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U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

# FDA OUTREACH MEETING

## "Ensuring Compliance with the New FDA Rule for Establishment and Maintenance of Records Implementing Section 306 of the Bioterrorism Act"

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Office of Plant and Dairy Foods
Center for Food Safety and Applied Nutrition

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QUESTION AND ANSWER SESSION

DR. BERU: So, questions?

MR. : Morning, Doctor. One of the things you talked about was the transporter.

DR. BERU: Yes.

MR. : And that route that you took from DOT. We have a lot of cargo that comes into the airport or to the harbor where we have a local trucker just pick it up for deliver. I am a customs broker, and what we do is we give Joe's Trucking a delivery order to pick it up.

He picks that up with maybe four or five other shipments going in the same direction. He doesn't track his route. All he knows is he picked it up from Japan Airlines, he delivered it to ABC Foodstuff. He doesn't have a route tracking.

Was that taken into consideration? What are you actually looking for from them so we can tell our truckers what to watch out for?

DR. BERU: Well, tracking is not really the route they took in this. In many trucking operations, we understand they have got places

where they drop off and pick up and so on. That's what we mean, capturing that information; not specifically the routes that were taken in delivering it.

MR. : Just -- he will have four shipments, one of boxes, one of -- you know, one of pens, one of T-shirts and stuff, but he will pick it up and show that he picked it up at Japan Airlines at 10 o'clock in the morning and delivered it to Gardine at 3 o'clock in the afternoon and has the signature of the person who received it. That would be sufficient, then, in your mind?

DR. BERU: Well, first of all, he doesn't have to establish and maintain records with respect to the pens and T-shirts. This applies only to food.

MR. : Well, no, I'm saying he's got four shipments. Three of them are nonfood and one is food.

DR. BERU: Right. With respect to the food, he has to establish and maintain records of who he picked it up from and who he delivered it

to.

MR. : That's what I was hoping was the answer. Thank you.

DR. BERU: But those elements have to be, you know, the firm name, description of the freight and so on, just like it says.

MR. : Well, normally on a delivery order we will put on it saying -- you know, that's a tough one. He's going to have to ask us to put better than just food samples. We get a sample of food come in, he'll probably -- like you said, the romaine lettuce or something, so that's something we have to kind of educate a lot of people on. But normally it just says food samples. He's picking up a box of food samples that came in overnight and he's delivering them to a local guy who's running some tests on it or whatever. His delivery order should be sufficient if it shows where it was picked up from and who it was delivered to, and our name will be on it to show who issued the DR and our record would show who the company was that sent it.

DR. BERU: Right. Right. The elements are there and -- yeah, that's basically the information we are looking for. And keep in mind, I mean we did give compliance time for coming into compliance these regulations. If you are a small business, you actually have two years; large businesses, a whole year.

The intent of the rule is not to force you to, you know, do expensive reengineering of process in order to capture data that you can't capture at this point. But to the extent that you have to educate your truckers to capture that information yourself, it is absolutely appropriate.

MR. : And my guess is you think something's bad and you want to track who had it and delivered it and --

DR. BERU: Absolutely. That's the whole intent, is to able to trace back to the source of contamination, and to trace forward also to remove food from the marketplace that is adulterated and causes harm.

MR. : Sure. So once you turn it

over to a warehouse, then that warehouse -- you look to their records.

DR. BERU: Absolutely.

MR. : And then it goes to whoever they delivered it to.

DR. BERU: Yeah.

MR. : Thank you.

DR. BERU: It's one up, it's one down. You are not responsible for transactions you are not responsible for.

MR. : Good morning. My name is Ralph from Carls, Jr., and I want a little bit more clarification on full-time employees. I work at the distribution center. We have two distribution centers here in California. One location up north has 100 employees, and one location in Anaheim has 500, and since I looked at the formula in the act, and it says you are supposed to -- full-time employees divided by labor dollars.

DR. BERU: Right. Well, but basically to come to the FTE calculations, you just look at the total yearly hours you paid in salary and you

divide that by the total number of hours in a year for an individual, it's 52 times 40, 2080. That gives you the FTE for your firm.

For compliance, what we have said is if you are a business and you have 200 employees in one location, another 250 in another location, and another 50 in another location, if the total is more than 500, then you have one year to come into compliance. If it is less, between 11 and 499, you have 18 months.

MR. : All right.

DR. BERU: If it is less than 10, you have two years.

MR. : So I don't have to take into account our restaurants' employees who are full time.

DR. BERU: Restaurants are exempt by this rule.

MR. : Okay. So it would be just the groups that work in the distribution centers?

DR. BERU: Distribution center, right.

MR. : All right. Thank you.

DR. BERU: And please do say, because we are transcribing this meeting, say your name and your affiliation, and I should have said this at the outset, but we plan to make transcripts of this meeting, as well as the other meetings, available on our Web site.

MS. : Hello. My name is Elen Rayfield, and I work for Home Ingredients. We produce lactose for pharmaceutical uses. Would this -- what would this be considered? Would this be exempt from the act as defined in what food is defined as?

DR. BERU: Yeah. The end use here is a drug use, and this rule is only about food.

MS. : Okay.

DR. BERU: So to the extent that -- I mean if you are a lactose producer and it's all going to the manufacture of a drug, then that would be exempt from this rule. But if you are supplying a drug as well as for food, then the part of it that goes to the food would be subject to the rule.

MS. : Thank you.

MS. : Hi. I'm Annette Smith with Cost Plus World Market, and my question is regarding recordkeeping for a particular item. If we have an item that FDA comes to that they are considering suspect, and that item is purchased multiple times throughout the year and goes to our distribution center, and then goes off to our stores, do we need to maintain records for that particular item since lot codes aren't required? Or can we give you the multiple times that shipment has come in throughout the year to satisfy recordkeeping?

DR. BERU: No, you don't have to -- at that level you don't have to -- the rule doesn't mandate that you record lot or code number information.

MS. : Right. I understand that.

DR. BERU: But you have to have in your records that you received a shipment of that item on -- because records, remember, have to be created on the date it was received. And so you would have to have information in your records as to the day

you received that shipment and subsequent shipments, and who you got that shipment from as well as who brought it to you, what transporter brought it to you.

MS. : Right. But if you come to us with a particular item, say that has gone out to one of our stores, do we need to be able to -- how, if we are not using lot codes, would we be able to identify that all the way back through the supply chain?

DR. BERU: Well, presumably when FDA comes to you, they will say when did you ship, because they will have information as to when that shipment was received by the one down from you, or rather one up -- we're talking one up. So when they ship that to you, they will come to you with that information, the date when that was shipped to you. So you should have information as to when you received that shipment.

MS. : So it wouldn't be a situation where you would say go to our store or a consumer has possibly ingested something that is no

good, and they know, okay, well, we bought this at the Van Nuys store or whatever. If -- I'm talking about tracing it back like that. How would we be able to do that if you are not going to be using lot codes?

DR. BERU: Well, the retail operator, if we get to the retail, that's why we're not keeping the one down with respect to consumers, because the consumer would be able to tell us where they got the food from, what retail store. And the retail store will have information as to what distributor they got that food from, and that's how we would do the trace back.

MS. : So then in an instance like that, where you were to have come to us, you would -- our multiple shipments, the records for those multiple shipments would be adequate?

DR. BERU: Well, that is the only thing you can provide, possibly, but there is a way, I think, to -- even if without recording a lot of code number information, presumably you do first in and first out with respect to products you get in

and you get out, and so that would conceivably limit the universe of shipments you consider in giving information to FDA.

MS. : And that limited group would be sufficient for the recordkeeping requirements?

DR. BERU: If that's all your current -- without, you know, putting in expensive reengineering, that is all the information you can provide, yeah. That will be the information you give us here.

MS. : Great. Thank you very much.

MR. : Good morning, sir. Gary Fleishman from Panamex Pacific Northern California. We import food ingredients in full container quantities, and we never see or touch the material itself. It comes into the port and then it is already sold to another company that is going to manufacture it into processed foods. So I guess for us, would the date of receipt be the date it comes into the port?

DR. BERU: Well, first of all, are you a broker then?

MR. : No, we are an importer.

DR. BERU: You are the owner of that food.

MR. : Yeah. Well, when it comes in. But as soon as it leaves the port, it transfers over to another company.

DR. BERU: Right. The date of the receipt would be the date it comes into your possession at the port.

MR. : Okay. So and the provider ahead of us, is that the trucker who takes it out of the port?

DR. BERU: Is that -- does it -- well, yeah, the trucker, because he or she is taking possession of that.

MR. : Right.

DR. BERU: They have to establish and maintain records with respect to the immediate previous source, which would be the port facility, I imagine in this instance.

MR. : Does that mean that --

okay, so we need the name of the driver or the trucker who actually takes it out?

DR. BERU: The firm name is what we are saying.

MR. : Okay. And then what about the trucker? He needs a person's name when he pulls it out of the port, or just the name of the terminal?

DR. BERU: The name of the firm that he is picking up the food from.

MR. : Okay. Thank you.

MR. : Good morning. My name is Art Keegan. I work for American Ingredients. We are a food supplement ingredient distributor, and I wanted to know if we were responsible for revealing our manufacturers to our customers down the line.

DR. BERU: Can you clarify that? I'm not quite sure.

MR. : Well, we distribute the ingredients.

DR. BERU: To manufacturers?

MR. : To other manufacturers,

but they are manufactured for us previous to that. We make a CBAY with our name on it and distribute it to our customers. Now are we responsible for revealing our suppliers to our customers?

DR. BERU: Okay. What we have said is you supply ingredients in this instance; right?

MR. : Yes, sir.

DR. BERU: Right. So you have to have information of who you are getting those ingredients from.

MR. : We maintain those records, but are we responsible of passing those records on to our customers?

DR. BERU: No, you don't pass those records. Then you have to establish and maintain your customers when you ship your ingredients. In other words, you shipped this ingredient to this customer on this date, including the quantity and the specific information that the rule asks for. It's not transferring records per se. You are the one, you have to create the records and maintain those records in the event that we have to access

them.

MR. : But we are not responsible for providing those records to our customers?

DR. BERU: No.

MR. : Okay.

DR. BERU: Your customers, when they receive the food from you, then are responsible for establishing and maintaining records. They will have you as the source of those ingredients. They have to create their own records.

MR. : Okay. And as far as maintaining those records for two years, that would be custody of the product, from two years from the custody of the product?

DR. BERU: Two years from the day that a record was created. Records have to be created when you receive and when you release. So it would be two years from the time the records were created. Remember, the records have to be created at the time the activity took place -- I mean when the food was released and when it was received.

MR. : If you maintain -- if you

warehouse the product for over two years and have the product still in your warehouse after two years, you are still responsible from two years on from there?

DR. BERU: No, no. In fact, the statute is very explicit. We cannot require that you maintain records for more than two years, you know. Personally I would like it if you had those records, but we can't force you to keep those records because the statute limits FDA to requiring records no more than two years.

MR. : Okay. Thank you.

MR. : Hi, there. I'm Gary Austerbach with Dax Global. We're a third-party logistics company and customs house broker, and I guess my question is somewhat similar to some that have been raised. We are responsible for the transportation movement through to the importer, but there are occasions where we don't physically take possession of that cargo, where we may outsource each aspect of that movement. Are then we responsible, even though we never had physical

possession, of maintaining those records for each part of the chain?

DR. BERU: Well, you know, most of the ownership, it is the activity that rules here. I mean if you manufacture, if you process, if you hold for the food package you receive, if you import, if you transport, you have to establish and maintain records.

Now in this case you have other folks picking up your food, although you own the food; right?

MR. : We don't own it, no. We act on behalf of the importer. The importer ultimately owns the goods --

DR. BERU: Oh, no, no. In that case, we are very clear, and I urge you to search the rule for -- you are acting as a broker, basically?

MR. : Basically, yeah.

DR. BERU: We address the very explicitly. If you do not own, you do not physically possess the food, you have absolutely no requirements under this rule.

MR. : Okay. And how would the importer -- would the importer then still come to us for that information? Because they would not be familiar with what third party we worked with, so they would only come to us. So how would they necessarily know that?

DR. BERU: Again, I'm not sure I am clear, but the importer presumably is having the food picked up by a truck to go to whoever they're selling it to?

MR. : We may have made those arrangements on their behalf so we are responsible for making those arrangements. We then would hire a particular trucker, have it delivered to that importer. That importer has no direct relationship with that trucker; their relationship is with us.

DR. BERU: Well, this is a very interesting question, and I don't think we have addressed it explicitly in the rule. My sense would be -- and again, this is probably one where we need to explicitly address it in the question and answer guidance document I mentioned -- but my

sense would be that if FDA, as it is tracking the food, goes to the importer and the importer can get readily that information from you within the required, as soon as possible, not to exceed 24 hours, that would probably be sufficient. I mean that's -- I'm just giving you a sense of an answer right now, without really going through it. But this is one problem you have to address through a question and answer.

MR. : Okay.

DR. BERU: Because we haven't explicitly addressed it. But brokers, we have said if they just are facilitating movement of food and they are not themselves owning the food or have custody of the food or possession of the food, then they have no requirements under this rule.

MR. : Okay, and a related question. We also act as an ocean carrier, so let's say a container comes in --

DR. BERU: Excuse me, as a what carrier?

MR. : I'm sorry?

DR. BERU: You act as what?

MR. : As an ocean carrier. We are responsible for the ocean transportation from overseas. So when a container containing food arrives into the port area, so it's entered the United States, is the ocean carrier responsible, since they are handling that local portion, of noting who they received that from overseas?

DR. BERU: No, they really are not transporting within the U.S. When I said transporters, foreign transporters are covered under this rule, we meant those that are actually transporting within the U.S. We didn't mean those that come to the port, drop off, and then --

MR. : Okay. So then the port area would not be covered by that, then?

DR. BERU: Well, within the port is within the U.S.

MR. : Okay. So, in essence --

DR. BERU: The ocean carriers, I am presuming they have operations and at that point they --

MR. : Well, yeah, they would

have to take it off the ship at that point. It's arriving within the U.S., they are moving it, though it may be a hundred feet, but they are moving it within the port area to have it ready for pickup. So at that point it's in the United States. So is that the ocean carrier's responsibility?

DR. BERU: Again, this is one where, you know, nuances of business practice that we may not necessarily have been aware at the time of development of the rule, but it seems to me that is movement within the U.S. Again, you know, what is the cutoff, you know, a hundred feet, 10 miles. But that would be -- that would constitute movement within the U.S., and that would need to be captured in the records.

MR. : Okay. So that's something you would clarify?

DR. BERU: Yeah.

MR. : Okay. Great. Thanks.

MR. : Good morning. I'm Steven Marquez with Boscovitch Farms. I oversee our

environmental compliance and sit on the board for food security. Our food security team would like to know if establishing and maintenance of records, is there software in the works, is FDA familiar with any companies providing some of that information out there yet?

DR. BERU: Yes. Many companies have let us know they are doing software.

MR. : We have talked to one which we use with our refrigeration system for anhydrous ammonia. It seemed a little expensive and they kind of wanted to come and set it up for us.

DR. BERU: Well, yeah, let me just say this. There are firms who are developing -- we know there are firms who are developing software to help covered entities comply with this requirement. We are not -- we haven't looked at any of the software. We are not endorsing one over the other. It is entirely up to you. I mean in the end you are the one who will be responsible for complying with the regulation and ensuring that whatever

software you are purchasing enables you to do that. Although we are aware that there are a number of firms developing this software, we haven't reviewed them. We are not endorsing any of them.

MR. : Also the logistics, are we required to notify and educate trucking firms coming in and leaving our facilities? Is FDA --

DR. BERU: Well, you know -- believe it or not, when the rule first issued, we did a series of public meetings. We are going to various trade shows. We have been invited by various trade associations as part of this educating process. We are doing a series of meetings now. We are doing the fact sheets, sort of an easy to answer question-and-answer format, of what the rule entails, and we are doing quite a bit of outreach. I mean to the extent you can do that, help get the word out, it will be great. I mean these meetings -- today's meeting isn't as well attended, unfortunately, as some of them -- for example, when the rule first published, I don't know, maybe perhaps there was more interest there, but we were

having crowds of close to 300, you know, per session.

So we are doing our best to get this out so that all covered entities know it. We have been talking to the transportation associations and so on, and so hopefully the center of this activity will get the requirements out to all the entities that have to comply with it. But to the extent that you can do that, it would be useful.

MR. : Great.

DR. BERU: But I mean you're not responsible for that, obviously, but to the extent you can do that, it would be great.

MR. : Thank you.

MS. : Good morning. My name is Allie Newman and I work for a manufacturer processor, White Way Foods, and I have a question regarding -- we deal with coordinating ingredients and packaging to several copackers, so with that, I guess my question is are the -- we have some copackers that are company owned and others that we own. So, you know, going back and forward with

documents, is it the copacker's responsibility to keep the records before and after, and as a brand owner, I guess ultimately it's our responsibility, too, to know what everybody -- you know, who's getting what and where it's going.

DR. BERU: Well, first let me address the company. I wasn't very explicit in the presentation, but you are not responsible for establishing and maintaining records with respect to movement of food within your own company.

In other words, if you are a manufacturer, yes, you are responsible for establishing and maintaining records of the ingredients received to do your manufacturing. But if you own the distribution center and then your distribution center ultimately gets that manufactured product to retail, then the requirements of that is you have to establish and maintain records of the ingredients you received, but the next set of requirements is that you have to have the retailer or the immediate subsequent recipient. You don't have to establish and maintain records with respect

to movement from your manufacturing side to the distribution center.

But if they are owned separately, of course, then the requirements apply.

Now copackers, they do take physical possession of the food, and so in that they are holding it, they are packing it, and so they have to establish and maintain records with respect to the fact that they got the ingredients from you.

In other words, there has to be records of the movement of the ingredients from you to the copacker and back.

MS. : Okay. And then from -- for instance, from the copacker, if it's transported to a warehouse, then as long as we have records going from the copacker transportation, then the transporter would keep the records, you know, going back to the copacker and then to the warehouse. We can show that link the whole way.

DR. BERU: Yeah.

MS. : We should be covered.

DR. BERU: That is the intent of the rule,

is to be able to follow movement of the food as it moves in commerce. So in that instance, yes, the copacker would have records of releasing food to the distribution center. The distribution center would have records of receiving that from the copacker, and that would be all the information that would be required.

MS. : Okay. Okay, thanks.

MS. : Good morning. My name is Jacqueline Sutton from Nimble Bakeries. I've got a couple of questions. He talked about a program, but is there some sort of form that the FDA is going to come out with that will be -- that we can get on the site that we can fill out, or we just come up with our form for documentation?

DR. BERU: No, there's not. In fact, very early on we considered that in the rule development process, that some sort of form -- but actually there was a huge outcry that that is too onerous, you are requiring us to redo our processes. And believe it or not, many of your companies out there do have a lot of this information we are requiring

in these records.

MS. : Okay.

DR. BERU: So early on we made the decision that what we will do is do a performance-based regulation. In other words, say what it is that we need to have in the records, but it's going to be entirely up to you how you capture that information.

So, yes, we did consider doing a form, a standard form that everybody can use, but that wasn't very popularly received, so it's up to you, whether it's paper or electronic. As I said, if between two or three sets of papers, records that you already keep, you have all the elements that we are asking for, then you don't have to do any more.

MS. : Okay. We receive product from Mexico. Is it our responsibility to ensure that the carrier delivering the product to us in the States has this documentation for the FDA?

DR. BERU: No. You don't have responsibility. The responsibility would be entirely the transporter's responsibility.

MS. : Once our carrier, our common carrier brings it in from Mexico, he should have the documentation?

DR. BERU: Well, you own the carrier?

MS. : No, we do not. The carrier is a common carrier.

DR. BERU: Then all the rule requires you is to have two sets of information, who the firm in Mexico is that is supplying you the food, and then --

MS. : We own the bakery in Mexico, but we have a common carrier bring it in to the States. But the common carrier would need to have the documentation for him and for us?

DR. BERU: No, the -- well, there are two things here. If you don't enter into an agreement with the transporter to basically establish or establish and maintain records on the transporter's behalf, then the transporter is responsible for establishing and maintaining records, you know, showing that he picked up the food from your bakery in Mexico and delivering it to you. You would be

the recipient.

On the other hand, your responsibility would be to establish and maintain records of the transporter, because that's your company. In other words, your company in Mexico has no requirements because it doesn't apply to foreign firms.

MS. : Sure. Okay. Is it our responsibility to ensure our outside carriers properly record the forms? I guess what it is, we have copackers that bake product for us, private companies, common carriers bring it down to our bakeries. So the copacker has to have the paperwork, and also the carrier?

DR. BERU: Yes. Everyone -- you know, in other words, it's not your responsibility to ensure that the carrier is maintaining records. It is the carrier's own responsibility to establish and maintain records. Similarly the copacker.

MS. : Okay. And then also we have our own trucks which we bake the product, the product goes out of our bakery to our depots. Of course, from our depots to our stores. So we have

to keep records for when our product leaves our bakery?

DR. BERU: No.

MS. : Okay.

DR. BERU: If you own that entire chain --

MS. : We own the entire chain.

DR. BERU: -- we refer to that in the rule as the vertically integrated company.

MS. : Okay.

DR. BERU: So in your instance what applies is you of course at your bakery have to establish and maintain records of the ingredients you receive, be it the flour or the yeast or whatnot. And then to the extent possible that information is reasonably available, you have to tie in the incoming product with the outgoing product. But next where a record is required, because you are using your own transporter, you are using your own distribution site, the next time you are responsibility for establishing and maintaining records is -- because you are a vertically integrated company, you are basically a

nontransporter, and so you have to establish and maintain records of the retail outlet you deliver to. So it ends up coming into your vertically integrated company, and the baked goods that go to the retail facility.

MS. : So for ingredients, we keep this report, and because of the ingredients goes into the product, we don't have to keep a report going out to the depots to the stores?

DR. BERU: No, movement -- all that is within your own company. The rules doesn't require you to capture movement within your own company.

MS. : Within our own company. Only if it's common carrier and we can also get it from ingredients. DR. BERU: Well, ingredients are food.

MS. : Yeah, I understand.

DR. BERU: So when you receive them into your bakery, you have to establish and maintain records of the source of your ingredient as well as the transporter who brings it to you.

MS. : Okay. Thank you.

MS. : Hi. Good morning.

DR. BERU: Good morning.

MS. : I'm working with Dannon Company. We manufacture yogurt, and I have a couple of questions for you, too.

The first one is I understand that we have lot codes on our products, so the lot codes are available for our finished products, and let's say that one truck is leaving our distribution center to deliver to customers, and in the truck we have one skew, one pallet, but with two different lot codes. We will have a really hard time understanding which lot code went to which customer. How can we address that?

DR. BERU: Well, remember, I said the lot code information isn't required past the distribution center. What we understood through comments we received is that, yes, when you manufacture, process, pack, your tracking lot code gets to the distribution center, but once it arrives at the distribution center, products are broken up. There's mixing and matching and so on,

and beyond that there is not the capability to capture the lot code information. So we are not requiring it past the distribution center.

MS. : Okay. So we don't need a lot code past the distribution center?

DR. BERU: No, only if you manufacture, pack, hold food. At that state, once it gets to the distribution center, from then on there is no requirement for capturing the lot or code information.

MS. : Okay, but we need to know what's going out from the distribution center to the customer?

DR. BERU: Yes. Yeah, you have to record the amount of the food, how it is packaged, the brand name and so on, yes.

MS. : Okay. And another question is can you clarify a little bit for me, we have some -- some of the discarded products are aimed for animal feed, so how can we capture the codes for the products we ship for -- to be animal feed?

DR. BERU: Again, there's no requirement to capture that. You have to -- of course, animal feed is food under the act, so you have to establish and maintain records that you are supplying whatever you are supplying to the animal feed processor. But there is no requirement for you at that point to capture lot or code number.

MS. : Okay, so just the quantity and the type and --

DR. BERU: Right.

MS. : Okay. Thank you.

TAPE CHANGE

MR. : . . . in San Francisco, we make a gin and a vodka and I know that under FDA rules or regulations, alcoholic beverages are considered a food. But at the same time, for the purposes of this, the Bioterrorism Act, I think you said something about distilling as not being covered by this? I'm a little confused.

DR. BERU: I don't recall where we have said that alcoholic beverages --

MR. : Well, it says as part of

the manufacturing processing is being exempt from the rule. In your presentation.

DR. BERU: I'm sorry. Say that again. Manufacturing --

MR. : Manufacturing processing was exempt from the bioterrorism rule in your presentation.

DR. BERU: No, no, no. No, I think you misunderstood.

MR. : Maybe I did, then, yeah.

DR. BERU: If you manufacture, if you process, if you pack, or if you distribute, if you receive, if you transport, if you import, you are covered.

MR. : All right. That's fine, then.

DR. BERU: Okay.

MR. : And with the ATTB, we are already doing all this, anyway, so --

DR. BERU: Right. In fact, that's what we are finding, but no, manufacturers' processes are covered under the rule.

MR. : All right. Thank you.

DR. BERU: I'm sorry if I --

MR. : No, that's okay.

DR. BERU: -- misinformed you.

MR. : Hi. I'm Wade Lutsenomia (ph). I'm with See's Candies. My question is in general, we manufacture our products and distribute them to our own retail stores. Are we actually required to have records of the transportation to those retail stores? Sometimes it is done by our trucks and sometimes it is done by a common carrier.

DR. BERU: As the rule now stands, if you use your own trucks and your own drivers, you don't have to. This is a retail store; right?

MR. : Right.

DR. BERU: Right. But if you use other transporters, because the other transporters, that isn't under your control. It's taking possession of the food. You have to establish and maintain records of that transporter having picked up the food.

MR. : Okay.

DR. BERU: That's not part of your --

MR. : But when we identify our immediate subsequent recipient, it would be the consumer. It wouldn't --

DR. BERU: Well, no. In fact, you don't have that requirement. If it is directly to consumers, you don't have the one down requirement.

MR. : Okay.

DR. BERU: If you only, at your retail store, you sell to other businesses also, then you have to capture that, to the extent that information is readily available to you.

MR. : All right. What about for mail order? You know, some of our products get sent by mail to customers. Do we have to identify what gets mailed out?

DR. BERU: Well, if it is to individual consumers, no. But if you are sending it out to businesses, who then are going to subsequently sell it, yes, you have to capture that information.

MR. : Okay. Thank you.

MR. : Good morning. I'm Mike Demoral (ph) with Dole Food Company. I have a few questions.

The first question is regarding the availability within the 24 hours. Is that to provide the information to an FDA person who will be at our facility, or do we need to factor in time to get the information to an FDA office?

DR. BERU: No, it is to provide it to an investigator who actually comes to your site.

MR. : Okay.

DR. BERU: Once you are handed a written request, you have to provide it as soon as possible, not to exceed 24 hours, and you have to provide it at that site.

MR. : Right. So we -- okay. And then I had several questions related to lot code tracking packaging or ingredients that are food contact substances but are not actually food. And your example of romaine lettuce is very close to our hearts, because we are very big in the lettuce business. So if we use that example, let's

say there's a twist tie that goes around the romaine lettuce that gets sent to our customers. The manufacturer -- from my understanding, the manufacturer of that twist tie is not included under the regulation? Is that correct? And will not need to provide us with lot code information regarding that twist tie?

DR. BERU: No. First of all, there isn't -- when we talk about the immediate previous source, again, you know, twist tie isn't one we have handled. If you said maybe plastic packaging, that would be more straightforward.

MR. : Right. Well, I understand that.

DR. BERU: Right. But so you understand, just so we are clear, if it is the plastic material that you package the lettuce in, then there is a requirement to identify the source of that packaging material. The finished material that contacts the food. Twist ties, again, you know, a logical extension is that you would have to identify the source of those twist ties, not lot

code information, the source, because it is contacting the food.

But again, this may be one where we need to clarify in the final rule.

MR. : Okay. And then --

DR. BERU: I mean through the questions and answers.

MR. : And then a follow-up to that is if we apply the twist tie in the field as we are harvesting the lettuce, I'm assuming it's excluded from the regulation because it's then a farm activity?

DR. BERU: Yes, it is. Actually initially probably we would have said, yeah, that sounds like processing to us, so you no longer are processing, but subsequent to that actually we have -- because our initial stance was even putting, you know, berries in clam shells on farm and so on constituted processing, and so that takes you out of the farm exemption. We have subsequently reconsidered. Activities such as that do not take you out of the farm exemption.

MR. : Okay. Thank you.

MS. : Hi, Annette Smith, the Cost Plus World Market again. I have a question about samples and unsolicited samples coming into our corporate headquarters. We have a big food division and we frequently get samples, both requested and unrequested, that come in all manner of transport from physically coming from overseas by a carrier to literally being dropped off by a potential vendor.

Would we need to maintain records? Which of those would we need to maintain records for, or would we need to maintain records for all of them?

DR. BERU: That's a good question. That's an area actually we are revisiting and will clarify in this next set of questions and answers that's coming out. As it stands now, the final rule, if the samples are intended to be consumed, we differentiate between two different types of samples. There are lump samples that are going to R&D and ultimately get destroyed. There's no requirement to establish and maintain records with

respect to those samples.

And then again there are samples that are consumed, and what we have said in the final rule is that then the requirement to establish and maintain records with respect to those samples applies.

Now having said that, that's what is currently the final rule, but we have through the first use of public meetings we conducted, been shown there are many intricacies as to how samples are handled, you know, where they are consumed, and so on and so forth.

So we are clarifying our stance with respect to samples in this next set of questions and answers, so I would just say stay tuned to that.

MS. : Will you be looking at unsolicited samples as well in your decision? I mean frequently we receive samples again that go immediately into the garbage or, you know, are coming in for labeling, you know, things we haven't even asked for.

DR. BERU: What I would imagine, for the samples that you are not further considering and you are destroying, essentially, there wouldn't be any requirement to establish or maintain records. But if you are then, you know, doing testing or whatever, and those samples are getting consumed, the rule as it stands now would require you to establish and maintain records. If it is to be destroyed, no. But if it is going to be consumed, that's where we made the distinction.

MS. : And if it's unsolicited and we don't --

DR. BERU: We don't address whether or not it is solicited or unsolicited. I mean if you receive food that is unsolicited but you still go ahead and test-market it or whatever in your company, then it is consumed, the rule would require you.

But, again, I mean we don't make a distinction between solicited versus unsolicited. The distinction we make in the final rule is between samples that are ultimately consumed versus

samples that are destroyed. And for samples that you do various things to and ultimately destroy them, there is no requirement to establish and maintain records. Samples that go into testing, for example, and are actually consumed by consumers, you would be required to establish a record.

Now, you know, having said --

MS. : Well, how would we control people, you know, vendors dropping things off at our facility we don't even know? How would we maintain those records if we don't even know who those people are?

DR. BERU: Well, presumably you know the vendors that are dropping them off.

MS. : I'm sorry?

DR. BERU: Wouldn't you know the vendors that are dropping it off at your facility?

MS. : Well, we might know who they are, but we wouldn't necessarily know how they arrived.

DR. BERU: Well, again, I would just say,

I mean there are a number of questions on the whole issue of samples that we are addressing in the next Qs and As. If that doesn't address all your concerns with respect to samples, we will deal with them in subsequent questions and answers.

MS. : All right. And when will that be published?

DR. BERU: This one, actually, like I said, we are actually striving to have it out before this series of public meetings. We had one in Kansas City yesterday, LA today, we're going to have one back at headquarters tomorrow, and then there are a couple next week, one in Atlanta and one in Minnesota, I believe.

MS. : So within the next couple of weeks?

DR. BERU: So we're trying to get them ready and have them out and be able to speak about them, actually. I wish I could, before the meetings, but unfortunately they are not ready. They have to be cleared by not only, you know, senior management but by the Office of the General

Counsel and so on, so we just can't talk about how we are handling them right now until we have a finished document that we put on the Web.

So given that we are striving to get them out by this set of public meetings, it won't be long before we get it out.

MS. : Say within the month?

DR. BERU: Don't hold me down to it.

[Laughter.]

MS. : Okay. Thank you.

DR. BERU: I have given time projections before and been wrong, so -- in fact, there may be some of you here who I promised we'd have them out by the meeting, so. . .

MR. : I'm Roger Clark with Williams Clark Company, Customs Broker. I have three questions.

The first one is the responsibility of the importer when it's contracted on the foreign side between a manufacturer and a foreign shipper on a throughbill lading all the way through to its destination and stored or delivered, which means

the importer has no control of the logistics movement of that cargo, the original manufacturer will turn this over to a second entity overseas which contracts with a carrier, a foreign carrier, to bring it into the United States, contract with say a railroad to move that on forward to an inland port, who in turn contracts the same carrier, contracts with a trucker to move that to its ultimate destination. What is the responsibility of the importer for recordkeeping? Is it just the first initial transfer off the bill of lading, from the manufacturer to the shipper, to the ocean carrier? Or is there any responsibility for --

DR. BERU: First of all, there is no responsibility on the foreign side. The requirement, as I said, applies only to domestic entities, and on the foreign side only transporters who actually are crossing the border and transporting into the U.S. are subject to these regulations.

So there is no requirement on the part of the manufacturer to establish and maintain records

to which carrier they handed off the food.

Now once the carrier comes -- are you making agreements as to who is picking up the --

MR. : No, no, no. The importer has no control over the logistics movement whatsoever.

DR. BERU: But the importer owns the food.

MR. : The importer, though, doesn't know how it's being transported to its ultimate destination.

DR. BERU: But owns the food.

MR. : They will be the owner of the product, but never have possession of it.

DR. BERU: Yeah. Well, as I said, it is -- you know, the rule says if you engage in covered activity. So whoever is picking up the food at the docks would need to establish and maintain records as to who they are picking it up from. In other words, the firm that owns the food, which should be, I imagine, your firm's name, and then of course when they deliver it to whoever is buying the goods ultimately, they have to establish and maintain

records of who they are delivering it to.

At the same time, whoever is being delivered to has to establish and maintain records of the transporter as the transporter having brought it, but also as your firm as the one that ultimately --

MR. : Well, what you are saying is that a foreign ocean carrier is responsible for maintaining the records.

DR. BERU: No, I didn't say that. Foreign carriers are not responsible.

MR. : Well, but the foreign carrier is contracting for the whole transaction. They are responsible for ultimate deliver.

DR. BERU: We haven't really dealt with this question. What I would really appreciate is if you could send me this question through an e-mail. We can make sure I answer it in the next Q&A.

MR. : Well, the second question I have is in regards to foreign importers of record, which are given basically a requirement of

24 hours after notification. If it's a foreign importer of record that doesn't reside in the United States, I'm assuming that your notification will go to the resident agent in the United States?

DR. BERU: Yes.

MR. : Who in turn will notify the foreign importer?

DR. BERU: Well, yeah, as to the agent, operator or agent in charge.

MR. : Right. But due to timeframes and time differentials, if your foreign importer is halfway around the world, you have a 13-hour time differential right off before they can even be notified if it's on off hours.

DR. BERU: Well, the rule says once you have the proper notification, written request for records, you have up to 24 hours to provide that.

MR. : Right. And where does that foreign importer of record present those requests?

DR. BERU: Wherever the investigator is asking for the records from.

MR. : Okay. And then the last question is will FDA be doing any audit compliance requirements as far as going out and making sure that these record are being kept properly, or is it going to be on a strictly --

DR. BERU: No, as it stands now, we have access to the records only if we meet that threshold that I mentioned. If we have reasonable belief that a food is adulterated and presents --

MR. : Basically it's an act of faith that everyone is complying with these requirements?

DR. BERU: No, having said that, we are looking to see if we have authority to do that, but as it stands now, that's the only time we have access to the records.

MR. : Thank you very much.

MR. : Hello. My name is Lou Kirpan (ph) from Rocket Cargo. We are involved in a lot of trade shows and corporate events. Who would be responsible in a trade show involving food and beverage products, the exhibitors or the

organizer of the show, to know where the product going into that show is coming from?

DR. BERU: It would be the exhibitor.

MR. : The exhibitor?

DR. BERU: Right.

MR. : Okay. Second question is on an import transaction, would the information captured by Customs and FDA on the various entries be sufficient for documenting the process if the ultimate consignee is listed on the Customs entry?

DR. BERU: No, I think whoever is receiving the food from the foreign source has to establish and maintain records as specified in this rule. The data elements that we have specified in this rule.

MR. : So just not -- the information that is in the Customs entry and the FDA import entry is not sufficient?

DR. BERU: I mean we have that information already. Are you saying because we have it, there is no requirement for the entity to establish and maintain those records?

MR. : No, what I'm saying -- what I'm asking is, if we have that information, we have compiled it and stored and organized that information --

DR. BERU: I see. I see. Well, what I would suggest is look at the quantified -- with respect to the data elements. It may well be. I'm saying that because I really don't know what all is in the Customs entry data base, but what I would suggest is look at the data elements that we are saying you have to capture, the name of the firm, immediate previous source, the transporter who brought it to you, the amount of the food, the type of the food, how it is packaged. If all that information is in the data base, then that's all you need. You don't have to establish separate records for this.

MR. : Thank you.

MR. : Doctor, I'm sure some of us will have questions after this is over. Would you be willing to give us your phone number to call with them?

[Laughter.]

DR. BERU: I prefer getting e-mails because we have someone compiling the questions and answers. Let me give it to you. I didn't bring enough cards, so if you have subsequent questions, it is nega.beru@fda.hhs.gov. Again, it is nega.beru@fda.hhs.gov.

If they are readily answerable, we will answer them. Otherwise, those that are raising new issues that we haven't tackled, I will inform you that we will be handling through the question and answer process.

It looks like we're winding down. Any more questions?

Again, I do urge you to stay tuned to the Web site because the first set of questions and answers clarifying these various issues will be on the Web site.

I also urge you to please read the preamble because many, many of your questions are clarified further there.

If there are no further questions, thank

you for coming, and I appreciate your attention.

Thank you very much.

[Applause.]

[End of question-and-answer session.]