



U.S. Food and Drug Administration

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Transcript of FDA Press Conference on the Pet Food Recall

March 30, 2007

FTS-HHS FDA

Moderator: Julie Zawisza

March 30, 2007

8:30 am CT

Operator: Please continue to standby. The call will begin momentarily. Please standby.

Please continue to standby. The call will begin momentarily. Please standby. Also today's will be recorded. If you have any objections, you may disconnect. Again, please continue to standby. Thank you.

Please continue to standby. The call will begin momentarily. Please continue to standby. Thank you. And if you would like to ask a question during today's call, please press star 1. Again, that's star 1 to ask a question for today's conference. Please standby. Thank you.

Julie Zawisza: Ladies and gentlemen, welcome to the FDA media briefing on the recall of the Menu Foods pet food. We're delighted you could be here this morning and join us on the phone and in the audience to talk about the status of the pet food recall and the findings to date.

This morning, we have two speakers. They're Dr. Steven Sundlof who is the Director of FDA Center for Veterinary Medicine. And we have Dr. Donald Smith, Dean of the College of Veterinary Medicine with Cornell University.

Dr. Smith we're very – Dean Smith, we're very delighted that you could join us today on very short notice. He's a veterinarian and a board certified surgeon and a member of the National Academy of Practices.

We also have several FDA officials who will be available to answer your questions later on. We have David Elder who is the Director of our Office of Enforcement. And we have Neal Bataller who has not joined us yet but we hope to have him shortly from our Division of Compliance and Center for Veterinary Medicine and Michael Rogers, Director of our Office of Investigation.

After our speakers make their remarks and present their own findings today, then we will take your questions then and hope to answer your question.

At this time, I'd like to introduce our first speaker Dr. Sundlof.

Steven Sundlof: Thank you, Julie and good morning. I'd like to bring you up to date on the latest developments in the investigation to the cause of deaths and the illnesses in pets that have eaten food manufactured by Menu Foods.

FDA recognizes that pets are very important to the American people. As a veterinarian, the care of animals has been my life's work and many of the FDA people who have been involved in this investigation have pets and are concerned about their welfare.

This investigation has been a massive effort drawing from main parts of the FDA and beyond and involving thousands of professionals across the country. Menu Foods is cooperating as this investigation continues and others – and other companies have been cooperative and responsive to our request for information including their record.

We are announcing today that the FDA Laboratories have found a substance called melamine in samples of pet foods manufactured by Menu Foods and in the wheat gluten used as an ingredient in the pet food. Additionally, Cornell University scientists have found melamine in the urine and in one kidney of deceased cats that were part of the original case testing site.

Melamine is used as a fertilizer in Asia and also has several industrial and commercial uses including a component of kitchen utensils and plates. There's little information - scientific information - in scientific literature on melamine exposure in dogs and cats. So, it's very difficult to determine a level that would be harmful or lethal.

The association between melamine in the kidneys and urine of cats that died and the melamine that was in the food they consumed is undeniable. Additionally, melamine is an ingredient that should not be in pet food at any level.

However, I want to make it very clear at this point that we are not fully yet certain that melamine is the cause of patients' - of illness and death in pets. But we want to share this information with you as the investigation has confirmed melamine.

As in any investigation we follow leads – use advance forensic and try to narrow down the cause. At this time, we do not know how the melamine got into the wheat gluten.

FDA's primary concern in this investigation is to identify the source of the contaminant, ensuring that the recall is effective and providing information to

the public. I want to assure you that FDA officials are working around the clock as this investigation continues.

And just talk a little bit about the level of effort that FDA has exerted thus far. FDA has dedicated each of the 20 district offices to this investigation. And approximately 400 employees from the FDA are involved in sample pet food collection, monitoring the recall effectiveness, and preparing consumer complaint reports.

At least three field laboratories are directly involved in active sampling and - sample analysis and each field laboratory is highly capable and standing by to conduct additional analyses as needed.

FDA's veterinarians and toxicologists from the Center for Veterinary Medicine and elsewhere in the agency have been researching potential causative agents, analyzing possibilities, evaluating the scientific and analytical information and guiding and supporting the overall efforts.

FDA is working with its regulatory partners in all 50 states, all 50 health agencies to inform them of the status of the investigative and analytical effort. FDA's emergency operation center remains activated and is managing the incoming information from pet owners and veterinarians and others and is making sure that the information gets to our scientists and to our inspection team.

More than a hundred samples of pet food have been collected and analyzed at our field laboratory. The agency continues to receive calls from veterinarians and pet owners who believe their pets may have been affected by the recall testing.

To date, the agency has received more than 8,000 complaints. Confirmation of these maybe related to the pet food recall takes time and it requires follow-up by our field staff. Veterinary reports and other evidence needs to be collected from each case before any of these reports can be confirmed.

With that, I will conclude my (open) – wait a minute – consumers should continue to check the Menu Foods website for brands of pet food that may have been recalled and we continue to recommend to consumers – that consumers access our website at fda.gov to number one, find up to date information on the list of recalled products, two, find instructions on how to report adverse events, and three, for answers to frequently asked questions.

Thank you. This concludes my formal remarks and I would like to now introduce Dr. Donald Smith who is the Dean of College of Veterinary Medicine at Cornell University who will make the remarks.

Donald Smith: Thank you Dr. Sundlof. It's a pleasure to be here and I especially want to thank the members of the FDA for working so closely with Cornell University over the last couple of weeks.

As was mentioned in my introduction, I serve as Dean of the College of Veterinary Medicine at Cornell, have served in that capacity for approximately ten years.

Cornell College of Veterinary Medicine dates back to 1868 when it was involved in the very first instruction of Veterinary Medicine at Cornell University. Since that time, we have grown both in our teaching capacity and our research capacity and our outreach capacity, the latter being attributed to our brand recognition which we take very seriously.

Part of that brand recognition is appropriated towards two major facilities we have at Cornell. One being our Cornell University for - Cornell University Hospital for Animals and the other being the Animal Health Diagnostic Center which turns in part under contract with New York State Department Agriculture and Market.

The Animal Health Diagnostic Center - the Executive Director of that unit being Dr. Bruce Akey, he and his staff have been working on this particular problem for possibly three weeks.

The reason we were contacted is that we have been involved in a number of investigative problems whether they're related to canine flu, avian influenza, the pet food recall in December of 2005 for various other problems.

We have approximately 230 members of our staff and faculty at the Animal Health Diagnostic Center. And the team went right to work when we heard from Menu Foods approximately three weeks ago.

We received some samples from them of cat food which have been part of the feeding trial. We did not at the time we receive the first samples know that there was any toxins involved but the cats were apparently refusing to eat some of the food from that trial.

About five days later, we understood that there were issues related to not just taste (unintelligible) but also toxic effects. We received at that time additional samples which we contained urine, tissues from affected animals and pet food itself. We did extensive testing both at our laboratories at Cornell and we also submitted some samples to our partners at the New York State Agriculture and Markets Food Lab which is part of the (consortium) with which we work.

Broadly defined, it's called the FERN - the Federal Emergency Responsive Network.

We specifically asked them to look at things related to antibiotics, antimicrobials and pesticides -- things that we were not as able to work on as they are.

On March 21st the lab at (Albany) made a presumptive evidence of a diagnosis of aminopterin present in the food and 36 hours later they confirmed that presence. We participated at the conference call and press release on March 23rd , a week ago today identifying their findings of aminopterin in the food.

We have not been able to, at Cornell, yet confirm the presence of aminopterin in neither the food, the wheat gluten samples or antibody tissues. Meanwhile, Cornell has engaged with veterinarians and colleagues around the country including several institutions and also individuals who have sent us samples.

Our team includes people in our Animal Health Diagnostic Center as well as the nephrologists and other internists. We also have been involved with a local laboratory which is (unintelligible) New York called Advion.

On Monday, March 26th and also Tuesday, March 27th, we also identified melamine in food, in the gluten, in urine of cats which had come from the feeding trial and also in urine from cats with (citantaneous) recurring illness and also the kidney from one cat that had died from the illness - from the feeding trial. And we reported that to the FDA on the afternoon of March 26 and also on March 27.

We have however, as Dr. Sundlof indicated, not come to closure or complete understanding of how the presence of melamine could cause the clinical and pathologic time that we're seeing.

I'd like to now refer to the photograph which we brought from both urine samples and also kidney samples. The photograph on your left is taken of crystals and we are seeing typically in the urine of affected cats. These crystals are spherical. They are brownish in color. They have reddening spikes, and they're very consistently seen with this particular condition in many – in the urine of many, many cats.

On your right, we have an electron microscopy image of the same crystal. And you can see in more detail the shape and also the surface characteristic.

We have not been able to match melamine or the crystals of melamine in terms of the morphology with the identification we're seeing visually in the clinically affected cat.

The second pair and the last pair of images that I'm showing - on the left side is the picture of normal kidney and on the right side is the picture of abnormal kidney. Let me back up and say, the pictures that I showed of the crystals are from colleagues at the University of (Wells) in Ontario, Canada. And the pictures that you're looking at now, the one on the right is from University of Pennsylvania. The one on the left is from Cornell University.

On the left, you'll see images of little tubules – small tubes - little tubules which are - the tubules are the area in which the urine as it's being formed is collected as it moves to the kidney and then will go on into the bladder and later be (voided).

There are two types of tubules that you'll see. One are called the proximal or more forward tubules and the others are called the distal or for the back tubules. And the difference which you'll notice relates to how the urine is formed as it becomes changed as it goes to the kidney to pick up (chalks) and all three modified for electrolytes and other substances.

The proximal tubules in the normal animal and the proximal tubules in the abnormal animal are not too dissimilar. Although they appear a little bit dissimilar on these images, what we're seeing on the right the abnormal kidney, the proximal tubular structure is not too different than what you might see in some cats in a normal situation.

However, there are vast differences in the distal tubular structure, we're seeing two things in particular, one is the loss of integrity or structure of the tubular lining and also inherent with that is the flopping of cells within the tubular. You'll see that debris within the tubules.

And secondly, we are seeing the area outside the tubules, interstitial area being filled with some of inflammatory cells. I would add, although it's not present in these images, the growth being crystals being formed indicate the – and at some samples we have, some samples that other laboratories have, the crystals are actually seen in the kidney.

I want to state once again, that there's no evidence yet to tie in the melamine, the shape of the crystals are identifying the crystals in melamine and what we're seeing in the kidney. So this is just presumptive relationships as Dr. Sundlof had mentioned.

In conclusion, I would just like to say that as a veterinarian, I also am interested and has spent my life devoted to – my professional life devoted to

Veterinary Medicine and the relationship of pets in the family and large dog and horses, et cetera.

This is something we take very seriously at Cornell, and as I walk around the hall day after day, I talk to people, students, staff, faculty, who are impacted in terms of the people they talk to and the people who share their stories about affected cats, and occasionally dogs with this condition.

I know, in talking to our colleagues that Menu Foods which you might be in touch with on a daily basis, they also are feeling the anxiety associated with the personal relationship that some of these affected pets have had with their families.

We continue to work diligently on this problem, work with the FDA and the colleagues around the country. And I thank you for your attention.

Julie Zawisza: Thank you, Dean Smith and thank you, Dr. Sundlof. Ladies and gentlemen, at this time we'd like to take your questions. And because we have a number of people on the phone, I think what I'll do is rotate from members of the audience and then people on the phone.

I'd like to ask Dr. - Dean Smith and Dr. Sundlof and Dave Elder and Michael Rogers to come up to microphones with me.

And we have the first question. Yes, in the back. No, you. Yeah.

(Kim Smith): I have a question for...

Julie Zawisza: Excuse me. Please state your name and affiliation.

(Kim Smith): My name is (Kim Smith). I'm with NBC News. My question is for Dr. Sundlof. (Tina) is asking for a recall of dry foods as well. With this new information of this toxin melamine, are we certain that this isn't something that can also be traced in dry foods?

Steven Sundlof: We are trying to trace out all of the contaminated wheat gluten that came from the source that we've identified as the source of the wheat gluten. Obviously there are many shipments of wheat gluten coming in that gets distributed to these various pet food companies who've identified one particular supplier - as the supplier that - the supplier of the wheat gluten with the melamine in it.

We are still tracing out all of the - all of that wheat gluten. We believe there is one company that we are aware of, that may have gotten a shipment of that wheat gluten. This is a company that does produce dry food. We are working with that company. We have notified them. We are trying to determine at this time whether or not they did use that particular product in the manufacture of the dry dog food.

At this time, we don't have any additional information. But as we learn anything we will alert the public.

(Kim Smith): One more quick question. Have you revised the number of affected dogs and cats at all? Is the number gone up for down or...?

Steven Sundlof: We do not have a number. We have taken I think somewhere in the order of 8800 phone calls so far from concerned owners and veterinarians who believe their pets may have been impacted by the recalled products. In terms of trying to sort out whether or not those are actually the result of the pet food or not, it's something that is going to take some time. We just don't have numbers on the actual number of animals that may have been affected by pet food.

Julie Zawisza: I'll take a question from the phone.

Man: (Shelly)?

Operator: Our first question comes from Elizabeth Weise of USA Today. Your line is open.

Elizabeth Weise: Thanks so much. Thanks for taking my call.

Julie Zawisza: We can't hear you.

Elizabeth Weise: Thanks so much. Thanks for taking my call. The question I had about the wheat gluten is, do you – I'm presuming you're not going to state the name of the company but can you tell us where it came from?

Steven Sundlof: Yes. You're talking about the – as far as the wheat gluten?

Elizabeth Weise: Correct.

Steven Sundlof: Yes. That company is from China.

Elizabeth Weise: Okay.

Julie Zawisza: Next question from the audience. (Daja Henderson).

(Daja Henderson): Hi. Can you talk a little bit more about the – about the manufacturers that have another shipment of wheat gluten and was producing dry animal food? What's the status of the food that was produced during that time period? Still on the market?

Steven Sundlof: At this time we're not even certain that any dry food was manufactured with that wheat gluten. That's what we - we just discovered it. We're working with the pet food company right now to determine this - just the - exactly the question that you've asked which is whether or not that product had gone into any finished dry pet food. Where that pet food is? And then we'll take appropriate action.

(Daja Henderson): Can I have a follow up question?

Julie Zawisza: Yeah, one follow-up.

(Daja Henderson): (Unintelligible) this week released numbers indicating the inspections were down. If there had been more inspections and more aggressive inspections, would it have had any effect on this recall?

Steven Sundlof: In this case it's highly unlikely because as I understand it, the - when we did those to the company after we learned of the contaminated pet food, we did an inspection and there was no violations. In this case, it was an (adenamine), a normal component of food that in likelihood would not have normally been picked up during inspection.

Julie Zawisza: I'll take the next question from the phone.

Operator: Andrew Bridges with Associated Press, your line is open.

Andrew Bridges: Hi, thanks for taking my question. So, the previous stand - the previous finding of the aminopterin stands?

Steven Sundlof: The FDA could not confirm aminopterin (we run). We have tested a number of samples both finished food and the wheat gluten and are unable to (effect) aminopterin in any of those samples. So at this point in the investigation, we are not focusing on aminopterin.

Andrew Bridges: Okay, but does New York stand by its finding?

Steven Sundlof: We don't have New York here to respond to that. We have Cornell University and I believe that Dean Smith indicated that they did not – we're not able to confirm aminopterin in the samples that they ran either.

Julie Zawisza: Do we have another question from the floor? Right there.

Man: (Unintelligible). Any indication of the wheat gluten in the human food chain? Does the maker make both dry and wet food? And could it have been used in wet food? And they usually track that in note, if they've had it for two or three months. And is melamine illegally used – is it illegal to use melamine in the United States as a fertilizer?

Steven Sundlof: It is not registered. Melamine is not registered in the United States as a fertilizer. It is used in a number of consumer products, not on the part of food supply however. Your other question about...

Man: The other maker, we have (unintelligible). Do they make wet food as well as – they have to keep records...

Steven Sundlof: I know. I believe they do produce wet food as well. I don't know if the cuts and gravy, it may be other moist food, but yes.

Man: And after two weeks now after those recalls, they're not able to tell you whether they use (unintelligible)?

Steven Sundlof: That's where we are in the plans right now.

Man: And when did they figure it out that they were, they had...

Steven Sundlof: I'm going to add Michael Rogers to respond to that since he's with our investigative report team.

Michael Rogers: Thank you. I think it's important to mention that this is an ongoing investigation and as Dr. Sundlof mentioned, they are aware that the suspect raw material was in fact shipped to another manufacturer and that firm has been made aware of (those findings).

We're working with that firm to identify their appropriate followup action. We can reiterate that melamine has no approved use in human and animal food. This is an ongoing investigation, the fact that we're presenting our SAIs, we're doing it today.

Man: But when did you notify, when did you find out (that somebody else had it)?

Michael Rogers: The FDA is in the firm - in the plant today.

Man: When did you ask it? When did you know that it was in the (dog(food?

Michael Rogers: I don't think it's appropriate for us to disclose that. The time - the firm was made aware of that. It's likely that the firm would make their response to that information probably very shortly.

Julie Zawisza: Let's take the next question from the phone, please.

Operator: Jennifer Mann of Kansas City Star, your line is open.

Julie Zawisza: We're having a lot of trouble hearing you. Can you adjust the volume there?

Operator: I will do that, thank you.

Jennifer Mann: Okay. Hi, Jennifer Mann from the Kansas City Star. Thanks for taking my call. The plant in Emporia, Kansas, Menu Foods said yesterday it was going to resume production today and is that still the case?

Julie Zawisza: I'm sorry to interrupt but we didn't get that.

Jennifer Mann: Yes. Menu Foods told me yesterday that they are set to resume production in their facility in Emporia, Kansas today. Does that still hold true?

Man: One more time, one more time.

Julie Zawisza: Did anybody hear that question? We're having a little bit of audio (unintelligible).

((Crosstalk))

Man: (Unintelligible) said that they're going to resume the production in their Kansas plant today. Is that true?

Julie Zawisza: Oh, okay. Do we have an answer to that question? I'm sorry, we don't have that answer. You'd have to contact Menu.

Can we try another one from the phone? Try to speak as loud as you can please.

Operator: Our next caller is (Larry Wheeler) of (Ganet).

(Larry Wheeler): Hi. Can you hear me, okay?

Julie Zawisza: We can.

(Larry Wheeler): What's the name of the company that has the raw product and what are the dry food products that they produce?

Julie Zawisza: I'm going to ask someone from our Office of Enforcement. Can you answer that question? We may not be able to answer it so I'm going to turn it over to someone who can.

Man: Hi, good morning. Basically we, what we have said so far, is about as far as we can go right now. The company that received the gluten that we found to be positive for melamine has been notified. We have investigators in the plants today to work with them to determine what if any finished products were made from that adulterated wheat gluten. And we expect the response to that inquiry to occur very soon.

(Larry Wheeler): Follow-up question, please. Given what's happened already with the wet food, don't you think it will be prudent and cautious on your part to give the pet owning public the opportunity to decide whether or not to continue feeding this dry food?

Man: Right. And as soon as we find out which dry food was manufactured if any, it will be communicated publicly.

(Larry Wheeler): Thanks.

Julie Zawisza: Next question from the floor? Yes.

(Mary): Hi, it's (Mary) (unintelligible) from (Titanium Broadcasting). There seems to be a difference in the number of pets that have been affected by this food in Canada versus the United States, Sir. Right now, are there any confirmed cases in the United States, in Canada rather? Do we have any answer to that or is the FDA working with any Canadian (people)?

Man: We notified the Canadian authorities as soon as we determined that the product has been exported to Canada and Mexico. We also contacted our Mexican contact. And we have been - I have been in contact with regulators in Canada on an infrequent basis but I have not received any reports of illnesses from Canada at this time.

Julie Zawisza: Thank you. Next question from the phone.

Operator: (Kodeth Richwood), Toronto Star. Your line is open.

(Kodeth Richwood): Yes, hi. I didn't - can you hear me, okay?

Julie Zawisza: Yes. We can.

(Kodeth Richwood): The question I have it's a little bit confusing now, we have two results as far as I can tell aminopterin and melamine. Now, can you - is this not going to confuse pet owners by producing two press conferences with two different kinds of sources of possible toxins?

Julie Zawisza: Let me ask Dr. Sundlof (and perhaps Dean Smith) to talk about the nature of the investigation (unintelligible).

Steven Sundlof: The FDA investigation, information comes in and that information often changes over time as we learn more and more. At one point, it was reported by the State of New York that their laboratory has detected aminopterin in the affected pet food. As in any normal investigation, those samples will need to be confirmed. Those results need to be confirmed by independent laboratory.

At this time, none of the independent laboratories whether it's the Cornell laboratory or the FDA laboratory - laboratories have been able to confirm the presence of aminopterin in those samples. And therefore we are focusing now on melamine.

Julie Zawisza: Next question from the floor. (Ellen), over here.

(Carl McPharlen): Thank you, good morning. This is (Carl McPharlen) with (Cox). Dr. Sundlof, you referenced there were 8,800 complaints as of this morning. Any geographical concentration to where most of those complaints are coming from or perhaps where the recalls are more concentrated the good – in the US.

Steven Sundlof: I don't believe - we have complaint coordinators in all 50 states. All 50 states are receiving phone calls - just the – the effort now is just to try and get those logged into the system and where we, you know, have probably only 1,500 of those actually logged in. So, at this time, it's just too early to tell if there's a regional distribution.

Julie Zawisza: Next question from the phone, please.

Operator: Steve Dale of USA Weekend Tribune. Your line is open.

Steve Dale: Hi. Thank you very much. I hope you can hear me, ok. I confuse fairly easily, perhaps. Two questions in one here.

The discrepancies, one is about the number of pets that may have died as a result. And I'm hearing a number that doesn't even reach 20 from the FDA to printed and broadcast reports of thousands and there is such an incredible discrepancy.

And also, I am telling you, I am getting emails daily from people who say, "Hey! My dog or cat is getting sick because of the dry food." Based on what you just said I can – I don't know what to tell people. I mean stay tuned. I don't understand how they can't know what they're making in their own plants.

Julie Zawisza: Could you repeat the part of the question please, the beginning please?

Steve Dale: The beginning of the question? The discrepancy concerning the numbers reported dead from near 20, and not quite even that from the FDA, as I understand it, to thousands in many broadcast and printed reports.

Julie Zawisza: So, your question is why is there a discrepancy between the numbers FDA has and the numbers you are hearing from other sources and why is it taking so long, is that correct?

Steve Dale: That's – yes, as well as the discrepancy concerning the dry food because I am receiving anecdotal - only anecdotal reports but a lot of them from people saying, my dog or cat has become ill, because of the dry food.

Julie Zawisza: All right, Dr. Sundlof will take that.

Steven Sundlof: In terms of the number of animals that may have been – may have fallen ill or died as a result of the contaminated pet food, we cannot confirm any numbers at this point other than those being (pursued) that we talked about earlier the 14 or 15 that discussed earlier.

This is- the volume phone calls that we're getting and a lot of those are from pet owners who are complaining that their pets only received dry dog food. So we are hearing the same thing that – from pet owners that have only fed dry dog food. But none of these – we have not had the luxury of time to confirm the cases that's being actually caused by pet food at this point in time. And that will come sometime later and after we're absolutely certain that the - all of the material that is potentially hazardous is off of the market and we have identified a causative agent.

At that point we will go back and try and put together what we consider the total number of animals affected. Unlike in the human food, there is no center for disease control for animals and normally that would be the responsibility of the Center for Disease Control to develop criteria for determining what is the confirmed cases of poisoning.

We don't have that – so it's going to take us a little longer to be able to get those results.

In terms of the dry pet food, again this is very early and may turn out that the shipment we know when to – the one manufacturer of dry dog food was not even used in the pet food. But we need to find that out. Once we do find that out if it was, we need to find out what the lot numbers are and we need to get that information to the public as quickly as possible.

Julie Zawisza: Thank you. Before we take questions from the floor, I'd like to find out how many people on the phone still have question. My sense is there may be quite a few. And I want to make sure (unintelligible). We ask the operator.

Man: (Shelly)?

Operator: Ah yes, we have eight more question.

Julie Zawisza: Okay. Why don't we take this - a couple more from the phone and then we'll rotate again.

Operator: Karen Roebuck of (Pittsburgh Tribune), your line is open.

Karen Roebuck: Hi. Thanks for taking my call. Two questions – one was the wheat gluten – is any wet gluten used in human food and secondly, what are the Chinese authorities doing as part of this investigation?

Steven Sundlof: To our knowledge at this time, we are not aware of any wheat gluten that came in. We know the company that imported into the United States. We followed all of the shipments. We're not aware that any that went into human food. We are continuing to search and make sure that that is not the case so we can't say we're at 100% certainty at this point.

But we have no indication that any of that material did go into human food. I'm going to ask Michael Rogers to talk about what we're doing at the ports now regarding Chinese wheat gluten.

Michael Rogers: As far as what we know with respect to the implicated raw material, the agency is initiating 100% review and sampling of all imported wheat gluten

from China and that's going to involve a sampling effort that's designed to look specifically for melamine (unintelligible) imported products.

Julie Zawisza: Next question from the phone please.

Operator: (Jane Zane) of Wall Street Journal, your line is open.

(Jane Zane): Thank you. Can you guys explain a little bit about your methodology – how you found melamine and how you explain, how you, you know, linked it to gluten?

Julie Zawisza: Dr. Sundlof.

Steven Sundlof: We were originally – we originally discovered this as a result - one of the pet food company affected, not Menu Foods but one of their – one of those companies that they – Menu Foods supplies its cuts and gravy foods to – actually, (unintelligible) (analysis) themselves and identified melamine. And we – once we were aware of that, we started looking specifically for melamine and found that in the wheat gluten and then further more in (unintelligible) pet food. And we notified laboratories including New York State and Cornell and I believe that is when Cornell started to look for the melamine and found it as well.

Julie Zawisza: I think we'll take one more from the phone and then we'll go to the floor.

Operator: (Lyn Terry) of the (Organen), your line is open.

(Lyn Terry): Thank you. Yeah, I have two questions actually for all those worried pet owners out there - what kind of food really is safe to feed your pet, if you'd like to make your own pet food, that's my first question.

And the other question I have is - which a lot of people are asking – what is the impact is this going to have on the regulation of the pet food industry?
Thank you.

Steven Sundlof: Again, we will - as soon as we learn anything about any pet food that potentially contains this wheat gluten, containing melamine, we will alert the public. Until we do, I think it's - we want to encourage the public to continue to use pet food that is not subject to the recall. And again, all of that information is on our website and the many good ones (thing).

The second part of the question I – oh, regulations. The pet food industry is subject to the same regulation as the human food industry. We have the regulatory authority to take whatever protective actions are needed. In this case, we're going to have to look at this after the dust settles and determine if there is something from a regulatory standpoint we could have done differently to prevent this kind of incident from occurring.

Julie Zawisza: (David), I know you've been waiting to ask your questions. So, go ahead.

(David): It's somewhat confusing for consumers. You have a manufacturer who has the wheat gluten. You don't know if it's in. They haven't called a recall yet and you just tell people to go ahead and feed food that has not been recalled yet. You don't know if the melamine is causing the actual death of these animals. What is the pet owner to think about what to feed their pet and what the FDA is doing for them?

Steven Sundlof: And again, we should know more about the one pet food company very soon. That will take in effect, (unintelligible). And again we will alert people immediately if we find out. This is an ongoing investigation. And we- as we

receive new information, we want to make sure that the public is aware of that. We understand that it's confusing to everybody- we're trying to make sense out of it. But that's part of the messy nature of the investigation.

And we know that there is a – the public is extremely concerned as we are about this issue. We feel it's better to give information when we can then - and recognizing that they change overtime and do whatever we can to reassure consumers that their pet foods is safe but not giving them same false expectations and talking to them when we find the problem.

(David): But there could be food out there with the (unintelligible) that they're feeding right now.

Steven Sundlof: It is possible but I think, you know, we're following every lead that we can. And my sense is that we have that - most of it under control (unintelligible).

Michael Rogers: I think it's important to know as Dr. Sundlof is – has indicated that the investigation is very much active and ongoing and we're pursuing every lead that we find.

When we talk about the numbers of consumer calls that we've received and those numbers may be perceived as alarming. And we take them very seriously. We are looking for new information that may help our investigation and we're open to any possibilities. So we're continuing to investigate. We're here today and in the past. We've continued to communicate to the public to provide the most current and accurate information we have.

However we recognize that information can change almost all of (we in the set of the) investigation and as soon as we have information about any pet food whether it's wet or dry that was manufactured from an ingredient that's

contaminated with melamine, we are going to notify the public. So they can protect the health of their animals.

We care about animals. We're pet owners ourselves. This is very, very important to the agency, to us individually in our personal lives as was professionally trying to carry out the jobs that we have at FDA.

Julie Zawisza: Thank you, (Citra?).

(Citra): Thanks. (Unintelligible) for a follow up. I was looking to do this 100% of review of the wheat gluten coming in to ports that's all (unintelligible) focused on the Pacific Rim area and secondly, what about wheat gluten that's come in in the last week that's may be on trucks headed somewhere?

Michael Rogers: I will address the first part of the question. The review from the import perspective involved all wheat gluten from China. And from a surveillance standpoint we may include other countries as well. As far as what's presently in the country, we initially focused on the original importer of record for the implicated products. And, we have a number of positive lots and we're tracing those lots forward (unintelligible) the (manufactured) products.

Julie Zawisza: Thank you. We have time for just one more question. I'd like to go to the phone.

Operator: (Alexandra Extin) of the Atlanta Journal, your line is open.

(Alexandra Extin): Hi. Thank you. We've got a lot of vets here that are just doing blood tests on animal, checking their kidney levels, things like that. We're getting a lot of vets that are saying they're getting high BUN levels but the pets don't seem to actually be sick. Do you have any indication at this time what's going to

happen with these animals? Are they going to become sick? Are they going to recover? Should people be taking their pets in for this blood test? What are you advising people to do at this point?

Julie Zawisza: Oh I'm sorry about that. (Unintelligible) to answer that question.

Donald Smith: The fact is that there are many cats and dogs with renal disease that may or may not be affected in any way, shape or form with the (contaminated) food. But I think it's very important that we try to match the signs and what the signs that we're seeing quite consistently are these crystals that I pointed out earlier with the change in the biochemical nature or studies of the blood or the urine. And so I think the important message here is to recognize that many things can cause renal disease especially in order of comprised (unintelligible) and this maybe just one of the differentials – certainly is one of the differentials to configure.

So in this particular case, my response would be, work closely with your veterinarian and pursue all avenues. But we are - again seeing in many, many of these animals, we're seeing these crystals which seem to be appropriate to this (end-result).

Julie Zawisza: Thank you. With that, we will conclude our press briefing today. On behalf of the Food and Drug Administration, I'd like to thank you ladies and gentlemen for your participation, (Wyeth) and the audience here and also on the telephone.

And I would thank our speakers, Dr. Sundlof, Dean Smith, Michael Rogers and David Elder.

If you have follow up questions, I invite you to (unintelligible) our press officers right there (Capt. Mcdermott) or (Mike Kernen) or call on me at (unintelligible) 301-827-6242. And please check our website for current updates.

If we do something (else over the weekend), we'll make sure that we notify by our web right now - our website right now has the most current information (unintelligible).

Thank you very much and have a pleasant day and (unintelligible).

Man: Thanks, (Shelly).

Operator: Thank you. This concludes today's conference. You may disconnect at this time. Thank you.

END