

cac

1

T4640

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"

Tuesday, March 9, 2004

El Paso, Texas

[TRANSCRIPT PREPARED FROM A TAPE RECORDING.]

02N-0276

MILLER REPORTING CO., INC.
735 8th STREET, S.E.
WASHINGTON, D.C. 20003-2802
(202) 546-6666

TR 10

AGENCY REPRESENTATIVES

FDA

O.D. Evans
Deputy Regional Food and Drug Director
Southwest Region
Office of Regulatory Affairs

Mary J. Ayling
Lead Inspections/Compliance
Food Safety and Security Staff
Center for Food Safety and Applied Nutrition

Elaine Johanson, Director
Office of Information Technology
Office of the Chief Information Officer
FDA

Questions and Answers Panel:

Kim Young
Supervisory Consumer Safety Officer
Office of Surveillance Compliance
Center for Veterinary Medicine

Kelle Fry
Division of Import Operations and Policy
Office of Regulatory Affairs

CBP

Howard Duchan
Bureau of Customs and Border Protection
Department of Homeland Security

P R O C E E D I N G S

MR. EVANS: I just wanted to ask you, if you do have questions, to go to the mike. I believe that they're trying to capture some of the questions and answers for future use.

So, if you have questions, go to the mike, and the panel will try their very best to address it.

Ms. AYLING: You have to ask us questions before you get your break.

[Laughter.]

So if you have any, we encourage you to ask them now, before we let you loose.

MR. : [Off mike.] I have a question on the registration. Are we--

MR. EVANS: Can I get you to go to the mike, please?

Ms. AYLING: It's in the middle.

MR. : [Off mike.] Sorry.

Can you hear me? Yes.

The question that I have is, should we provide this registration number to our customers?

Are we obliged to give this number? Or should it be handled confidential?

Ms. AYLING: Well, the statute itself says that the agency cannot disclose registration information. So even though we are required by the statute to maintain a list of who's registered, and their registration numbers, we're specifically prohibited from us disclosing it. But you're not prohibited from disclosing it.

And I think this is another thing that we have quite a few questions and answers about that, because some people--some facilities have not wanted to divulge their registration itself. Others have tried to come up with a way that they can confirm that they've registered but without revealing the registration number itself.

What Elaine was going to print off, but didn't--that could be used as proof of registration if you blacked out the number; if you didn't want to reveal the number.

The one thing that we do discourage is putting your registration number on a label--

something like that--that anyone could reproduce or pretend they were you. But it's not against the regulation, nor can we prohibit anyone else from disclosing their registration number.

MS. JOHANSON: I'd like to add that that printout has both your registration and your PIN number on it. Anyone who has the registration and PIN number can go in a system and alter your information.

MS. AYLING: So, even though you could use that of proof of registration, it would be a really good idea to not include your PIN--you know, to black it out or something like that. I know it's been a challenge for a lot of firms because they've been asked--you know, "I won't do business with you unless you can prove that you're registered. Give me your registration number." And the challenge is how to prove registration without providing that number and, Lord knows, you wouldn't want to provide the pin.

MS. FRY: Yes, the PIN you should keep.

MR. : The other question is

about if we have a need to change the emergency names and phones, should we go back to the WEB page and update it? Or there's another--

MS. FRY: Yes, you should go to the WEB site, if you entered electronically--even if you didn't, I would definitely go back in and make the changes under "Update."

MR: : Thank you.

MR. : If I have a facility and I'm approved, and I'm purchasing a product to come in, and I don't know if he is approved or not, where does that leave my product?

MS. FRY: If you're importing a food product and you don't know if the foreign facility is registered--

MR. : It doesn't--does it have to be foreign? It could be within here, also.

MS. FRY: Well, I think when it's going to be most noticeable--that would be the right term--the most noticeable if it's the scenario where you're a domestic importer and you're importing food manufactured by a foreign facility.

If the food comes into the U.S. and the prior notice--which we'll discuss after the break--doesn't include the registration number of the manufacturer of that food, it will have failed to provide us adequate prior notice and the food could be held until that's corrected.

So, the bottom line is when you import a food you need to assure that the facility that manufactured that food is registered.

MR. : Okay. On the foreign. But can that not happen locally?

MS. FRY: It could happen domestically where you're trading with somebody and they aren't registered. That isn't going to be your problem. It would be their problem; that the food--you know, that they're not registered.

MR. : Okay.

MS. FRY: Does that make sense? I mean, it is very different from import to domestic, because on import you're bringing the food in, so it is your problem. Domestically, from what I've understood most people have asked--it's been part

of purchase agreements that the facility be registered. But that's something that's more associated--

MR. : So that's something that the facility should ask--okay--if they're registered or not.

MS. FRY: Right.

MR. : Because if they're not in compliance and I produce a product--okay?--and it comes back through my chain, it has to be pointed back to that particular facility. Okay. Thank you.

MS. FRY: Kim has something to add.

MR. YOUNG: Right--a couple of items on that. The registration is not an approval. We have other regulations that will go to inspect, to see that the firm is following GMPs or whatever. So it's not an approval per se, it's just that you're registering your facility with the FDA.

Another aspect is the registration: you are not--we're not requiring you to police the industry; in other words, asking you to confirm

that the business that you're doing--working with is registered. No, it's not required that you ask that--for the registration number. I mean, you can do business with a firm and not ask for that number at all.

MR. : Okay. Thank you.

[Pause.]

MS. AYLING: It's a long walk, isn't it?

[Laughter.]

MS. AYLING: But we can see ya comin'.

MR. : Hi. I have a bit of a unique situation. We're manufacturers of medical devices. We were not required to register through you guys because we don't have any food items.

MR. YOUNG: Correct.

MR. : However, we do manufacture some gowns and drapes in the Dominican Republic that we pack out in Juarez--our facility here, across the border.

We do use one of the classifications that is under the HTS guidelines for FDA, which is a 9801 U.S. Goods Return.

Now, right now, our product is being certified, but way are getting, through ABI--this is electronically--we are getting a notification that says "prior disclosure"--well, I have it right here--it says, "prior disclosure not submitted."

How are we going to address that issue?

MS. FRY: After the break.

MR. : [Laughs.]

[Laughter.]

MS. FRY: We'll ask for--I would ask you to ask that again after the break when we talk about prior notice--

MR: : Okay.

MS. FRY: --because--

MR. : You're going to make me go through this again, huh?

[Laughter.]

MS. FRY: It's just a hint to sit closer to the mike next--

MR. : Great.

MS. FRY: That is something that we have been working on with prior notice on the harmonized

Tariff Code Classifications, or flags. And you've picked one that's probably--if you could describe something as kind of the biggest conglomeration or mess--

MR. : Right.

MS. FRY: --in the tariff codes, it's the U.S. Goods Return, because it includes everything from airline parts to Q-tips to food. So--

MR. : Okay.

MS. FRY: --we'll take care of you after the break.

MR. : Great.

MS. FRY: Which means you have to come back--right?

[Laughter.]

MR. : I'll sit closer.

MS. FRY: Okay.

[Pause.]

MR. : Hi.

MS. FRY: Hello.

MR. : I work at the Santa Teresa Livestock Border Crossing, and I was wondering

where is livestock in this? How--because we cross the cattle live up there, so how is this whole process going to work there?

MR. YOUNG: Now, with the live cattle, which does come under the FDA, the cattle is coming from farms. So the farms do not have to register. So there's no registration required.

MR. : No registration required.

MR. YOUNG: No registration required.

Now, when we get into the prior notice aspect--because you will have to fill out prior notice.

MR. : Who's going to do the prior notice? The farmer? The broker? The facility?

MS. FRY: Anyone.

MR. YOUNG: Anyone can do it, just as long as it does get accomplished.

Now, there's person that's coming up, I guess has some other add-on question to it.

MR. : I'm sorry--it's about the same thing.

Are we going to be able to transmit a prior notice without our registration number, being that the farmers are exempt?

MR. YOUNG: Yes. There is--I don't know, do we have an example of that later on?--

MS. FRY: I sure hope you do.

MR. YOUNG: --that would go through--

MR. : Okay--through ABI. I'm mean, through ABI. I saw that one of the requirements on the ABI screen is the registration number. Are we going to be able to transmit the prior notice without a--

MS. FRY: I guess you're going to have to stay until after the break, too.

[Laughter.]

MR. YOUNG: in other words, we'll explain that in the prior notice aspect.

MS. FRY: We'll talk about that in prior notice. Because, as you know, there are two different systems for prior notice, an they're both being perfected--if you could call it that--so that they will handle all of this.

So the main question for the registration part is: live animals are the product of a farm, and a farm doesn't have to register. It's exempt from registration. Okay?

MR. : Okay.

MS. FRY: So stick around.

Any other questions on registration?

[No response.]

MS. FRY: Okay--15 minute break.

MR. EVANS: Why don't we synchronize our watches--and where are we? About 10:20?

The registration location is going to be across the hall, in case some want to visit with her.

If we will take 15 and get back no later than 20 'til.

One other thing before we leave, I believe the Graduate School has informed me that some of the handouts did not make it in time to be on the table outside this morning. So when we conclude, if you would go back by the table, we think that they're coming in sometime after the break, and

they'll be there before we actually close. So there will be a couple of additional handouts for you to pick up. Thank you.

[Taping interrupted, and resumed].

MR. YOUNG: I think, at this point, we're ready for questions.

[Pause.]

Did you use up all your questions during registration? We covered everything you were concerned about--for prior notice--in the presentation? you guys know everything that needs to be known, right?

There we go.

MR. : I have a quick question on cancellation of prior notice through ABI system. Does that mean we also have to cancel the entry and submit a new entry?

MR. YOUNG: Yes.

MR. : Okay.

And, on the--you touched on the transfers from FTC to bonded warehouse, where the merchandise was in the FTC prior to December 2003. And I was a

little bit confused by your response to that.

Could you elaborate on that?

MR. YOUNG: We don't have a way, at this point in time to avoid the system saying that prior notice is required, because all the system sees is a warehouse entry. So you may have to file prior notice for the goods, even though they were there prior to the enactment of the law.

MR. : We--

MR. YOUNG: The issue's being looked at. I don't have a better answer than that for you.

MR: : The problem is that the ABI system keeps rejecting the entry, because there is no foreign manufacturer registration number.

MR. YOUNG: I don't have an answer for you. All I can tell you is that we're aware of the problem, and our computer people are working on it, and I just don't have a better answer than that at this point in time.

MS. FRY: Yes, this is a new issue to me. I hadn't heard this before, so this is something we're going to have to be working on together to

get an answer out to you guys.

MR. YOUNG: I don't know.

MR: : What we're proceeding to do right now is do a "non-ABI" entry. Would that be appropriate at this time?

MR. YOUNG: At this point in time that might be the only way to get around it--unless you want to file prior notice, which you say you can't.

MR. : We can't.

MR. YOUNG: Yeah.

MS. FRY: Are you talking about a straight warehouse entry?

MR. YOUNG: No, it's coming from a foreign trade zone. So it's already in the country. It was in there prior to the law taking effect, so there was no prior notice initially when it went into the zone.

MS. FRY: And so they can't just use the confirmation number they got when it went in?

MR. YOUNG: There is no confirmation number.

VOICE: [Off mike.] It went in before

December.

MS. FRY: Oh, before--I'm sorry.

MR. YOUNG: Right. Yeah, paper might be the only way until they fix--figure out something to get the system to adjust.

MR. : Thank you.

[Pause.]

MR. : Hi. I have a question about shipment by FedEx. Sometimes I have to send samples to a warehouse--it's already registered. But what happens I have to send samples to an office that is not a warehouse, and is not registered. Do I have to ask to my client to get a registration number for that?

MS. FRY: you're talking about--you're sending it to a U.S. firm?

MR. : No, I have a company in Mexico I have to send samples to warehouse, for example, here in the U.S. But what happens is I have to send samples from Mexico--food samples--to a specific office, but it's not a warehouse, or it's not registered. Do I have to ask that company

to please register with FDA?

MS. FRY: This is a registration question, not PN.

MR. YOUNG: Okay. You are sending--let me repeat what I think you're saying. you're in Mexico, you want to send a sample to someone in the United States.

MR. : Okay.

MR. YOUNG: Right. With that, you have the registration number of your company--

MR. : My company is already registered.

MR. YOUNG: Right. And then you have to do prior notice.

MR: : Yeah.

MR. YOUNG: Right. There's no registration number for the company in the United States that you need.

MR. : That's right. So what happen, I have to ask that company to get that one registration for that.

MR. YOUNG: No, it's basically, you're

giving them your registration number, as a foreign facility.

MR: : Yeah, but when I tried to do the prior notice by the system, the system asks me for that registration number for the importer.

MS. FRY: Okay. I misunderstood your explanation earlier. But if you're talking about you're transmitting prior notice to a firm in the U.S.--

MR. : Yes.

MS. FRY: --to a firm in the U.S.--

MR: : yes.

MS. FRY: --that's not registered.

MR. : Okay.

MS. FRY: That's not required as part of prior notice. You're required to give the registration number for the manufacturer and the shipper, not for the importer.

MR. YOUNG: No, that's not what--he's asking if the company receiving the sample needs to be registered--correct?

MR. : So I can--

MS. FRY: Well, now, as far as prior notice is concerned--no. I guess we have to distinguish: are you asking a registration question, or are you asking a prior notice question. Because in your transaction to send prior notice, that registration is not required.

MR. : Yes, but when I try to submit prior notice, the system asks me for that registration for the importer.

MS. FRY: Are you talking about PNSI?

MR. : Yes, when I try to do it by myself--

MS. FRY: If you're talking about the FDA WEB system--

MR. : Yes. That's right.

MS. FRY: It does allow you to put in the registration number of the importer, but that's as a shortcut so that you don't have to put all of the rest of the address information. It's not a requirement.

MR. : It's not required.

MS. FRY: No.

MR. : Okay. Thank you.

MR. YOUNG: If you have questions, Elaine has the system in the other room. We can go through it without and you can show us where you're having complications, or where you see that the system is confusing to you.

MR. : This is going back to livestock coming from Mexico. Are the farmers exempt from having to be registered?

MR. YOUNG: Yes, farmers are exempt from registration.

MR. : But we do have to give the PN prior.

MR. YOUNG: Correct. Correct. And the question before was: you had to put a registration in there. We can go next door and we can walk through and show how to--

MR. : You bypass that?

MR. YOUNG: --handle it. Right. Correct.

MR. : Okay. And how about the facility where those animals are going to cross from? Does that have to be registered, or is that

also exempt? Because they do cross on foot from Mexico to the States.

[Pause.]

I'm not sure if you all are familiar with the way we import cattle from Mexico, but that's the way we do it here at Santa Teresa.

MR. YOUNG: Okay. So you said pedestrians--

MS. AYLING: [Off mike.] [inaudible] What was the question?

MR. : My question is, the facility, does that have to be registered; in other words the cattle arrive--

MS. AYLING: [Off mike.] The facility that the cattle arrive at?

MR. : Mm-hmm.

MS. AYLING: [Off mike.] And they're held there?

MR. : They're held there.

MS. FRY: What--is it a feed lot?

MR. : No.

MS. FRY: No?

[Laughter.]

MS. : [Off mike.] Because the feed lots were exempt--right?

MR. YOUNG: Correct. Feed lots are exempt.

MS. AYLING: [Off mike.] So--what would you call it?

MR. : In essence, it acts not as a feed lot, but it's just a rest area.

MR. : It's a rest area of 24 hour period. The cattle get there a day before; USDA checks them, and then the question is who receives the number, and when? You know, because they've--is USDA going to receive that number before they check them? Before they inspect them? Because, you know, we're--

MS. AYLING: [Off mike.]
[inaudible]--isn't going to worry about it. And I don't think you should either.

I think it's one of those things that [inaudible] figure out a way to fit it in. And, you know, we've talking about transport vehicles,

where there's a stopover overnight, and they don't have to register, because they aren't really storing the food. Because it's part of the regular transportation process.

Now, doesn't this sound familiar?

MR. : Yeah.

MR. YOUNG: So, in other words, it falls into the--

MS. AYLING: [Off mike.] [inaudible] if it's part of the regular transportation process is that they stopped off for the night. Okay?

MR. YOUNG: That's--

MS. AYLING: [Off mike.] So I don't see any point in registering a facility like that.

MR. : Okay. As a broker--

MS. AYLING: [Off mike.] Now, if you feed them, then you've got a restaurant or a--

MR. : Right. Right.

MR. YOUNG: And you do not have to register.

MR. : No, we don't process anything. It just gets across.

As a broker, I had a situation back in December where, when I was trying to submit, it was telling me that I had to have clearance from another government agency--in this case, which would have been FDA--and I kind of ran into situations with Customs there, which we were able to--they were able to help us out by physically inputting the information through their system.

I'm wondering if that's going to occur again, or is this going to--

MS. AYLING: [Off mike.] Well, we were talking registration. But you still need prior notice. So that's what they would have been talking about.

MR. : Okay. Then we'll talk about that.

MR. YOUNG: Right. you need prior notice. Correct.

MR. : So, basically, no registration. Okay.

MR. YOUNG: Correct.

MR. : Prior notice, who's going

to get it? You?

MS. FRY: Can I just give a little more information on that. You had talked about having them go look at the WEB system, but as far as entries coming in over ABI, you have the ability to, one, say that the manufacturer isn't required to register. you also have the ability to say that someone is a grower.

And I don't have the data transmission layout here with me, but you have the ability to say that registration is not required. And if you don't have a copy of that, you can get it from CBP.

MR. : Are we going to be able to transmit prior notice without a registration number?

MS. FRY: I'm sorry, I didn't hear the question.

MR: : Okay. Are we going to be able to transmit the prior notice without a registration number?

MS. FRY: If the firm is exempt, or if the firm is a grower who is not required to register.

MR. : Okay. So there's going to be an indicator?

MS. FRY: That's what I'm saying. There already is a whole record layout that you should be able to get from CBP that gives you the affirmation of compliance code that you can transmit. And there's also an indicator for a grower that can be transmitted.

MR. : Thank you.

[Comments off mike.]

MR. : [Off mike.] Is there a pull-down [inaudible]?

MS. FRY: Each filer has their own software, and, you know, I can't tell you how the opportunity to transmit that data is provided to them by their software vendor. But they do know what the data requirements are, and they should be able to transmit that information.

MR. : [Off mike.] So it may be a [inaudible].

MR. YOUNG: It could be, but we haven't had any reports that it has been.

MR. EVANS: No, I don't think that it is. I think it's in the basic filing of your information. And, again, I'm not a computer person, but I believe there's a place for you to say that the registration number isn't required. I believe there's a box--"because it meets one of the following definitions," that says it's either a grower or a farmer, or whatever it is. So you would mark that appropriate box, and then the registration would not be a mandatory field, so you wouldn't have to fill it in.

MS. FRY: Yes, let's we don't want to get too caught up on boxes and that kind of thing, but there is a record layout, and there is a particular record that says you can transmit an affirmation of compliance code; the affirmation of compliance code is this three digit code; and that allows you to say that no registration is required.

All of that record layout information is available from CBP. If you have any questions, I'd suggest you talk to your ABI client.

MR. : I've got one last

question. Regarding USDA, now--which, of course--I just wanted to know--they were also requiring for us to give them that prior notification. Is that--

MR. : That's my worry, you know, because they've got to inspect that cattle. And if they don't got that number, they're going to hold that cattle in the dry pens, with no water and no feed. Like last time, they were there for five hours with no water and no feed.

I just want to clear that up before we do anything else.

MR. YOUNG: Which part of the USDA? Was it APHIS, or was it--

MR. : APHIS--yes, sir.

MR. YOUNG: APHIS is under ours, so they were probably looking for--it's the same as Customs looking for it.

MR. : Exactly.

MR. YOUNG: Okay. Why they're doing that in addition to the submission, I don't know.

MR. : But they will have a role in this whole--involvement?

MR. YOUNG: Well, if they have access to the system, it should show that you filed it.

MR. : They don't have access.

MR. : They don't have access there, you know.

MR. : In other words, USDA sits on the Mexican side where they inspect the cattle. And it's normally--we're looking for it before it comes--

MR. YOUNG: I tell you what--I don't want to belabor this. I'll give you my card. Give me a call, and we'll figure it out and we'll make sure it doesn't happen.

MR. : Good deal.

MR. YOUNG: Okay?

MR. : Thank you.

[Pause.]

MS. FRY: Howie, would you say that other reports like that should come to you, as well? Because right now, unless FDA has put a hold on a shipment, there shouldn't be shipments held because there's no confirmation number.

MR. DUCHAN: Yeah, I hate volunteering for that, but if you guys have--if you have problems with the system, I have my card here you're all welcome to take, because I've got plenty of them. Just send me an e-mail, or pick up the phone and call and let us know what the issue is, and we'll send it to the right people so that we can address it and hopefully fix it.

[Pause.]

MR. YOUNG: Any other questions?

[No response.]

MS. FRY: I have a couple that were handed to me, so I'll try to cover a couple of these. I think we've answered a couple of them.

"Farms are exempt but local filers seem to be having problems getting PN without registering the farm first. Can this be addressed?" I think we already covered that--that if there is no manufacturer; if the product is in its natural state and there's no manufacturer, they're not required to transmit a registration for a manufacturer. And if the grower is known, but not

required to register, they also don't need to transmit a registration number. And there should be nothing in the system that's causing a problem with the entry transmission. So if you have specific examples of that, I suggest you talk to your ABI client rep, because you shouldn't be having problems right now.

[Pause.]

Another one is: "Filer broker transmits data for PN and sometime later, two hours, gets the PN authorization number." First, I'll say if it takes two hours to get your PN confirmation number there's something severely wrong with the system. You should be getting them in about 15 minutes. So let us know if that actually happens.

I guess the question basically is, when does PN--when does the time clock start? And I think we've covered it in a couple of discussions. And the clock does start as soon as FDA sends out the PN confirmation number.

[Pause.]

I don't know if you can answer this, Mary,

but there's a question about Help Desk availability?

MS. AYLING: [Off mike.] What is the question?

MS. FRY: Do you want to elaborate?

MR. : [Off mike.]

[inaudible]--having trouble getting through to the Help Desk, or they'll be hold for an extended period of time. [inaudible] frustration [inaudible]?

MS. AYLING: Actually, what we did was we kind of--whatever the opposite of expansion is. It was originally 24/7 with the Help Desk, and the Help Desk is now business day. I think--Howie, you had it up there. I think it's 7:00 a.m. to 11:00 p.m. on business days; so that's Monday through Friday, except for holidays. So that's when the Help Desk is working.

The other think people can do is e-mail.

What we'd like to kind of differentiate with the Help Desk should be questions that people have about an on-going situation like, you know,

the system's slow, or I can't get this information in. Questions that have to do with clarification of "Do I have to register," or "Do I have to give prior notice during this time"--those are probably better e-mailed to the FERLS e-mail address that we had up there, that we can address those questions more generically.

Other than that, I'm not really sure about the Help Desk. Umm--well, there you are. I was going to say, "We can find Elaine."

MS. JOHANSON: I've been here.

The Help Desk--the reduction in hours at this time is a result of costs. The less paper that we get, the more money we have for Help Desk. So if you--that's our issue right now.

There's a great deal of information on the WEB site. I believe that many of your questions can be answered there. And e-mail is always available. Many, many people who aren't even on the Help Desk, including myself, have access to that e-mail. And when things start getting--there's a lot of messages, we start

handling them, as well.

Sometimes with e-mail you can get a much quicker response, actually. So that's what I would recommend is to go through e-mail when you can. Look at the WEB site. It's extremely expensive to run the Help Desk in the paper process. It's very inexpensive to run the electronic process.

And so, again, the more people use electronic, the better service we can have, via the phone line.

MR. YOUNG: But the help desk is from 7:00 a.m. to 11:00 p.m. Eastern Time.

MS. : [Off mike.] Are you going to change the time frame for prior notice?

MR. DUCHAN: I'm glad you asked that.

Customs and FDA are working closely together to try to bring the prior notice time frames as close as humanly possible to the Trade Act time frames.

So there will be some movement done. I don't know when it will show up, and I don't know what the final results will be. But we are working

on it.

MS. : [Off mike.] [inaudible]
actually enforce the whole [inaudible]?

MR. DUCHAN: I don't know when. I mean,
we may go into enforcing it before the time frames
change. We will probably not do that until
after--if the time frames change, it probably
wouldn't happen before the fall.

MS. : [Off mike.] We surely have
problems with air schedules where we don't get the
documentation until the airplane arrives.

MR. DUCHAN: I understand the difference
between wheels-up and the four hours, but at this
point in time that's what we have to follow.

MS. AYLING: Even with wheels-up, you'll
still have to have that information before the
plane arrives--right?--

MR. DUCHAN: Right.

MS. AYLING: --on advance manifest rule.

MR. DUCHAN: That's why it's prior notice.

MS. : [Off mike.] Sometimes
they're all--surprise, surprise. We have an air

shipment--and the airline calls, and we don't even know it.

MS. AYLING: Right. I hate to say this, but the whole purpose of the Bioterrorism Act was kind of to do away with those surprises. Some more unfortunate than others.

But that's why Customs has the electronic--I always call it "the advance manifest rule, but that's really not what it's called. It's the Advance Electronic Information Submission--or something like that.

And what Howard was talking about earlier, about a plan that FDA and Customs are working on, that is a plan so that we can, as much as possible, associate those time frames.

MR. DUCHAN: Correct.

MS. AYLING: And the plan is to say how we're going to go about trying to do it, but I don't think you'll see reduced time frames or changed time frames, I think would be the better term by FDA until you see a final rule. Because we can't make that kind of change to the interim final

rule that we issued without issuing either another interim final rule, or issuing the final rule itself.

So the plan will be out there for comments sometime this month. What is this, the 8th, 9th? So sometime before the end of the month, and you'll have 30 days to comment on our plan, on how we're going to do this.

[Pause.]

MS. FRY: Any more questions?

MR. DUCHAN: There's one other point that I'd like to clarify. You don't really run into it on the southern border, but you do on the northern border, and that's if you have goods that come in by ferry, it's treated the same time frames as though it were on a truck, because the truck is on the ferry. So it would have to meet the same time frames as a truck.

VOICE: [Off mike.] If the truck is on the ferry.

MR. DUCHAN: If the truck is on the ferry; or the passenger, or the cart, or whatever it is.

VOICE: [Off mike.] [inaudible]

MR. DUCHAN: Yeah, I don't see a ferry coming across the Rio Grande.

Any other questions?

[No response.]

MR. EVANS: Well, I guess that's the close.

I want to express our appreciation for you attending, and I also want to apologize for my going over a bit. And I didn't look down at the watch and I took away from some of Howard's time. And so we'll need to work on that a little bit for next time.

But, again, we certainly appreciate your attendance, and hope that you see the benefit in it.

Thank you so much.

[Session concluded.]

- - -