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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"

Q&A SESSION

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P R O C E E D I N G S

MS. FRASER: I'll take your question next.

In terms of confidentiality of registration information, we get a number of questions from people about--"can I share my registration number." The Bioterrorism Act says that the FDA cannot disclose to members of the public whether a facility is registered, or any of the information used to generate the registration list.

So, generally, under the Freedom of Information Act, you, as public citizens, or anyone, can submit inquiries to the government to get access to records. And, generally, that information is disclosable unless it falls within a certain exemption like privacy, trade secrets or a statutory exemption.

Here, there is a statutory exemption that precludes us from telling you--anyone--registration information.

That being said--and what we say to people is: you should treat your registration as you would

your driver's license number, your credit card number, your social security number. There are instances where you will have to disclose it to people with whom you are doing business. For example if you are a foreign facility and you want to import food, or you're someone here and you want to import food from a foreign facility, it's part of the prior notice requirement that Dennis will talk about--the registration number of a manufactured food product is required on the prior notice. So those facilities will have to tell someone who is filing the prior notice for that imported food their registration number. And we encourage them to do that, under the same way that you would disclose any other information about your business that you consider to be something that people should safeguard between themselves, much like you would share your social security if you're applying to a bank loan or something else.

So, there's a distinction between what we can share and what you will want to share or need to share as part of doing business.

Somebody had a question--

MR. BAKER: Yes, sir?

MR. : [Off mike.] Yes, on page 21, "Household goods" [inaudible] manufacturers outside the U.S., how then can individuals submit a prior notice without knowing the registration of the manufacturer?

MS. FRASER: Yes, if we can hold the prior notice questions, I think we will cover that when Dennis goes through it. But as a private individual, the requirements for prior notice are different from what you would have to do as a business with respect to that to some extent, but it is--prior notice is still required.

MR. : [Off mike.] [inaudible]

MS. FRASER: It the food is going to be consumed by anyone in the U.S.--yes. so there are some times that trade samples are either brought in or made in-house--made domestically, and they're test marketed, or they're even given to employees to sample and: "do you like this," "do you not?"

"Consumption" is by one or more. And so

it depends on what you're doing with the samples. But to the extent they're consumed, then registration is required.

MR. : [Off mike.]

MS. : [Off mike.] [inaudible]

MR. : I have two questions. The first one deals with warehousing--public warehouses. We use a considerable number of public warehouses to store our goods. Is requesting the number for registration from the public warehouses something that we should do and hold on file?

MS. FRASER: I think that--if you're using public warehouses, then you have an independent duty as the operator in charge to make sure that your portion of the warehouse is registered. so the first thing I would do is to ask the owner of the warehouse if--you know, whoever you entered into that contract with--have they registered the warehouse? If they say yes, then that would be an instance to ask them for a copy for your records. If they say, "No, we don't know anything about it. We're just here--"--then I would say you should

register your space separately, and then you would have that confirmation of registration back as part of your own records.

MR. : Okay. And the second question is about the registration.

We actually filed a paper form in December. And we have not gotten anything back yet. Do we need to get the number back before we can get on-line and make up dates and do that kind of thing? Or is the on-line registration process--do we get an account number, and then we can go in and do the updates? Do you follow what I'm asking?

MS. FRASER: Yes. I believe that you said that you sent in an application?

MR. : A paper form in December, correct.

MS. FRASER: [inaudible]-it's taken about--

MS. FRASER: There's two parts to your question. I think, in terms of--your facility may not be registered with us yet because it's still in

the queue to be processed. But even if it is--even it you're gotten your registration number back, if you want to now go on line and access either that registration, or modify it, or put in new registrations, the first step you will have to do, regardless, is set up an account.

MR. : Correct.

MS. FRASER: Same thing with prior notice.

MR. : I guess that's my question. Can I go in and set up an account--

MS. FRASER: Yes.

MR. : --without knowing that registration number?

MS. FRASER: Yes. They're two separate steps.

MR. : Okay.

MS. FRASER: Now, the one thing you may want to do, if you're tired of waiting for us--

MR. : [Laughs.]

MS. FRASER: --which--our apologies--but, you know, there's so much staff we have to process these.

MR. : I never get tired of waiting from the government.

MS. FRASER: No--I know. You still can register that facility.

MR. : We can online.

MS. FRASER: Yes, you can register it online--and then send us--just send us an e-mail to the help desk saying that you had processed the-

MR. : It's a duplicate registration.

MS. FRASER: Right.

MR. : Okay.

MS. FRASER: If you happen to get a new registration back because the right hand and the left hand don't quite connect like we'd like them to all the time--and we try--then I'd say go in and cancel the second one when you get that one back.

MR. : Okay. Excellent. Thank you.

MR. BAKER: Other questions? We don't want to deter you from asking a question by having you come up to the mic, but we do need to record

this.

No other questions?

[No response.]

We'll have the panel here after our next session, so if you think of something in the interim, registration or prior notice, when we get to the prior notice section, you can certainly ask those questions then.

So, with that, I guess we'll take about a 15-minute break. You can be back here at 10:30. We'll go from there.

Thanks.

[Taping stopped and resumed.]

MS. FRASER: --typical transportation process. The cargo's coming in. It's sitting there for some relatively short period of time waiting on the moving van to come and pick it up, then I would say you're more like holding goods in the usual course of business as a carrier. Registration would not be required.

If someone's moving it into storage because they're not going to get there for a month,

two months--whatever that other time period is--then you're more like a warehouse and you would have to register.

MS. : And so we'd have to register if we have more than one facility across the country?

MS. FRASER: You would--

MS. : We'd have to register each individual--

MS. FRASER: Correct. If you're more like a warehouse, then you would have to register each facility separately.

MS. : Okay.

Another question: if they have maybe a collection of 200 bottles of wine, for example, and they do not know the manufacturer, they don't have--or it was grown, etcetera--the information necessary for registration--will it be refused? Or what would be the process at that point?

MS. FRASER: Umm--that's one of our biggest area of comment, and one that we are looking at for the final rule.

Currently, and through August 12th, it won't be refused.

MS. : Okay.

MS. FRASER: With respect to food that is purchased for an individual to send as a gift--and, presumably, an individual to send to themselves as a gift, you--the requirements for prior notice say that rather than require the registration number for each facility--of each manufactured product, they can look at the label and give us the name and the address that's on the label.

And so that would be an alternative means for personal shipments are goods that are purchased and then sent to an individual as a give. That's still--for your 200 bottles of wine might get you 200 prior notices with different addresses.

We are looking at personal shipments, generally, which would include household goods, and household goods returned, and other items. But, currently, prior notice would be required for those.

MS. : Okay. So we just have to

put in comments and, hopefully, that will be--

MS. FRASER: Yes.

MS. : --changed a little bit.

MS. FRASER: We're looking at it--yes.

MS. : Okay. Thank you.

MS. FRASER: Part of the--you know, part of the challenge we have is the way the Bioterrorism Act is written, it basically says--Congress was very broad, and it basically says that prior notice is required for all food imported or offered for import into the country.

There weren't--so when people--you kind of can see body reactions when you say "samples," and this. Well, you know, the language of the statute. And as an agency, we can't make up law. We have to operate within the boundaries of what Congress gives us. So some of our challenge is how can we reconcile some of these comments that people are saying, "Well, we shouldn't have prior notice for this," with the language of the statute.

So when you submit comments, the ones that are the most helpful to us are not only, "This is

sill and you need to change it," but "Here's how we think you have a means--"--or discretion under the statute, or legal authority, or something along those lines. Because that's where we have to go to be able to create an exemption.

MS. : Well, thank you very much. You've answered all my questions.

MR. : Hello. I have a question in regards to the FDA's country of production. I just want to clarify that it's equally a separate independent review and release, compared to the country of origin through customs.

MS. FRASER: They sometimes may be the same, but it's a separate definition.

MR. : So each agency has their independent review and release--

MR. BAKER: They need to provide both of them.

MR. : Okay.

MR. : I just wanted to clarify a couple of things.

On prior notices--are prior notices not

allowed to be given on foreign companies--for instance, that would make packaging components like bottles or something--if they're not registered? So, in other words they have to register, but are packaging components not required to give prior notice?

MS. FRASER: They're not required for either.

MR. : Oh, the foreign--

MS. FRASER: They're exempt--food contact substances, including packaging materials, are exempt from both registration and prior notice.

MR. : So, for instance, if you buy your bottles in Mexico, you're not required to have that facility registered then, right?

MS. FRASER: No.

MR. : Okay.

MS. FRASER: I made somebody happy today. [Laughs.]

MR. BAKER: But you are responsible for the quality of that product. So that hasn't changed.

MR. : I've got several questions. Do you want them all at once, or one at a time?

MS. FRASER: No, my memory chips are failing. [Laughs.]

MR. : Birdseed products, are they classified as livestock feed? Pet products? Or are they exempt?

[Multiple simultaneous comments.]

MR. : Animal food.

MR. HACKMAN: Birdseeds are considered animal food.

MR. : Both wild birdseeds and caged birds?

Mr. HACKMAN: There's a discussion right now with regard to the jurisdictional issues. Wild animal game is regulated by the Food and Drug Administration--for most of wild game. There are programs in which there are exotic game operations that are under voluntary inspection by the Department of Agriculture. But right now, the intended use is for food for animals, therefore

registration and prior notice are required.

MR. : Okay. In regards to registration, if farmers in the United States are exempt, are farmers in Canada exempt from registration?

MS. FRASER: Yes.

MR. : If I buy a raw commodity from a farmer in Canada, does that commodity still have to--is it subjected to prior notice?

MS. FRASER: Correct.

MR. : Okay. My next question is the feasibility of the timeliness of notification. If I buy a railcar of oats out of Canada, once that car goes from terminal to terminal, and gets put onto a train coming into the United States, that four-hour window of notifying when it crosses the border becomes pretty difficult to pinpoint.

How do we arrive at that information?

MS. FRASER: Part of that is something to work out with the exporter or the shipper on that end. But it's not--we have to receive notice between four hours before arrival and five days

before arrival. So, you don't have to get it in within--at--

MR. : So it's five days before--

MS. FRASER: You have five days to four hours. And if it's coming in by sea, it's five days to eight hours. So it's a window.

MR. : Okay. Now, if I understand right, if there is a change in the time of that, I do not need to resubmit a new--

MS. FRASER: Correct.

MR. : --submission. So if that car is in route, and I've submitted that it's going to cross on Tuesday at two o'clock, the car is bad-ordered, or in need of repair and sits up there for another three days, I don't need to resubmit?

MS. FRASER: Correct.

MR. : Okay. Thank you very much.

MS. : [Off mike.] I want to clarify--a solid-tuna-pack machine is exempt from prior notice--is that correct?

MS. FRASER: The machine itself is

exempt--correct.

MR. : I have a question on the food samples coming in--whether it's beer, cheese, whatever--from domestic companies that bring in like or similar products from a foreign country, might include taste sampling or laboratory analysis.

How do we get around--not get around, but--we don't know the manufacturer's ID number. It's not public. What do we do?

MS. FRASER: That's another big area of comment, is on--and, again, it goes back to the language in the statute and the requirement for a prior notice; and, in particular, for competitors' bringing in samples to test and, you know, even if the facility is registered, whether--it's unlikely the facility would give you the registration number to bring it in.

So we are looking at that. The commenters have suggested, so far, that, along the lines of what have done for personnel shipments of saying "Look at the label and put in manufacturer, and

address that's on the label," to let companies or entities file prior notice without the number, but to file other information. So, we're looking at that, as well, in terms of the comment process.

I guess what I'd say, in terms of your comments--you know, one area of commenting is, "We should be exempt, and here's how we think we should be." Another area of commenting could be: in the alternative, if you didn't agree with the first argument, what are alternative means of providing prior notice that still accomplish the same objective? So if you have other suggestions along those lines, we'd welcome those as well.

MS. : I have a question. As a broker, sometimes we're a third party to the transaction, and we don't have visibility. What happens if I get a call from an importer: "The shipments are ready in Denver, and prior notice has not happened." Can we hold that shipment 'til the process is complete? Or--what happens at that point?

MS. FRASER: Umm--we'll talk "post-August

12th" and "pre-August 12th."

MS. : Okay.

MS. FRASER: Pre-August 12th, the shipment would be able to proceed without being held, because we're in a period of enforcement discretion.

When we're in full enforcement, the food would arrive and we would see that it did not have prior notice; or Customs would see, when it arrived, that it did not have prior notice, and a choice will be made whether we think there's enough safeguards, security about where it's going to allow it to proceed to the port of destination; a port where entry may typically be made. It still will not be allowed to be delivered to the owner or the importer or the consignee until prior notice is filed and we have reviewed it--and that may happen while the shipment is en route. So it may be proceeding simultaneously.

But I would say, we would encourage people to file prior notice as soon as they can after they've figured out something hasn't happened the

way it should have. We also have said in the rule that notwithstanding the two-, four- and eight-hour time frames, if you have filed the prior notice--and let's say it's the eight-hour time frame that applies because it came in by sea--if you file it and we've assessed it, determined that there's no need to hold it for any reason other than usual course of business, then we will let it proceed and not just wait eight hours to wait eight hours.

So--you know--get it in as soon as you can.

MS. : So, basically, we could submit the information through the ABI system. If the food is here and it has been refused, then you have to use our systems. Customes will shut you out of the ABI system.

If the food is in route and it hasn't arrived at its destination yet, then you can use the ABI system.

MS. : Okay. Thank you.

MR. : We ship a great number of

samples of product that we bring in by truckload containers, but they're small samples--like three ounces--to a laboratory for checking prior to shipment into the United States.

Could those, then, be addressed to an individual and then be exept? The samples, I mean?

MS. FRASER: I think if you're looking at--there is not an exemption for personal shipments. If you're looking at--if you're asking is registration exempted, there is only a personal-use exemption in registration which is non-business. And samples tend not to fall into te personal--

MR. : Prior notice is what I'm--

MS. FRASER: Well, for prior notice there is not a personal shipments exemption for business--I mean, samples tend to be business, not gifts.

MR. : Yes, they are.

MS. FRASER: So you would not fall within--even if you address it to an individual, it would not meet the personal exemption.

MR. : Thanks.

MR. HACKMAN: Let me add something, too. Regarding your question that you just asked. The Center for Veterinary Medicine is evaluating that question. It was sent in from one of the national organizations that represents people who ship grain and feeds. So when we respond to that question--just look at our question and answer page, it will be posted there. We're evaluating that exact question right now.

But right now, prior notice--as Leslye just stated, prior notice is still in effect if it's commercial.

MR. : Just for the purpose of clarification, to make sure I understand it: as far as packaging components, like bottles and caps, for instance, are concerned, foreign manufacturers are exempt from registering, but domestic ones are not? Or--

MS. FRASER: Both are exempt.

MR. : They are, huh.

MS. FRASER: Yes.

MR. : Okay.

MS. FRASER: There's--those are all food contact substances which are under FDA's overall jurisdiction. But we have created exeptions in both the registration and the prior notice rules for food contact substances. So both domestic and foreign food contact substances--manufacturers, packers, holders--are exempt--from these. You have to comply with all the other regulations that apply to them.

MR. : Question in regards to the recordkeeping: you said that the final rules are interim rules and will be published by the end of the month--is that correct?

MS. FRASER: We're hopeful.

MR. : Okay. At that point in time is there going to be--if "grace period" is the right term--a grace period for implementation, like there is right now on prior notice?

MS. FRASER: Ahh--yeah. With respect to those rules, I can't tell you the details of what we will or won't do. I can only talk about what

we've proposed. And so in the proposed rules, what we had implemented that persons would have osme period of time after publication of the rules to come into compliance. And the proposed time frames were based on the size of your business, and it was six months after publication for large companies; 12 months after publication for small companies which--I'm not remembering off the top of my head, but might have been 10 to 500, somthing like that; and for very small companies--I think it was 10 and below--was 18 months.

So it wasn't an enforcement discretion period, it was a compliance date period. It would kick in eight months after--we got comments on whether the time frame should be extended; that that wasn't enough time. And we're addressing that in the final rule.

MR: : Okay. Thank you.

One other question--back to registration. Our business sells livestock feed. We are the manufacturer, and we have a number of dealers throughout the States. Out dealers are asking us

are they exempt, or should they be registered. And we always tell them about the 50-percent rule: if 50 percent of your sales are going to consumers, you're exempt. If more than 50 percent of your sales are to businesses--that is, other livestock producers or, if you're wholesaling to another feed dealer--then you have to be registered.

Their question is: how do we define what a business is? If he is selling horse feed to a guy that has five horses,who, in turn, is breeding horses, selling horses, is he required to survey his customers to find out if they are truly, indeed a business, or is it a hobby, or is it a consumer?

MS. FRASER: Umm--

[Laughter.]

MR. : I'll let you mull that one over, and I'll sit down.

[Laughter.]

MS. FRASER: Yeah. Dennis set me up, here. I feel like I'm at the circus in the dunking booth. If you can't answer the questoin you get dunked into the pool. [Laughs.] I don't know--I'm

getting close to the pool.

We--generally, I don't think we have, you know, an obligation that they have to do a survey, per se. And, you know, there are some of these folks--you know, your five-horses guy, that may be close to the margin. I think we would count a farm that's doing business, or a horse-breeding enterprise that's doing business as a business, versus, you know, whether that guy is starting out as a small business and he's got five horses, and he's looking at--you know, he's holding himself out as a business, that's how we would look at it, versus someone who--you know, these are his family pets, hobby, or each one of his children owns a horse and that's what they do.

Some of it is going to be what's reasonable to believe. I think we tend to think most people won't be that close to the 50-50 line, where these couple of folks are going to make the difference.

My own personal--you know, this isn't FDA--my own personal thing would be: when in doubt,

register. It's relatively painless. It doesn't cost you anything if you're a domestic entity. If you're a foreign entity then you may want to rethink that a little more and have some clarity, since you have a U.S. agent requirement, and some of these folks are charging some pretty hefty sums to be agents.

But I think, as a domestic entity it's fairly straightforward just to get a registration number.

MR. BAKER: Other questions?

Registration, prior notice or anything in between?

[No response.]

MR. BAKER: Well--

MS. FRASER: My feet are still dry.

[Laughter.]

MR. BAKER: You're getting good at this.

I want to thank you all for attending; asking questions.

I want to encourage your comments during the open comment period. Obviously, we're still

evaluating various scenarios, various situations out there. So your feedback is critical to what we do.

And, again, if you have any questions, we're as close as on-lne to getting questions answered.

And, hopefully, you found this information today. You may have gotten some questions answered. And we'll be doing further outreach in various parts of the country. I think we have El Paso next--no, Fresno's next, and then we're bouncing around to different parts of the country.

So thank you for your attention and time here. And we'll close it for the day.

I thank the panel, too.

MR. : [Off mike.] Registration, if we'd like to register?

MR. BAKER: Oh, yeah.

MR. : Room 305?

MR. BAKER: 305 upstairs if you'd like to go through a registration and actually get registered.

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