that is a very, very critical, important question to air carriers. And if that could be further reviewed or included once again in a Q&A, we would appreciate it. Because there appears to be some significant conflicting answers to that.

PANELIST HODES: You're on my network, Faith, so why don't you send me an e-mail with the exact wording of your question.

MS. POLLACK: Okay.

PANELIST HODES: And I'll get a definitive response. And that's another thing: anybody here that isn't on my network--now this is not Food and Drug, although I can pass along Food and Drug stuff. But if you're on my network--or not on my network and want to get on it, just leave me your card, if it has an e-mail address on it, and I'll add you to it.

You might get some stuff that you don't want--about steel or something like that--but all you have to do is press the delete button in those cases. But I am sending a lot of this stuff out to the network, and it seems to be--I seem to be

getting a lot of positive feedback on that.

PANELIST LAKE: Let me just interject here: I think--what I'm hearing is this is a very important question, and also that you've gotten conflicting answers.

So what I think we need to commit to is to take this back and to be sure that [technical difficulty] and Customs and Border Protection look at this jointly, and be sure that we have a clear answer that we both are going to give, and it also sounds like something that probably should appear in a Q&A that, you know, is clear and made very public.

MS. POLLACK: [Off mike.] Okay. Thank you.

MR. [PANELIST]: I think this is similar to the policy--there were questions, I know, about--the freight left on board. You know, it's going up the east coast, and this one's eventually going to get off-loaded in Boston, but the first stop is down South--you know, what is the port of arrival? And I think the answer was: where it's

going to be off-loaded-- If that container is never leaving the ship.

MS. POLLACK: [Off mike.] That is [inaudible].

PANELIST LAKE: That's my understanding.

MR. [PANELIST]: Well, we did capture the question, and I concur with Bob in that there should be an FDA/CBP review of that so there's clarity for all of our investigators and agents--

PANELIST LAKE: We need to be sure that everybody--you know, that we all have the same understanding of both the question and the answer. And so we will commit to do that.

MS. POLLACK: [Off mike.] So--super. And what I'll do is [inaudible] that admin message, which seemed to make sense, and it was clear to us. So, I think there are still [inaudible]. Thank you.

PANELIST HODES: Let's see--where were we?
[Slide.]

In-bond--electronic or paper, includes an indicator of prior notice compliance. So that

will--

In-bond processing with prior notice indicator--the prior notice requirements: how to process. Automated in-bonds will query the ACS prior notice data base and return a status message to AMS/ABI.

[End Tape Side A.]

MR: : --power feeds to that room. There are a couple of generators. There's--supposedly uninterruptable power supplies and all that. It shouldn't have happened.

We did--I think anybody would look at it and say we did due diligence, but something bizarre happened there.

So we're going to see what that was. That just shouldn't have happened.

There's also been a couple of nagging bugs in the underlying software that's there. There's that famous "okay" error that some people may have run across, where we've been working with the vendor to get that sorted out. It's in the underlying software underneath, so it's not really

got to do with our application.

But we hope to have that part resolved. So--there were, again, some other things that had come up. It's a number of different things that have come up, and again, the system--at least the prior notice has only be running for three months.

I guess what I can assure you is that the servers and the basic infrastructure that's there is more than enough to support this. The things that have happened have been those out-of-left-field kinds of things that, you know, you try to avoid but something just happens.

We take it very seriously.

MS. : Yes, the bigger issue's been with the brokers that are trying to go in and, you know, put their prior notice data in and they're either told to come back later, come back Saturday--you know. And that's really impacting our business, I think.

But--can you add more servers? Or is there a way to--

MR. [PANELIST]: It really isn't a server

issue. I mean, again, you're going to have to take my word for it, but the servers that are there are-- there's--

MS. : It should be adequate.

MR. [PANELIST]: --a whole bunch of servers, and they're more than powerful enough to handle the hold. It's never been an issue, in terms of inadequacy of the servers. The things that have happened have been network-type issues, and electrical-type issues that bite almost anybody. I don't care if you're MicroSoft or whoever. These things unfortunately happen.

MS. : Okay.

MR. [PANELIST]: I don't expect that you will see anything other than reasonably reliable service as we get more and more into this, particularly as we get out of this enforcement discretion situation.

MS. : Okay.

I have another question. I think what I heard is that if a penalty is issued for inadequate or failure to provide prior notice, it's the

submitter that's going to be penalized? Is that what I understood? Or is that still up in the air a little bit? I'm not sure if it was finalized.

MR. [PANELIST]: It's going to go against whoever is the bonded party. So, in other words--but [technical difficulty] there hasn't been a penalty scenario yet that has been defined, other than what's existing currently within--I'm talking from a Customs standpoint.

MS. : Mm-hmm.

MR. [PANELIST]: As far as Food and Drug, whatever their penalty is, that's, you know, what's going to be enforced.

So--and I don't know what that is at this point. So how's that for an answer? [Laughs.]

[Laughter.]

MS. : Okay.

MR. [PANELIST]: We don't know at this point.

MS. : Okay.

MR. [PANELIST]: Because nothing has been--you know, nothing has been done so far, and

we haven't had a what we call FPNF situation here, where it's been defined yet.

MS. : Yeah.

MR. [PANELIST]: So it's still up in the air as far as I can tell you. You know, that's all I can say right now. There's nothing you can go to that's going to tell you what happens if you do this or you don't do this.

MS. : Okay.

MR. [PANELIST]: And Bob is writing now, but he's going to speak basically on the enforcement strategy for FDA right now--which is under development.

MS. : Okay.

PANELIST LAKE: Well, actually, just in response to this question, I'm going to make a note that that's another one that we perhaps need to take back and talk some more about.

I mean, what you're saying is right. I mean, we haven't actually--because we've been in enforcement discretion, the penalty situation has not come up. But what you're asking is, "Well,

what happens when it does come up? Who is going to get hit by the penalty?" And so we will take that back and have some discussion, and try to get some clarity around that as well.

MS. : Thank you.

I also understand that in the first phase there have been educational materials that have been given back to-- I think, it's the carriers, possibly filers.

We haven't seen any of that, and I'm wondering, has that been in place? Or are you actually sending out educational materials to brokers and carriers? We just haven't seen evidence of it in our company.

MR. [PANELIST]: As far as I know, the only thing we've done that I'm aware of is we provided CBP with the names of filers that are filing nothing; you know, that are basically, say, enjoying the free ride while it's here.

MS. : Mm-hmm. Will that be passed back to the filers at some point?

MR. [PANELIST]: I assume that's the

reason Customs wanted to do that was for their outreach--to find out why.

MS. : So there wasn't an invitation to this meeting, huh--for the egregious violators? [Laughs.] Okay.

If anybody else has questions, I'll let somebody else--

[Laughter.]

MR. [PANELIST]: Well, thank you. While everyone else is trying to get their questions together here--and we do encourage you to ask questions now, because what we would like to do is, you know, capture those questions, start working on those now as you are notified of the comment period, as well.

This is a learning and a very--if I could say it--a very strategic process that we're going through now. We are in an enforcement discretion mode, because there are technical difficulties we have to work through to get everything up and running. We have to make sure, through these outreaches, that we're getting the information out

there; we're explaining the process, we're listening to you, bringing the information back in and making the process a little bit better for all concerned.

So we are, you know, soliciting all the questions you have now, and there's no such thing as a silly question. We'll take all the questions we can to make sure that what we do is consistent to the intent of the regulations out there.

so I encourage you to take you--you know [technical difficulty]--if you would, you know, mention your questions. If not, you can do that later.

A couple of things I want to follow up while you think about that is: right now the requirement--the interim final rule--it is a requirement to file prior notice, and of course we want the information submitted that is adequate to supply the needs of that.

Howard indicated that right now we are in an enforcement discretion mode. He gave you the specific dates on which we would kind of--if you

will--move into different phases of enforcement. And I invite you to pay attention to that, because as we run through the process--and Mike indicated that we are--FDA is basically capturing information on those filers or importers that are not following the prior notice requirement. And that information is going to Customs in this particular time as an outreach effort to notify them of everything else.

But Howard also indicated that for those who are egregious in their neglect of filing prior notice, there will be penalties once the strategy has been fully enforced out there.

So I just bring that to your attention.

Again, I would like to remind you: on the confirmation process, if you're submitting through ABI/ACS, that confirmation will come back through that system, through Customs CBP, back to the submitter. If you're going PNSI--which is the web-based FDA system--that information and confirmation will come directly back to you, and you can utilize it as necessary.

Other questions?

MS. WILLIAMS: My name is Joanne Williams, and I'm with Liner Services in Gulfport. And I have a question on the website. After we get our confirmation, let's say a day later we need to make changes or corrections to it, you had mentioned that we just needed to update. But I was wondering if there will be special instructions on how to do this, where we can--what particular items need to be updated?

MR. [PANELIST]: I think the update went away when we shortened the timeframes on reporting. Essentially, if certain items change, we're saying you don't have to tell us, because, I mean, I think we ask for estimated total quantity. So if the quantity changes somewhat--but if the manufacturer changes, therefore, the fact of the registration you gave us is invalid and everything else, really that's a cancel and resubmit.

MS. WILIAMS: So we'd just cancel and resubmit.

MR. [PANELIST]: I believe there is a "memorize" function in there. So you could take

the previous prior notice, pull it up, and now edit it. I mean, it's functionally, I guess, the equivalent of an update. But technically, it's a cancelling you're early prior notice and submitting a new prior notice, and you'll get a new confirmation number. So it's not really an update, per se. It's a replacement.

[Pause.]

MS. ROYSTER: Good afternoon. I'm Priscilla Royster with the Irwin Brown Company. I'd like to revisit about the containers. We clear for an entire vessel that is an AMS carrier. Do we still have to list all of those container numbers?

MR. [PANELIST]: [Off mike.] [inaudible]

MS. ROYSTER: Are they interfaced through the AMS system?

MR. [PANELIST]: These are all food containers?

MS. ROYSTER: Yes, sir.

MR. [PANELIST]: They're all going on--they're all going on a single in-bond movement?

MS. ROYSTER: No, sir. They're all on a

consumption entry, and it's a vessel of food products.

MR. [PANELIST]: I would have to say you--in other words, for what reasons are you--in other words you're going to submit your prior notice by product--[technical difficulty] category code and harmonized number.

What is the thing with the containers--

MS. ROYSTER: Well, we can have upwards of 200 container numbers. Should we file all 200 container numbers? Or as that interfaced through the AMS--

MR. [PANELIST]: [Off mike.] One shipment--

MR. [PANELIST]: Are the containers all--

MR. [PANELIST]: --one product, one manufacturer--

MR. [PANELIST]: --are the containers all coming from one facility?

MS. : No, sir, they're different product codes and different FDA--

MR. [PANELIST]: Each product code--

MR. [PANELIST]: Right.

MR. [PANELIST]: --requires a separate prior notice. So you would have the container numbers that pertain to that.

MS. : Okay--even upwards of a hundred container numbers?

MR. [PANELIST]: I am not sure--

MR. [PANELIST]: Well, no, no. I think--

MS. : Because we do reference it according to bill of lading numbers, which also would connect with those container numbers.

MR. [PANELIST]: Yes--[technical difficulty]--the answer is I think, yes. At least the way you've described the question, you've got a number of different containers. They don't all contain the same thing. And the prior notice system is tied to what are the line items of food that are coming into the U.S.

So that's the key. And you may have actually even more line items of food than you have containers.

And, yes, that is a lot of stuff, but that

is the way the law was structured.

MS. : Thank you.

MR. FRAZIER: Other questions?

[Pause.]

One more question, please.

MR. [PANELIST]: Well, while they're thinking about questions, let me note that in the documents I referred to that are about to publish, particularly the joint plan from FDA and Customs and Border Protection, we are also, in that, asking questions. So we are looking for some further input from the affected community, as well--specific questions that have not heretofore been answered, that we would like further input on.

So, in addition to commenting--having the opportunity to comment on things that are already in the interim final rules, we are asking some additional questions. So that's another reason to pay some attention to that, and we would like your input on that, as well.

MR. FRAZIER: Okay. Just as a reminder, all the presentations that you were able to see

today are in your packages. And, also, the contact numbers, the websites--all that information are in your packages.

If you wish to--we'll be around for a few minutes after this outreach session here for individual questions. But, of course, we would like to have everyone benefit from any question and answer that we have now. So we ask you--you know, if you have questions now, to do that. But we will be around for a few minutes afterwards, if you would like to come up with other questions or just comments related to the process.

And there may be, in your package, too, a comment page, if you have comments about the outreach session; how we can do this a little bit better in the future. If you want to make those comments, as well, please do so. You can leave a written response at the table outside, or you can just mention it to one of us, as well.

MR. [PANELIST]: Yes, but let me--just a cautionary note on that. If you have real comments that you want FDA and CBP to consider officially,

they really do need to be submitted to the dockets for both of these, as in the past. I think the primary value for--you know, after we're done here, would be if you have other questions that you have thought about that, you know, you forgot to ask or maybe you wanted to approach one of us directly on a particular question--that's fine. And you can make your comments, too. But those comments are not going to go in the record. And so if you want comments to go in the record so that there will be a response at some point, then you need to submit those comments to the docket.

MR. : Just a quick question. In PNSI system, is there an area there for questions or comments on technical issues related to the process? I don't recall seeing anything there?

MR. [PANELIST]: Do you mean the answers to--

MR. : No, basically, if you're going through--

MR. [PANELIST]: [inaudible]

MR. : Yes, if you're going

through the process and you have questions about, you know, "What's this?" Is there a drop-down--

MR. [PANELIST]: You mean like the "Help," or--

MR. [PANELIST]: Yeah, help.

MR. [PANELIST]: Yeah.

MR. [PANELIST]: Yeah. We did mention that there was Help Desk available from 7:00 a.m. to 11:00 p.m. for questions on the system. But there are on-line for help in the directions in getting through the process, as we..

MR. [PANELIST]: Yes. Registration and prior notice.

MR. [PANELIST]: For both systems.

MR. [PANELIST]: [Off mike.] It's for help, but it's not for asking us questions related to the interim final rule.

MR. [PANELIST]: I think what Mr. Russo just stated is that there's "Help" functions on how to get through the system, but there's not--and correct me if I'm wrong, Ray--there's not a place to ask questions, as if they were supposed to be

submitted to a docket.

MR. [PANELIST]: No, you're right.

MR. FRAZIER: Well, hearing no questions, I would like to, again, thank you for participating in the outreach session, and encourage you to be on notice for the Federal Register notice that's coming out shortly in those three areas that Mr. Lake mentioned that you can provide comments to.

And, for the official record, you have to respond to the Federal Register notice, to the docket number associated with that Federal Register announcement.

So, unless I hear any more questions--again, I thank you. Enjoy the weather here. And if we can be of help, please let us know. thank you very much.

[Applause.]

[Session concluded.]

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