

FDA Press Conference on Chili Products (Botulism) Recall

FTS-HHS-FDA (US)

Moderator: Robert Ali
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Operator: Welcome, and thank you for standing by. At this time, all lines have been placed in a listen-only mode until the Question and Answer Session of today's Conference Call. This call is also being recorded. If you have any objections, you may disconnect at this time.

I would now like to turn the meeting over to Mr. Robert Ali. Sir, you may begin.

Robert Ali: Thank you very much, (Calvin). I'm (Rob) Ali from the FDA's Media Relations office. Thanks and welcome to this briefing on the recent recall of canned food. Also thank you for your patience as we work around some technical difficulties and postpone this call so we could ensure that we had the maximum number of representatives on this call.

Our three speakers this afternoon are Dr. Robert Brackett, Director of the FDA's Center for Food Safety and Applied Nutrition, Dr. Kenneth Peterson, Assistant Administrator for Field Operations, Food Safety and Inspection, and Captain David Elder of the United States Public Health Service and FDA's Office of Enforcement.

We also have several other FDA officials and Mr. Mike Lynch from the Centers for Disease Control to answer any questions as they may occur in this briefing. The three speakers will go first and then we will turn it over for a

Question and Answer period with the intent to be off the call in about 50 minutes, so you can file your stories and so our speakers can get back to the challenge at hand with this recall.

At this time, I would like to turn it over to Dr. Brackett.

Robert Brackett: Thank, you (Rob), and good afternoon to all of you. Today the Food and Drug Administration and the Food Safety and Inspection Service is taking another opportunity to warn the public about the botulism toxin threat in hot dog chili sauce, manufactured and distributed by Castleberry's food on Augusta, Georgia.

As part of our public health mission, we feel that it's paramount to warn consumers as early as possible about the potential risks and impact of their health. And this is of course, something that the FDA became aware of the possibility of botulism cases on January 18, and then informed the public later that evening based on some preliminary tests.

The FDA issued a nationwide consumer warning over the weekend about the presence of botuline and toxin in hot dog chili sauce manufactured and distributed by Castleberry's, and the company has voluntarily recalled the suspected product. A complete list of the recall products can be found on both the USDA and FDA Web site. The link is www.fda.gov and go to Hot Topics on the top right of that.

While the tests that we have done are considered preliminary, FDA continues to warn consumers against the use of these products because botulism can be fatal in some cases if left untreated, and is always serious. To date, four cases of botulism have been reported through the CDC from Indiana, which there were two cases, and Texas, in which there were two cases.

All four persons reported to have consumed Castleberry brand hot dog chili sauce the day before the illness began and this is the only food identified and common among the four patients, so it's the most likely food vehicle, and Dr. Lynch can talk about that later on if you have questions.

We have begun confirmatory tests which should be completed by the end of this week which should confirm that it was active botulinum toxin and the type toxin that was there. Just as some background about this illness, botulism poisoning can begin from six hours to two weeks after eating a food that contained the toxin.

Symptoms can include double vision, blurred vision, drooping eyelids, slurred speech, difficulty swallowing, dry mouth and then this muscle weakness that progressively moves down the body from head to feet affecting the shoulders first, then descending into the upper arms, then to the lower arms, thighs, calves, and so on.

Botulism poisoning can also cause paralysis of the breathing muscles and this can result in death unless assistance with breathing such as mechanical ventilation is provided. So our advice to consumers are if they have any of these products, or any food made from these products, they should discard them, throw them away immediately.

And the way that we're recommending doing this, and this is on the CDC Web site, is to double-bag the can in plastic bags that are tightly closed and then place them in a trash receptacle for non-recyclable trash outside the home. As part of the recall, the product should no longer be found on retailer shelves.

So we're trying to get to the retailers as well, to make sure they are pulling these products. Retailers that have any of these products are asked to remove them from use and do not accidentally get them re-introduced for sale, service or donation, so they should be marked appropriately so they don't make it back into re-stocking.

Castleberry's is working closely with FDA and USDA and CDC to determine the source of the contamination and as more information comes in, we will make that available. And my colleague here wanted to make sure that we became aware of the botulism cases on July 18. I may have misstated that and informed the public later that day.

And so with that, I will end and turn this back to (Rob) Ali.

Robert Ali: Thank you very much, Dr. Brackett. At this time, Dr. Kenneth Peterson from the Food Safety Inspection Service will have a brief statement.

Kenneth Peterson: Thank you. Again, good afternoon everybody. As you just heard, but the FDA and USDA did an initial recall last week on Wednesday and Thursday and then subsequent investigations by the Agency identified that this problem processing-related problem at Castleberry Foods in Augusta, Georgia, had been going on longer than we had first anticipated, and so both agencies expanded the recall this past Saturday.

Both USDA and FDA are working closely together coordinating our activities to ensure that the public health is protected. The reason that both agencies are involved is that this facility is what we call a dual jurisdiction establishment meaning on certain days, they produce FDA-related product under their authority, and on other days of the week, they produce meat-related items

under USDA authority. So both agencies share responsibilities for regulatory activities in this plant.

A couple of things to emphasize, consumers again are urged not to eat, not to open these cans, and they are to destroy the product. We strongly encourage consumers to physically check their homes and cupboards to be sure that they do not have any of this product on their shelves. We think it's important to actually look, so that another member of the household doesn't inadvertently come across the product and consume it.

For the meat-related products, and here we're largely talking about chilies and various corn beefs, hash products, there's approximately 75 products, each of the meat-related ones has a USDA seal of inspection on that label that says within that establishment EST 195.

The complete list of products is on the meat-related products is on the USDA Web site, and that is ffis -- Food Safety and Inspection Service -- ffis.usda.gov. It's also important that consumers go to that Web site to find the specific items, but essentially it's all items from this firm that may still be in commerce.

And the FDA Web site, as we suggested also, there's coordination between the two Web sites. There's two different listings; there's an FDA listing; there's a USDA listing. The citations are coordinated, but the consumers do have to go to one or the other.

Then our efforts here at USDA at this point are focused on identifying the actual product distribution and ensuring that through our recall checks the products have been removed from store shelves so that it is no longer available to consumers.

With that, I'll turn it back to the Moderator.

Robert Ali: Thank you, Dr. Peterson. At this time, David Elder from the FDA's Office of Regulatory Affairs, Office of Enforcement, will have a brief recap of enforcement actions taken to date.

David Elder: Thank you, (Rob) and good afternoon, everybody. Castleberry's initiated their initial recall on July 18 and expanded it on July 21. Their efforts thus far have included issuance of two press releases placing phone calls to major distributors followed by emails and issuance of recall letters. The firm has also contracted with the third party to assist in the coordination and the execution of this recall which includes their plans to visit several thousand retail locations across the country to ensure that the products are removed from store shelves.

Production has ceased. Products are on hold. They will not be distributed and production will not resume until FDA is satisfied that all conditions that resulted in this recall and these dangerous products have been corrected.

In a recall of this magnitude and of this importance, immediate communication of recall notices and action pursuant to them, it is imperative to support food safety. USDA, FDA and our state regulatory counterparts are collaborating on recall audit checks to visit retail locations and distribution points to ensure that recall notices have been received, that appropriate action has been taken to remove product from distributions, chains, and to remove product from retail store shelves.

All affected products must be off store shelves now. It is imperative for public health that retailers support these actions to remove product from store

shelves and it's imperative that consumers are made aware of products that could hurt them.

We appreciate any efforts that the media can do to help communicate this urgent public health matter and that is the principle purpose of this phone call today and we do appreciate your support. These products can hurt people and they have to be off the store shelves and consumers have to discard any that they have at home. And that's all I have for now, (Rob), thank you.

Robert Ali: Thank you, Captain Elder. At this time, before we get ready to take Q&A, just wanted to remind folks that there are several recent press releases on both fda.gov and ffis.usda.gov, the most recent being from Saturday evening and then one from last week.

As we get ready to take over the questions, we'd just like to ask people to state their name and their affiliation and to do your best to withhold it to one question and one follow-up so we have ample time for your colleagues to ask their questions. Operator, we'll take the first question.

Operator: Thank you. Just as a reminder, if you would like to ask a question, press star 1 on your touchtone phone. Our first question comes from Elizabeth Weise from USA Today. You may ask your question.

Elizabeth Weise: Yeah, thanks for taking my call. Two questions. First, Dr. Elder, you said in a recall of this magnitude; how large is this? How many bottles or cans are we talking about and can we break that down between the chili sauce and all the other things?

David Elder: Hi, Elizabeth, it's David Elder, not Dr. Elder.

Elizabeth Weise: Oh, David Elder. I apologize.

David Elder: It's a compliment, I guess. We're still gathering distribution information, and our focus thus far has been on assuring that the recall is communicated effectively, that distributors and retailers are removing the product from the store shelves and we're making many efforts, including this call today, to alert consumers to remove the product from their shelves, as well as to discard any product that they may have made from this product as an ingredient.

So we don't have exact volume figures on the product produced during this timeframe, although we can say that it's very high. This is a very big recall.

Elizabeth Weise: When you say -- I'm just trying to get some sense of -- I mean is it bigger than the pet food recall?

David Elder: I don't have those comparative figures for you, but we have seen that this firm produces perhaps more than 10,000 cases of product per day. And the product typically has a two-year expiration date and all sale by dates are involved in this recall for these products. So it's a lot of product; it's just hard to put a real good estimate on it for you.

Elizabeth Weise: Thanks.

Robert Ali: Thank you, Elizabeth. Operator, next question, please.

Operator: Our next question comes from Kevin Freking. You may ask your question and please state your organization.

Kevin Freking: This is Kevin Freking with the Associated Press. The company said this morning that some 16 cans from a sample tested positive for having the

botulism toxin. Could you tell us where those cans were located, where they came from?

David Elder: Yes, this is David Elder. Those cans were collected by FDA at the firm's warehouse in Georgia.

Kevin Freking: Does it say anything at all about how much could be out on store shelves?

(David Elder): Well, we hope that all the products are off the store shelves right now. All the products are subject to the recall. I don't know that that testing necessarily correlates to how much product may be on store shelves.

(Bob Brackett): This is (Bob Brackett). This is, I think, one of the main purposes of this call is we really want to get the word out to even smaller retailers that might not have been aware that the products were on the store shelves, as well as the consumers who may still have these in their home.

There's no way to really know how much is left on the store shelves, but our goal is to get it all off.

(Kevin): Thank you.

Dr. (Peterson): This is Dr. (Peterson) with the USDA. Most of these cans are - in fact, virtually all of them are really consumer size cans; 10 ounce cans, 12 ounce cans, 15 ounce cans and so the distribution can be to of course the large grocery chains, but down to very small retail outlets.

And so given this volume of cans, as Dr. (Brackett) indicated, it is critical that both retailers and consumers actually go check both their storage areas and

their shelves to be certain that this product has been removed from the shelves, but they're consumer size cans.

Man: Thank you. Any follow up (Kevin)?

(Kevin): No, thank you very much.

Man: Operator, we'll take the next question, please.

Operator: Our next question comes from (Rick Weiss). You may ask your question and please state your organization.

(Rick Weiss): Hi, it's (Rick Weiss) at the Washington Post. With all due respect and I'm sure we in the media are happy to get the word out as best we can about this, but I really don't think you folks are being as forthcoming as you could be with regard to the scale of this problem.

You must have a sense of roughly how many days or weeks production was going on that might have been at risk and in order of magnitude, at least, of the number of cans or jars of this product that are out there. And I'm not clear why you're not willing to give us at least an estimate with the recognition that of course it's not an exact number.

And when we're asking you about what's out there, of course, you hope it's all off the shelf, but the question obviously is not what's on the shelf, but what went out to the marketplace.

(Bob Brackett): This is (Bob Brackett) and I'll let Dr. (Peterson) comment, as well, with respect to total amount. I mean, if you just do the math on what the production over a (three)-year period of time, the fact that there are 10,000

cases - or over 10,000 cases a day and if you estimate 24 cans, you're talking about tens of millions of cans that may have been involved.

That doesn't mean that's how many are still out on the shelves, but that's sort of the scale.

(Rick Weiss): Thank you.

Dr. (Peterson): Yeah, Dr. (Peterson), and so the scope, I think as we suggested in the press release, is going back two years, so 104 weeks of production which is aggregate as was just suggested, millions and millions of cans.

I guess part of the thrust here is given kind of the size of the cans and we've all probably seen them at some point or another, we just think this distribution will be unusually large; school - not schools but small retail outlets or church kitchens, just places that may have this for a variety of reason to serve a variety of customers. So that's really the point.

I appreciate the difficulty you have to get the word out, we just think given the nature of this illness, it's just important to try to give it another effort.

Man: Thank you, Dr. (Peterson). (Rick), any follow up?

(Rick Weiss): No, that's good for now, thanks.

Man: Operator, next question please.

Operator: Our next question comes from (Elizabeth Lee). You may ask your question and please state your organization.

(Elizabeth Lee): Hi, it's (Elizabeth) with the Atlanta Journal Constitution. A two-part question, first I wanted to clarify if everything from the plant was taking off or just from the one production line as the Castleberry's people said this morning, but following up on that, is the FDA testing other products from this plant to look for botulism toxin or was it just hot dog chili sauce that you've run the test on these 17 cans?

(David Elder): This is (David Elder). Our investigation is going to be comprehensive. I can assure you of that. Thus far, we have test results on 17 cans and 16 of which were found positive for the botulism toxin.

I haven't been in the plant, myself, but I understand that the recall is associated with products produced on a certain bank of retorts. It's hard to characterize it any more than that from my position here.

Dr. (Peterson): This is Dr. (Peterson). That's correct. There's a (unintelligible) bank of retorts, of course, you wouldn't know what that is, but all of the products that are listed are from that particular bank. And so the specific products that are listed happen to be associated with the individual retort which is basically a processing at the pressure processing facility.

So you can think of it as a production line. So all of the products listed are from that line. The firm does produce other products in bigger cans or perhaps the same size can, those are not subject to the recall, and so the products listed are all of those that are produced on these lines going back for the shelf life which is two years.

Man: Thank you ma'am. Did you have a follow-up?

(Elizabeth Lee): No, unless someone wants to address, you know 16 out of 17 sounds to me as a pretty huge number. Can you put that into perspective and let you mind - expect to sound in this case, that level of contamination?

(David Elder): Well, those were - I can tell the 17 cans that were collected were collected because they exhibited signs of potential contamination in that they appeared to be swollen. So it wasn't a strictly random sample. It was a targeted sample based on products that looked suspect.

(Elizabeth Lee): Okay. Who is speaking, I'm sorry?

(David Elder): That was (David Elder), again.

(Elizabeth Lee): Okay. Thank you so much.

(David Elder): Sure.

Man: Operator, next question, please.

Operator: The next question comes from (Deidre Henderson). You may ask your question.

(Deidre Henderson): Hi. Thanks for taking my question, and I'm sorry if you've covered this in an earlier call. Four cases of botulism have been reported; two from Indiana and two from Texas, our four people consumed this hot dog chili sauce original. Do you have any sense of the timing of the production of that sauce? Is it earlier in the two-year frame or later in the two-year frame?

Man: Could you repeat your question, please?

(Deidre Henderson): Sure, I'm trying to get a sense of whether these two people in Indiana and two people in Texas reached into the cupboard for hot chili sauce that they had sitting around for a few months or did they just buy this?

Man: (Bob), I think they're getting at the estimated production data associated with the illnesses.

(Bob Brackett) Yeah, and both of those, and I'll ask Dr. (Lynch) to talk about this, too. Both of those cases were produced in the same production dates.

(Deidre Henderson): Do you have those dates?

(Bob Brackett): That was I believe May 8 production date. Is that not right, (Mike)?

(Mike Lynch): Yes, late May - late in the day May 7 and early in the day on May 8 it would be.

(Deidre Henderson): So all four of those chili sauces that implicated in human illness?

(Mike Lynch): Yes.

(Deidre Henderson): Okay, and then my second question is with the dramatic symptoms associated with botulism, if there were problems with previous product, would you have seen a spike or did you check with CDC to see if they saw a spike?

Man: Dr. (Lynch), if you're on the line, can you address that please?

(Mike Lynch): Yes, we had not seen any other cases associated with this product before the four that have been recently identified. We actually did go back and look back at other recent cases of botulism that have been reported to see if there

could be any connection to this product. And so far we have not identified any earlier cases that should be connected to this product.

(Deidre Henderson): Thank you. Who was that please?

(Mike Lynch): This is Dr. (Michael Lynch) from the CDC.

(Deidre Henderson): Thank you very much.

Man: Thanks (Deidre). Operator, next question please.

Operator: Our next question comes from (Dawn Helf). You may ask your question and please state your organization.

(Dawn Helf): Salt Lake Tribune. Can you give us any more specific information on where the products were shipped? There's 80 different products consumers are supposed to go through. Can you give any indication or specifics on, say, the chili or the pet food where it might have been shipped?

(Bob Brackett): This is (Bob Brackett) from the FDA. We're trying to track down the specific distribution records now, but we can say that we view this as a nationwide recall that all states would be involved in this at this point.

(Dawn Helf): Do you have - and that's all the information you can give? Is there anything particular to the West? The purpose of my question is we've only found one or two products in the distribution center here so far.

(Bob Brackett): Still - and (David Elder) could be able to talk more to this, too. We have not gotten any more specific information. We have requested that information from the firm and we are going to be tracking that down to get a better view.

But as Dr. (Peterson) mentioned, at this point, we just want to let everyone know to get rid of it.

(Dawn Helf): Thank you.

Man: Operator, next question, please.

Operator: Our next question comes from (Lori Young). You may ask your question and please state your organization.

(Lori Young): Yes, this is (Lori Young) from the Augusta Chronicle. I'm just wondering a couple of things. One, I'm wondering - I wanted to clarify that you-all said you think you would know by the end of the week whether in fact it was the August plant, and also if you - I know you mentioned it was comprehensive testing, but I wanted to clarify. I assume that means you were testing things other than the hot dog chili to see if they have the same problems as the hot dog chili?

(David Elder): This is (David Elder). We do expect - when I mentioned the 16 out of 17 positive test results, that was on a screening method that we consider to be reliable, but we do have a confirmatory test that we expect the results from at the end of this week.

Your question specifically said whether or not it was the Augusta plant, and the Augusta plant has seized production and has recalled all of these products within a two-year expiration date.

Our investigation will continue to ensure that we have identified the root cause and to ensure that appropriate corrective action is taken before any production resumes in that plant.

Did I address your two questions or did you have another in there?

(Dawn Helf): Well, mainly I just wanted to double check when you'll know for certain because it's certainly shut down here. But the other thing is are you testing more than just the hot dog chili or are you testing things like the hash and other things that were recalled, as well?

(David Elder): I'll defer to Dr. (Peterson) for any testing of products to fall under the USDA's jurisdiction, but FDA testing is focused on the hot dog chili sauce so far, and additional samples, I'm sure, will be collected and analyzed as part of this investigation.

But our immediate efforts and purpose of this call, again, is to seek your support and to take any steps that we can take to ensure that the communication of this recall is as effective as it can possibly be to prevent any more injuries from this product.

Dr. (Peterson): This is Dr. (Peterson) with USDA. We're not doing any specific testing on these products really for the - and it's typically what we do. Once the recall is initiated, the decision has already been made that we believe that product in this case is unsafe.

And so committing resources for additional testing doesn't provide us much information. We already believe that it may be contaminated and so we've given the window of concern and we're just focusing on getting the product

identifying where it went and obviously the purpose of this call to get the word out.

Man: Thank you very much. Operator, next question please.

Operator: Our next question comes from (Barbara Kardeen). You may ask your question and please state your organization.

Ma'am, please check your mute feature. Your line is open.

Man: Operator, we can go back to that person. Next question, please.

Operator: Our next question comes from (John Workasen). You may ask your question and please state your organization.

(John Workasen): FDA Week. The 16 cans that tested positive, were those also processed May 7 and May 8.

(David Elder): Yes, they were in that timeframe.

(John Workasen): And which FDA labs tested these products?

(David Elder): That was from our - I'm checking. I believe it was our Arkansas laboratory, as well as our Atlanta laboratory.

(John Workasen): Atlanta, you said?

(David Elder): I said Arkansas and Atlanta.

(John Workasen): Okay, thank you.

Man: Thanks (John). Operator, next question please.

Operator: Our next question comes from (Tommy Pew) you may ask the question and please state your organization.

(Tommy Pew): Thank you, I'm with (McClanche) Newspapers. I was hoping one of you gentlemen could tell me about the conditions of the four people who were injured and whether they are all hospitalized at this time.

(Mike Lynch): This is (Mike Lynch) from CDC the four patients were all hospitalized and they are seriously ill but I defer further questions about their condition to the State Health Department or their clinicians caring for them.

Man: Thank you Dr. Lynch any other follow-ups sir?

(Tommy Pew): No thank you.

Man: Operator our next question please.

Operator: Thank you our next question comes from (Elizabeth Weiss) you may ask your question and please state our organization.

(Elizabeth Weiss): Yes, hi (Elizabeth Weiss) with USA Today again a quick follow-up when you say 10s of billions of cans of product produced over the two year period do you mean just the chili sauce or do you mean the chili sauce, the meat products and the dog food?

Man: That would be the combined products of all the identified products it's not bracketed.

(Elizabeth Weiss): Okay and I am presuming that it's not that there is new information out for this call but it sounds like this is a really big recall and you the press really didn't pick up on that first and you want to make sure we get the word out am I reading that correctly?

(Bob Bracket): This is (Bob Bracket) that's exactly right. We were first notified of course about the more limited recall last Wednesday night on the 18th and then we also had a media call on Saturday and just in our own checking around we found that many consumers and, in fact, many of the retailers still had not really heard about this. And considering the scope and size of it and considering the you know how dangerous botulism is we wanted to make sure that we went the extra effort to make sure we communicated as thoroughly as possible to consumers and to retailers this message.

(David Elder): This is (David Elder) if I could add to that by just pointing out that our efforts to communicate this through this process are complimented by the efforts of FDA investigators, USDA inspectors and our counterparts at many state and local health agencies. We will be visiting hundreds or thousands of retailers ourselves to assure the effectiveness of this recall and to ensure that any affected products that may still be on store shelves is pulled. We are just trying to make every effort humanly possible to communicate this in the most effective and timely way as possible because as Dr. (Bracket) had mentioned the scope of the recall and the severity of the consequences if someone consumes these products.

(Elizabeth Weiss): Can I ask just a quick follow-up? My understanding with botulism is that there are free floating spores that exist pretty much anywhere in the atmosphere so it's not that this one plant would have been contaminated with

botulism because they are everywhere but somehow these researchers weren't reaching the correct temperature to properly kill it off?

(Bob Bracket): That's true. The botulism spores are sort of ubiquitous in nature. There are not a lot of them around. The reason why the certain times and temperatures are used to can foods is specifically to kill the botulinum spores. If something happens to either cause under processing where they don't get the time and temperature or if they are subsequently contaminated after processing such as if there is a leak in the seam it's possible that the untreated spores can get back either into the cans or the ones that were left there and didn't get killed can outgrow.

This organism grows in anaerobic conditions that is in situations where there is an absence of oxygen much as you do see in a canned food and that's typically where we see these. On side two with commercially canned foods this is exceedingly rare.

Dr. (Peterson): This is Dr. (Peterson) and just one add on and so what Dr. (Bracket) said about the toxin is important which is why we're telling consumers to discard the product because being a toxin is really no amount of heat that a consumer could deliver that would inactivate the toxin so you can't kind of cook it at home and make it safe and so discarding it is your only option.

Man: Thank you, operator next question please.

Operator: Thank you. Just as a reminder if you would like to ask a question please press star one on your touch-tone phone. Our next question comes from (Sandra Young) you may ask your question and please state your organization.

(Sandra Young): Yes hi, thanks for taking my call. I wanted to know you said that if anybody at home has these products throw it away immediately, double bag them in plastic bags and take them outside of your home. I wanted somebody to kind of explain and walk us through why something like that is necessary, the double bagging. Why can't you just throw them away? Are you afraid that if the cans are punctured during the recycle process, the trash recycling process it could get in the air? What's the significance of the double bagging? Get it outside of your home if it's in a sealed can?

(Bob Bracket): This is (Bob Bracket) I guess the idea here is for the same reason one might double bag toiletries when you are going through an airport. There is a chance that the pressure can cause leakage. That leakage could have the toxin in there and this toxin can actually make someone ill if it is breathed in, that if its aerosolized much as one would have if a can were ruptured or if it happens to get on one's skin. It gets through a break in the skin so it's just really an extra measure of caution to make sure that no body, not even the handlers in the kitchen but somebody who might be picking up the trash outside might get this on them.

(Sandra Young): Thank you.

Man: Thank you (Sandra) any follow-up? Operator next question please.

Operator: Thank you our next question comes from (Rick Weiss) you may ask your question and please state your organization.

(Rick Weiss): Hi the Washington Post. Thanks for the follow-up. Two quick questions, one from the CDC prevention can you tell us anything about the background in terms of number of cases of botulism you normally see in a year and so that we understand what you're comparing these four cases to and how many

others you might be trying to find links to so far. And secondly to the FDA folks can you say something about whether you are satisfied so far with the record keeping of the company in terms of your ability to figure out where this stuff went? I know you're not done doing it yet but does it look like everything's in order? You're going to be able to get those answers in a reasonable amount of time?

(Mike Lynch): Hi this is (Mike Lynch) from CDC and I guess I can answer the first question. We see about 25 cases of food born botulism reported to CDC each year and almost all of them are due to home-canned food. Occasionally they are due to foods that might be mishandled at home and the point was made a few minutes ago that the occurrence due to the outbreak of a commercially canned food is extremely rare. We haven't seen that in over 30 years in the US. And we conduct surveillance for botulism cases through our state and local health departments. If clinicians expect botulism in a patient that they are seeing they call the state and local health department who calls us for consultation and for release and administration of anti-toxin if it's deemed necessary so that is how we are monitoring for reports of new cases and we haven't seen any cases reported since these cases that could be related to the outbreak but we continue to monitor for new cases like that.

(Rick Weiss): Thank you.

Man: Thank you (Rick) operator next question.

(Rick Weiss): And with regard to the distribution question?

Man: Yes (Rick) go ahead.

(Rick Weiss): I'm sorry I had a second question for someone at FDA regarding the distribution records from the company.

Man: (David Elder) can address that quickly.

(David Elder): Sure (Rick) this is (David Elder). We are in the plant, we're working closely with the FDA and the State of Georgia to – I'm sorry I said we're working closely with FDA, we are FDA – we're working closely with our counterparts at USDA, FSIS and State of Georgia Department of Agriculture to conduct this inspection.

The recall is actually being administered out of the corporate head quarters. Bumble Bee is the owner of the Castle Berrys and they are located in San Diego so our Los Angeles district office is monitoring and coordinating the recall efforts with Bumble Bee is actually initiating the recall. So we're active trying to conduct the inspection, observe the operations, account for the recall and we have a lot of record demands into the company and we are working with them to get the records that we need as quickly as possible and as quickly as we need them. So our need is certainly there and we are trying to get them as quickly as we can.

(Rick Weiss): It sounds like you don't have them yet.

(David Elder): You know we're working on it.

Man: Thanks (Rick) operator next question please.

(Rick Weiss): You mean you are working on getting them?

(David Weiss): I can't say we have none, I can't say we have all. There is a lot of records that we need. We're reviewing what we have and we are certainly going to have more and more requests for records coming in because we need to be absolutely sure as the investigation proceeds that we are being as comprehensive as possible which you know requires quite a bit of record review.

Man: (Rick) you all set?

(Rick Weiss): Yes.

Man: Operator next question.

Operator: And that question comes from (John Wilkerson) you may ask your question and please state your organization.

(John Wilkerson): FDA Week thanks for taking a second call from me. Were all the products that tested positive were they all FDA regulated?

(David Elder): Hi this is (David Elder) again yes. Those that were collected by FDA at the warehouse were FDA regulated products.

(John Wilkerson): Okay and when was the last time that that production facility had been inspected?

(David Elder): It was earlier this year, February 2007.

(John Wilkerson): Thank you.

Man: Thanks John, operator.

(David Elder): By FDA I defer to USDA to discuss when they may have inspected.

(John Wilkerson): Okay.

Dr. (Peterson): This is Dr. (Peterson) with USDA. As I suggested at the top when they're doing the USDA regulated products, the meat related products we have an inspector that would visit that plant on that day of production checking to see that their production is as it should be. The actual processing flaw is something that FDA's part of the investigation.

But the actual processing error by the plant is not something that you could just, the casual person could observe and they had to run some tests to kind of figure out the FDA theory on what actually happened. But when they're actually operating the USDA inspection would be in the plant on that particular day and so they do the USDA product one or two days a week on an ongoing basis and so we would be there when they do that product.

(John Wilkerson): Thank you.

Man: Thank you Dr. (Peterson) at this time we'll ask for one last question if there's anybody that has one more question. Anybody we haven't taken yet?

Operator: Yes, we have a question from (Julie Schmidt).

Man: Go ahead and take the question please.

Operator: One moment.

Man: Operator then that concludes this portion of the briefing. We thank everyone who joined us today especially those who were very patient as we arranged another time and another call-in number. I certainly appreciate your patience as we worked through the technical difficulties of getting you that information.

There will be a replay of this. It will be posted in about an hour and it will be up for about three days. That number is 1-800-695-4244, 1-800-695-4244 and that's the replay number. As you come up with any follow-up questions please don't hesitate to call the respective agencies press offices and those numbers are available on the releases that are up on the Web sites. Again those Web sites are FDA.GOV, FSIS.USDA.GOV, and the press office phone numbers are on those releases. Thanks again for your interest in this incident and this press conference thanks and have a great rest of the day.

Operator: That concludes today's conference call thank you for your participation you may disconnect at this time.

END