Transcript of FDA Press Conference on the Pet Food Recall March 20, 2007

FTS-HHS FDA

Moderator: Cathy McDermott March 20, 2007 3:30 pm CT

Coordinator: Good afternoon and welcome to the Pet Food Recall Conference Call.

All lines will be in a listen-only mode until the question and answer session. At that time, you may press star-1 to ask a question.

At the request of the company, today's conference is being recorded.

I would now like to introduce today's conference host, Ms. Cathy McDermott.

Ma'am, you may begin.

Cathy McDermott: Thank you, (Rosie).

This is Cathy McDermott with the Office of Public Affairs at the Food and Drug Administration, and welcome to our call.

This is a media telecon of an FDA update on the recall of pet food manufactured by Menu Foods. This will be a 30-minute call. If you would like to ask a question, please state your name and affiliation. Today, our speakers will be Dr. Stephen Sundlof who is the Director for FDA Center of Medicine, Mr. Daniel McChesney, the Director of the Office of Surveillance and Compliance at the Center for Veterinary Medicine at the FDA, and Mr. David Elder, the Director of the Office of Enforcement for FDA's Office of Regulatory Affairs.

At this point, we will turn it over to Dr. Sundlof.

Would you like to make an opening statement doctor or just go into questions and answers?

Stephen Sundlof: Thank you, Cathy.

I will make an opening statement just to let folks know that we don't have a lot of new information today. I will tell you what we know.

One of the things I want to state right upfront is that we really appreciate the effect that the media has had in getting this message out to consumers. We are receiving -- the FDA is receiving -- lots of telephone calls and I think that this really helps us prevent any further losses of animal lives as a result of consumers recognizing that there is a potential hazard if they are feeding any of these products.

So, just to recap, on Friday, Menu Foods Incorporated, a private-labeled pet food manufacturer based in Streetsville, Ontario, Canada recalled its cuts and gravy style dog and cat food produced at its facility in Emporia, Kansas and then also its plant in New Jersey.

The recall was prompted by consumer complaints received by the manufacturers and by routine tasting trials conducted by the manufacturers

where some cats and dogs developed kidney failure after eating these infected products.

To date, we are aware of 14 deaths that have been confirmed and all of these information comes from the firm Menu Foods.

One dog and 13 cats have been reported so far and let me break that down for you. Nine of the cats were from the company's tasting trials, no dogs in the tasting trials died, four cats belonging to individual consumers have died that we are aware of and one dog from a consumer that we are aware of. So in total, our total number that we have confirmed is 14.

We are receiving many calls from consumers. We have not had the chance to confirm those yet so this is not our primary concern right now, but we are taking all of those calls in trying to get as much information as possible from them.

Right now, we are really focusing on the recall and trying to find the potential substance or substances that were responsible for causing illnesses and deaths in cats and dogs.

FDA is doing everything possible to identify the cause and extent of the problems and as quickly as possible, including obtaining samples that we know were implicated in some of these cases of illness and deaths and reviewing the manufacturing process that the company uses to produce the pet food.

The company suspects that the problem still maybe linked to a shipment of wheat gluten since it change in a wheat gluten supplier was the only change to the manufacturing process that coincides with the reported death. As part of the ongoing investigation, FDA is looking at all possible contaminants, not just the wheat gluten but including the wheat gluten and we are screening for substances that we know to be toxic to the kidney. Analysis is ongoing however and at this point, we have no firm leads.

We are also working backward from Menu plants looking at sources - all the sources of wheat gluten that were shipped to the company's Kansas City and New Jersey plant. So we are trying to trace all of the wheat gluten that was used by Menu Foods in their Kansas City and New Jersey plants.

And once again, Menu Foods has identified the potentially contaminated products on the Internet and that number that the - the URL is www.menufoods.com/recall. And consumers who have any of these products to immediately stop feeding them to their pets and return any unopened products to the place of purchase.

Now, based on the information that we currently have, the problem is limited to those products identified by the Menu Foods in the recall and - however, the investigation is still ongoing and if we find that the problem is broader, we will get that information to you as quickly as possible.

And I will conclude my remarks there just to reiterate so that consumers should look for clinical signs in their clinical - signs in their animals, kidney failure such as loss of appetite, lethargy, and vomiting and should consult their veterinarian immediately if they are demonstrating any of these signs.

So with that, I will open the phones for questions.

Coordinator: Thank you.

At this time, we're ready to begin the Q &A session.

If you would like to ask a question, please press star-1. To cancel your question, you may press star-2. Once again, that is star-1 to ask a question.

Our first question comes from Carrie Peyton Dahlberg of Sacramento Bee Newspaper.

Carrie Peyton Dahlberg: Yeah. I wonder if you could clarify I think yesterday's - there were reports that animals in the testing center, they have died. Was there some animal other than a cat or dog?

Stephen Sundlof: No. We originally told ten animals. We have done some further clarification on that and our - as we understand it now, that there were no dogs that died in the taste testing that the company was performing. There were nine cats that died in those case trials.

> As I understand, just for information, that those were routine palatability testing that the company does which they do - they conduct every quarter so there may even some confusion that that might even in response to consumer complaints and our understanding is that that was routine taste testing studies that the company performs.

So again in that, there was - let me just tell you the total numbers of animals involved. There were, as I understand it, there were 25 cats and 15 dogs that were in those taste trials. And of those, ten cats died as the result of the - presumably of the food. No dogs died in those trials.

There were an additional four - there were additional five animals, four cats and one dog, that were consumer-owned animals, a privately-owned animal that the company has indicated have died presumably from the pet food.

Carrie Peyton Dahlberg: Great. Thanks. And could I just follow up quickly? What in wheat gluten can damage the kidney?

Stephen Sundlof: Well, this is where we - our - what we are trying to find out because wheat gluten itself, we don't know generally associate with any kind of food contamination or food issues.

So, in likelihood, it may - you know, one of the things we're looking at are toxins that are produced by molds that potentially could contaminate wheat gluten although generally not thought as a primarily source of those mold toxins, or it might - the product might have gotten contaminated by a chemical or some other substance.

And right now, we are looking at a number of suspects. So far we have not found anything that popped up as - would have - we would have thought that would have been in there that might have caused this disease.

Carrie Peyton Dahlberg: Okay. Thank you very much.

Coordinator: Our next question comes from Abigail Goldman of Los Angeles Times.

Abigail Goldman: Good afternoon.

I have a couple of questions. First of all, can you tell us how many calls you have gotten to your hotline, FDA Hotline numbers, from consumers?

Stephen Sundlof: Yeah. We don't know the number. Again, we have various districts around the state. We've been touching base with them. There are quite a few calls coming in. They're being logged in right now and so we don't really have good numbers or any numbers that I can report at this time.

Abigail Goldman: And awful clarification again on these testings. You have originally said nine animals died as a result of the palatability test and I believe what I just heard you say was ten cats died so I just want to make sure we've got these numbers correct.

Stephen Sundlof: Okay.

Abigail Goldman: And then can you also comment on whether this is standard procedure that companies do these sorts of taste tests that can result in animal dying? And then lastly why there was a delay between those animals dying based on yesterday timeline that you gave us? Why there was a delay between those animals dying and these products being pulled off the shelf?

Stephen Sundlof: Okay. Let me clarify the numbers first of all.

There were nine - the nine animals are nine cats and those nine cats were in the tasting trial. There were an additional four cats that we're aware of by virtue of the company reporting that belong to consumers and one dog that was a, you know, consumer-owned dog.

In terms of the tasting trials, I'm not aware. I don't really know whether other companies do this. I'm assuming that this is probably routinely done. It's not to test whether or not dogs developed toxic signs or become sick from the food; it's to determine whether the dogs like the taste of the food. It's - before, I believe, as I understand that the companies do this quarterly tasting trials in order to make sure that their products are palatable when they put them out in the market so that they will have a high quality product that dogs want to eat or cats want to eat when they purchase - when the consumer purchases the product.

It doesn't have anything to do - as I understand, it was not intended to be looking for adverse effects but they - in this case, they observed those as a result of feeding this food.

And I don't - you know, I can't really comment about the delay between the time that they learned of this and they introduce the recall. I can just tell you that we were - the FDA was alerted last Thursday evening.

Next question.

Coordinator: Thank you.

Our next question comes from (Susan Shanahad) from the People Magazine

- (Susan Shanahad):Hi. I was just wondering and you may not know this yet, of this I'm assuming thousands of phone calls that are coming into these FDA Call Centers. Do we know if there are other animal fatalities or are these just worried consumers or do they have sick cats, do we know yet? If there maybe other substantial death tolls within those calls?
- Stephen Sundlof: Well, we know that some of them are complaints of deaths but I don't have the number around that. We do know also that there are some complaints that are coming from products that are not on the recall list.

So we're getting a variety of people that they're - again this has been an issue that people have really responded to and so we are in the process of trying to sort through all of those calls.

Certainly, where we have the information from veterinarians, we are trying to obtain additional information for instance on the clinical work up or if the animal dies, if there is an autopsy, we want information on that.

- (Susan Shanahad): As a follow up, I'm just wondering is there any way to tell yet how quickly these symptoms may appear. If you fed your animal this food two weeks or a month ago and they seem to be fine, are they okay? You know, what exactly should consumers look for in terms of problems with their pets when they know they have a problem?
- Stephen Sundlof: Okay. Well, the thing that is indicative in all of these to my knowledge so far do involve kidney damage. And so, the normal clinical signs that are associated with kidney damage are loss of appetite, lethargy, the cat or the dog just not act formally, and vomiting and that may be accompanied by increased urination or an increase thirst, so any of those signs.

And we don't know - I mean, it's possible that signs could develop later on. Most of the signs that we - signs that we've been aware of seem to be - seem to occur within a few days of consuming the food but again there may be animals that developed clinical illness later on and any of those signs should be a signal to talk to their veterinarian.

(Susan Shanahad): Okay. And just one quick last question.

Cathy McDermott: Oh sorry. Excuse me, we need to move on in the next reporter. We have a number of people waiting in the queue.

Thank you.

(Rosie)?

Coordinator: Yes. Our next question comes from Matthew Philips of Newsweek.

Matthew Philips: Yes. Hi.

In its role of regulating the tested industry, does the FDA conducts regular inspections of pet food manufacturing facilities similar to the ones in the processing facilities that Menu Foods was operating in Kansas and New Jersey?

Stephen Sundlof: Hi. We - it's very much like the way that we inspect food plants.

Matthew Philips: Hello?

Stephen Sundlof: Yeah. We're having connection problems.

It's very much the same as how we regulate human food plants and that they are inspected, that it's generally based on risk, how risky the - we feel the facility is based on previous inspections and other things.

I'd like to maybe ask David Elder if he wants to add anything to that.

David Elder: Thank you, Dr. Sundlof.

As Dr. Sundlof pointed out, the inspection resources are prioritized based on risks and there is certainly a limited amount of resources in the animal drug and the feed program so we prioritize them based on the risk associated with the particular products being inspected being manufactured.

We do focus resources in the pre-approval program of animal drugs and animal drug inspections and inspections of companies that may feed that is medicated, that has medical ingredients in it. Certainly people know that we spend quite a bit of resources in the BSE program and quite an extent of our resources is spent on feed for food producing animals.

Inspections of manufacturers of companion animals is more and typically conducted on a forecast basis which basically means that we maybe following up on a consumer complaints or something like that. The routine surveillance inspection that manufacturers of food for companion animals is limited.

- Matthew Philips: When you say limited, how often are we talking about here like when was the last time that any of these processing plants were inspected by the FDA? Do you know that?
- David Elder I do know that the plant in Kansas City, the first time FDA visited that plant is in follow up to these consumer complaints.

Their plants in New Jersey districts in New Jersey, in Pennsauken, New Jersey has been inspected under FDA's BSE program.

Matthew Philips: And the last time that occurred was?

David Elder: Last year, I believe.

And we also have, you know, a partnership with our state agencies. We have a network of regulation in the human food area, in the animal food area, you know, across the board of regulated products.

So our state counterparts and local counterparts also do inspections of food being produced for animals as well as humans.

Cathy McDermott: Can we have the next question please?

Coordinator: Sure. Our next question comes from Janice Gin of Kron-TV.

Janice Gin:Hi there. Actually I had very similar questions about how pet food is
regulated. So you're saying the last inspection was from local forces last year?

- David Elder: I'm sorry. I don't think I said that. I said the last inspection was last year by FDA at the facility in New Jersey.
- Janice Gin: Okay. Then what about Kansas City?
- David Elder: I said that our inspection began as a follow up to this particular recall.

Janice Gin: Okay. And can you kind of tell me what basic procedures manufacturers are, you know, kind of - are they suppose to abide by?

David Elder: As Dr. Sundlof indicated, the manufacturing of pet food is, you know, similar in nature to the manufacturing of human food. We expect the manufacturers to comply with FDA's regulation to ensure that the food is wholesome.

Janice Gin: Okay. I'm sorry. Can you be a little bit more specific such as do you go in for testing? I know you said it's by consumer complaint but in...

David Elder:	I didn't mean to say that's the only reason we go in but in this companion - with manufacturers of food for companion animals, in the greater scheme of things, FDA prioritizes our resources based on risk and the risk of manufacturers of food for food-producing animals is greater than the overall risk associated with companion animals.
Janice Gin:	Okay. And are these companies
((Crosstalk))	
David Elder:	the consumer complaints but if some indication that an inspection is warranted.
Janice Gin:	Okay. Now, are these companies also supposed to have their own testing or inspection?
David Elder:	They are absolutely supposed to have their own quality assurance program so that the products that they make are wholesome and fit for consumption by animals.
Cathy McDermott: If we can move on to the next question.	
	Thank you.
Janice Gin:	Thank you.
Coordinator:	Thank you.

Our next question comes from (Anita Manning) of USA Today.

(Anita Manning): Hi. Thank you very much.

Can you tell me what other products are made in these plants other than dog and cat food?

Stephen Sundlof: It's my understanding that this plant only makes dog and cat food.

(Anita Manning): Okay. Thank you.

Stephen Sundlof: And I don't think they make any dry. I think they - my understanding is that that they only produce this moist - semi-moist - I guess, moist dog food and they are supposed to be producing that.

They are required to produce it under the regulations that deal with low acid canned foods so there is specific regulations that apply to this type of moist canned product and the product in the pouches treated similarly.

(Anita Manning): But then why did FDA look at that Pennsauken plant under its BSE program?

Stephen Sundlof: Because they are handling materials that are prohibited from feeding to certain ruminant animals and as a result of that, they have to, yeah, they have to label products appropriately. In one case - I think in not in the - was that the New Jersey plant?

Yeah.

In the New Jersey plant, they were producing a diet for zoo animals, in fact, the zoo cats. And we require that they label their product with a statement "Do not feed to cattle or other ruminants." So that was the reason for that inspection.

(Anita Manning): So it's not just companion dogs and cats, it's also zoo animals. I mean, I guess other kinds of canines and felines.

Stephen Sundlof: In that way, in the New Jersey plant apparently.

(Anita Manning): Just in the New Jersey. Okay. Thank you very much.

Coordinator: Thank you.

Our next question comes from (Jenny Sudamar) of New York Times.

(Jenny Sudamar): Hi. Thanks for taking my call.

Do you know yet who the suppliers of the wheat gluten is? Who else that the supplier may have supplied wheat foods?

Stephen Sundlof: What we are doing is - the answer is no. We know - you know, we have a name of a broker and the broker gets shipments from various places. We're trying to identify what all of the sources that came into that plant are; so we don't know at this point in time where all of the wheat gluten may have come from.

(Jenny Sudamar): Who is that broker and where is he or she and where did they get their shipments from the United States or Canada or where?

- Stephen Sundlof: Right now, we're not releasing that information. We're trying to work with that broker to try and find out where all of the shipments may have come from.
- (Jenny Sudamar): I mean, were the shipments were they are they international or are they (unintelligible)?

Stephen Sundlof: That's what we're trying to find out.

Next question.

Coordinator: Thank you.

Our next question comes from (Stephanie Roberts) in Phoenix.

(Stephanie Roberts): Yes. Could you tell me in the preparation of dry food, would this wheat gluten be used or that the preparation of dry food that would fill any toxin?

And also, would you spell your last name?

Stephen Sundlof: Okay. I'll start with the last question. It's S-U-N-D-L-O-F.

My understanding and folks you can correct me, but as I understood that the wheat gluten was used to make the gravy - to thicken the gravy in this particular product. And if that's that case, I know - I was told that it's not used in dry dog food.

Cathy McDermott: Next question please.

Coordinator: Thank you.

Our next question comes from (Kelly Ryans) of (WCMC-TV).

(Kelly Ryans): Most of my questions have been answered. The real thing that we're trying to get again is the piece that quantifies the number of calls particularly at your Atlanta Call Center.

Stephen Sundlof: I just don't have that information. I'm sorry.

- (Kelly Ryans): Okay. All right. Thank you.
- Coordinator: Thank you.

Our next question comes from (Dan Worhis) of (Wichita Eagle).

(Dan Worhis): Yeah. My question is about the plant. Is the plant still open? How have they changed production and have they had to do any kind of decontamination or anything like that?

Stephen Sundlof: I'm going to ask David Elder if he has any information on that.

David Elder: Sure, Dr. Sundlof.

The plant is in production. I guess there's certainly been a lot of discussion about the wheat gluten and the firm has changed their supplier of the wheat gluten.

However that theory is not being discounted by FDA but it's not being relied on solely as the theory too. Our investigation will pursue whatever avenues the fact point us to. But they are in production and the change that they made was changing the supplier of what they believe to be the cause of this, specifically the wheat gluten.

- (Dan Worhis): What if other troubles develop? Other complaints, I mean, you're still getting them.
- Stephen Sundlof: Now well, I mean, if we do get complaints that are still ongoing obviously, we will be investigating those but, you know, it's my understanding at this point that all of the complaints that been received so far have been within that timeframe that the recall is bounded by and that us up through March 6.
- (Dan Worhis): So, is it fair to say that well, let me just ask you. Have they done any kind of decontamination or any kind of cleaning of the equipment or anything like that?
- Stephen Sundlof: I don't have that information. Right now, we can certainly inquire and get back to folks tomorrow.
- (Dan Worhis): Thank you.
- Cathy McDermott: Next question please.
- Coordinator: Thank you.

Our next question comes from (Mac Gaffee) of Fox News.

(Mac Gaffee): Good afternoon.

I'm just trying to see this. Is the FDA giving a general guideline as to what pet owner should be feeding their pet cats and dogs? Should they be staying away from wet food altogether? That's a lot of calls that we're getting here is to whether they should just blanket switch to dry food?

Stephen Sundlof: Now, we are not giving out - we're not giving out advice. We think that their veterinarians should be the ones.

We have limited our concerns to those products listed in the recall and outside of that, we believe that the - any remaining pet food out there is safe.

- (Mac Gaffee): Thank you.
- Cathy McDermott: Next question.
- Coordinator: Thank you.

Our next question comes from (Connie Escobitar) with San Jose Mercury News.

- (Connie Escobitar): Yes. Can you tell me you didn't answer you didn't really clarify this question previously, answer to this question which is about how many deaths have you heard -- animal deaths -- that you heard of outside of the taste trials and the one or two others that you mentioned? I mean, could we be talking about dozens or hundreds across the U.S.?
- Stephen Sundlof: I really don't know the answer to that because I just, you know, been hearing that, you know, we've been receiving calls. Some of them include animals that they believe have died as a result of this food but I've not gotten any numbers myself.

(Connie Escobitar): Do you fear that is a pretty widespread number or pretty large number?

Stephen Sundlof: Yes. I mean, even one is too many and, you know, so again, our really - rather than trying to count the number right now, our main goal is ensure that the recall is effective and that consumers understand that if they have this product, they first of all need to discontinue feeding it and they need to be observing their pets closely. And if they demonstrate any of those signs, to seek veterinary advice immediately.

(Connie Escobitar): Okay.

Now you said Menu Foods is still on operation. Its plants are still producing product with a new supplier of wheat gluten, are these products out in the shelf now or will they soon be, you know?

Stephen Sundlof: I don't know. I mean, my - I don't know whether or not they are or not.

(Connie Escobitar): Okay. Okay.

Tell me now, were both the plants affected here by this possible wheat gluten contamination in New Jersey plant and the Kansas plant?

Stephen Sundlof: The products seem to be coming from the Kansas City plant. The reason that they - the New Jersey plant is included in the recall is because they received some of the wheat gluten that the Kansas City plant received.

> Now, here's what we know about that so far is that there was - there appears to be one shipment of wheat gluten that came from this supplier that has since been changed but that included many lots of wheat gluten.

And so, the Jersey plant didn't get all of the same - you know, they didn't get the - all of the same material that the Kansas City plant got. In other words, they may have gotten one or two lots but the Kansas City plant had, you know, received the whole shipment and that was many lots.

So, it appears at least at this point in time that there have not been any adverse events and again, we got to look at all of the information when it comes in. But it appears to be coming from products produced in the Kansas City plants and not the New Jersey plant.

- (Connie Escobitar): Okay. Can you tell me...
- Cathy McDermott: Excuse me. We have we need to move on.

(Rosie), we have time for one more question from someone else.

Is there another question?

Coordinator: Our next question comes from (Romana Hussein) of Chicago Sun Times.

(Romana Hussein): Hi. Good afternoon. I had a quick question.

The last time I checked, there are 40 brands of cat food and 51 brands of dog food that were on the recall list. Has that list changed at all? Have the numbers changed? Have there been more additions to list since it is last printed?

Stephen Sundlof: No. I believe the list is still the same.

(Romana Hussein): Thank you.

Cathy McDermott: Great. Thank you all for joining us today.

At this point, the media telecon will conclude. Please continue to access our Web site. We will provide updates as appropriate and if we - as we said yesterday, if another media telecon is appropriate for tomorrow, we will certainly send out an advisory as soon as possible.

Thank you for joining us.

Coordinator: Thank you for attending today's conference call. Have a nice day.

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