Update on the *Salmonella* Typhimurium Investigation
FDA/CDC Joint Media Teleconference
January 27, 2009

Coordinator: Good afternoon and thank you for standing by. All participants will be able to listen only until the question and answer session of today's conference. At that time if you would like to ask a question, you may do so by pressing Star then 1.

Today's conference is being recorded. If you have any objections you any disconnect at this time. I'd like to turn the call over to your host for today, Mr. George Strait. Sir you may begin.

George Strait: Thank you operator. And welcome everyone. My name is George Strait from the FDA's Office of Public Affairs and this is an FDA Teleconference for Credential Media to ask questions about the ongoing investigation of the Salmonella Typhimurium outbreak link to peanut butter.

We have speakers today from the FDA and from the Center's for Disease Control and Prevention. Our speakers for this afternoon are Dr. Stephen Sundlof, Director, Center for Food Safety and Applied Nutrition at the FDA. And Michael Rogers, Director of Division of Field Investigations, FDA, and Dr. Robert Tauxe, Deputy Director Division of Food Borne Bacteria and Mycotic Diseases at the CDC.

Now after the speakers make brief remarks we'll move to the Q&A segment. The reporters will be in a listen only mode until we open up the call for questions.

When asking a question, please state your name and news affiliations. Also please limit yourself to one questions and one follow up so we can get in as many questions as possible.

At this time I'd like to turn it off to - turn it over to Dr. Stephen Sundlof. Stephen.

Stephen Sundlof: Thank you George and thank you everybody. This is part of the FDA's continued efforts to keep the public informed about this outbreak of Salmonella Typhimurium associated with peanut butter and peanut butter products.

Today FDA has concluded its investigation of the Peanut Corporation of America facility in Blakely, Georgia. Now this is the plant which FDA has determined to be the source of the current outbreak. And to update you on that investigation I'm going to ask Michael Rogers with our Office of Regulatory Affairs to comment. Michael?

Michael Rogers: Thank you Dr. Sundlof. My name is Michael Rogers and I'm the Director of the Division of Field Investigations in the Office of Regulatory Affairs. And as Dr. Sundlof mentioned messages to inform the public about today relate to the conclusion of the inspection at Peanut Corporation of America, PCA.

That inspection was initiated on January 9, 2009, shortly after this firm was implicated as a possible link to the ongoing outbreak. And our inspection of PCA concluded today. Inspection team included FDA Investigators, FDA Microbiologists, as well as representatives from CDC and the Georgia Department of Agriculture.

At the conclusion of the inspection a FDA 483 which is a list of deficiencies observed by the inspection team at the facility was issued to the firm that identifies a number of good manufacturing deficiencies associated with the firms manufacturing process. Specifically the team identified approximately 12 instances in 2007 and 2008 where the firm as part of their own internal testing program identified some type of salmonella and released a product after it was retested, in some case by a different laboratory.

The inspection also identified a number of deficiencies related to the firm's cleaning programs and procedures for their manufacturing equipment as well as failure to take steps to mitigate Salmonella contamination or crop contamination in the facility.

The inspection also revealed environmental samples that were collected during the inspection that tested positive for Salmonella.

The agency will be working to post the, as I mentioned, 483 on its website. And with that I'll turn it back over to Mr. Strai).

George Strait: Actually Dr. Sundlof, I think you got some more and then Dr. Tauxe at the CDC.

Stephen Sundlof: Okay, thank you George and thank you Michael. I'd like to now provide an update on the status of the ongoing recall itself. FDA continues to work with the company, PCA and corporate purchasers of the product who identified affected products and facilitate their removal from the market.

FDA along with its State counterparts has visited nearly 1,000 firms who purchased products originating from PCA to facilitate the recall. FDA continues to work with CDC, State Officials and the Peanut Corporation of

America to test additional peanut containing products, track additional distribution sources and review distribution records.

As FDA gathers additional information about these products, we expect a list recall products to continue to expand. Consumers can identify the product potentially at risk by looking at FDA's searchable list of recalled peanut products on our website. And I think you all have that www.fda.gov.

This list is being updated on a regular basis as we find out new information, so consumers are encouraged to check it frequently.

If a product is not FDA's list of recalled products, consumers may wish to look at the company's website or call the toll free number listed on most packaging.

Information consumers may receive from the companies in this manner has not been verified by FDA. And just to let folks know that consumers will not find the name PCA or Peanut Corporation of America listed on product packaging because the company distributes its product to over 70 other food processors that use their own name on the packaging or redistribute the product to other processors.

Now if consumers are in doubt about the safety of their products they should not eat them until the scope of the recall is clear. That concludes the FDA's comments and now I'd like to turn the microphone over to Dr. Robert Tauxe at CDC for an update on the outbreak itself.

Robert Tauxe: Thank you very much. This is Dr. Tauxe. I'd like to briefly update you on the findings and the ongoing epidemiologic surveillance that CDC and our state partners are conducting.

As of 9:00 p.m. January 25th, we have confirmed that 501 persons from 43 states and additional 1 person in Canada has been infected with the outbreak strain of Salmonella Typhimurium.

Of these 108 or 22% were hospitalized. Eight deaths have been reported that appeared to be associated with the outbreak. The most recent illness reported started on January 9. The outbreak appears to be ongoing. The numbers of new cases have decreased modestly.

Now as previously reported our epidemiological studies showed a strong association with peanut butter crackers of two brands, but not everyone recalled eating these crackers and we don't think the crackers alone count for the whole outbreak by any means.

Other peanut butter containing products produced by a variety of companies may have been made with the ingredients that are under recall now. CDC and State Health Departments are investigating the association of other brands and foods that contain peanut butter with illness.

And currently states are testing a variety of products containing peanut butter in their labs. A second type of Salmonella has been found in unopened containers of the King Nut Peanut Butter, the brand that comes from PCA. It's important to recognize that our PulseNet surveillance system is not observing an increase in human cases caused by this second strain.

And as previously noted the FDA has identified two other strains of salmonella in the plant in specimens collected from cracks in flooring. PulseNet is also not observing an increase in human cases caused by these two

strains. So the human illness, all the human illnesses associated with this outbreak is being caused by Salmonella Typhimurium at this point.

And finally, we have exactly the same recommendations for consumers as the FDA. We have joint recommendations and I would just add that for those people who do not access to the internet and so they cannot look at the FDA's searchable web base, they can call our 1-800-cdc-info number that's 1-800-232-4636, which is open 24 hours a day, 7 days a week. And the people who answer the phone there can look the product up on the FDA website for the person. Thank you very much.

George Strait: Thanks Dr. Tauxe. We can now take questions. I think out first one is from - operator?

Coordinator: Thank you. At this time if you would like to ask a question you may press Star then 1. You will be prompted to record your first and last name. And to withdraw your question, you may press Star then 2. Once again, to ask a question please press Star then 1 and record your first and last name.

The first question comes from Maggie Fox of Reuters, you may ask your question.

Maggie Fox: Hi, thanks very much. Can you give us the names of the other strains of Salmonella that have been found? And clarify exactly how many strains of Salmonella have been found at the plant and in peanut products?

Robert Tauxe: That information will be available hopefully tomorrow when we release the - what's called the 483 that Michael Rogers talked about, the results of the inspection. I don't have those species in front of me right now.

Michael Rogers: This is Michael Rogers, let me add to that. As I mentioned and Dr. Sundlof mentioned, we will be posting the FDA 483 on our website tomorrow. The list of observations would represent - represents deviations from the regulations, identify that the firm did in fact have an internal testing program that identified Salmonella. In many cases though, they did not identify the species, just that it was Salmonella. In some case you will see though do identify an actual species.

Maggie Fox: Can I follow up then since I don't have an answer to this one? I understand more than half of the cases that have been reported has been among children. Can you further characterize who the victims are and how you believe they became infected?

George Strait: Dr. Tauxe.

Robert Tauxe: Yes, thank you for the question. Yes, from the beginning of this outbreak it's been clear that many cases occurred in children in fact right now the halfway mark that is the mark where half the cases are older or half the cases are younger is right at 16 years. And 21% of our cases are less than 5 years old.

The association that we have seen with eating peanut butter containing products hold across the ages and we think that the reason that there are a lot of children and reason that there are a number of people in the older age groups is because those are the people that eat peanut butter containing products.

Maggie Fox: Thank you.

George Strait: Thank you. The next question.

Coordinator: The next question comes from Ricardo Alonzo Zaldivar with Associated Press, you may ask your question.

Ricardo Alonzo Zaldivar: Thank you for taking my question. I can hear some crosstalk on the line. Can you hear me alright?

George Strait: We can now (Roberto).

Ricardo Alonzo Zaldivar: Okay, thank you. And my question has to do with the info that Mr. (Rogers) gave us there. Now you said the in approximately 12 times in the past couple of years as part of its own testing the company identified some kind of Salmonella and released the product after it was retested. Now could you give us a little bit more on that? I mean should they not have done that? Should they have - why is that significant is basically what I wanted to know?

Michael Rogers: its significant because at the point at which Salmonella was identified it shouldn't be there based on the manufacturing process that's designed to mitigate Salmonella, actually eliminate it.

I can tell you that the inspection also revealed, and you'll see in the copy of observation, that there were no steps taking as far as the firm to address as far as cleaning or minimize cross-contamination or subsequent the combination after these positive Salmonella found in finished products and some of the starting materials.

Ricardo Alonzo Zaldivar: Okay and to follow up. Should they have done something different? Should they not - clearly you said the cross contamination, the cleaning, all that, but should that product not have gone out back in 2007 and 2008?

Michael Rogers: I would characterize those observations as significant GMP deviations that had an adverse effect on the quality of that product making it adulterated.

Ricardo Alonzo Zaldivar: Okay, thank you.

George Strait: Thank you, next question please.

Coordinator: The next question comes from Elizabeth Weise with USA Today. You may ask your question.

Elizabeth Weise: Hi, thanks for taking my call. Mr. Rogers another question. So, what your saying is this plant and I've read that they have a program in place where they are supposed to consistently test for Salmonella, when they got a positive Salmonella on their peanut butter they went lab shopping until they got a lab that tested negative and then they shipped the stuff out?

Michael Rogers: I don't recall using the term lab shopping.

Elizabeth Weise: Well not, I'm saying that. But is that what they did? I mean they went - they kept going to different labs until they got somebody who test - who said it was negative?

Michael Rogers: I'll characterize it this way. The inspection revealed that the firm internal testing program identified Salmonella in the facility related to a specific sample that they pulled. In some cases there was a subsequent lab used that reached a negative conclusion about that particular sample.

Elizabeth Weise: Can you give us the name of that lab?

Michael Rogers: No.

Elizabeth Weise: Okay.

George Strait: And our next question.

Coordinator: Our next question comes from Lisa Stark with ABC News, you may ask your question.

Lisa Stark: Hi, just one clarification that I want to follow up on this line of questioning. Did you say, and I'm not sure I heard it right, you said a second type of Salmonella has been found in an open or unopened container of the Kind Nut Peanut Butter? Dr. Tauxe I believe you were talking about that.

Robert Tauxe: Yes, I was and that's an unopened container.

Lisa Stark: An unopened. But as you say, there has been no sense of this strain of Salmonella at this point has - you have not seen any human cases or an uptake in human cases on that stain of Salmonella, correct?

Robert Tauxe: We have not seen an uptake in human cases, that's correct.

Lisa Stark: Okay, thanks for clarifying that. To follow up on what was going on at the lab. Two questions. One is just to make sure we're clear on this. Are you saying that the actual product that tested positive was then shipped out after another lab deemed did not get a positive on it? The actual container of peanut butter or peanut paste?

Robert Tauxe: The 42 identified situation where that would be true, yes.

Lisa Stark: Okay.

George Strait: Lisa?

Lisa Stark: Yes.

George Strait: That's one plus one.

Lisa Stark: Well one was a clarification and one was a question.

George Strait: Oh, okay.

Lisa Stark One last thing. Where was the government, the state and the FDA in all of this? I mean you guys are supposed to be looking at the plant. The state was doing its inspections and obviously as you said on a conference call last week, they're doing them on behalf of the FDA. So if the plant was doing this why was not anyone who was overseeing the plant aware of this?

Robert Tauxe: What we can effort to do is make the firm's inspectional history available on our website. This particular firm was under state contract and we're still evaluating what the previous inspections revealed. We also need time to assess the outcome of this inspection.

We talked about the FDA 483 but that just one piece of the inspectional process. From here the inspection team needs to write what we call the Establishment Inspection Report. Our compliance branch within the district needs to evaluate that evidence and sample results and how they support these observations on the 483. And then the agency uses that information to come to a final agency decision regarding the final classification of this facility.

One that happens I would expect some discussions to occur between ourselves and the Georgia Department of Agriculture to looking into the history of this firm.

George Strait: Dr. Sundlof.

Stephen Sundlof: Yes this is Dr. Sundlof. Just to help with that question a little bit. The firms are not always willing to, well let me just say that we don't have access to all of the information in most cases when we do routine inspections. And this is information that the firm did not provide to us when we did our initial inspections. And it was only after talking to the firm and actually using some additional authorities that we have gained under the - since 911, under the bio-terrorism act that we had access to those records.

So on normal routine inspections generally we don't have access to all those records. Now having said that, this was clearly a violation of good manufacturing practice standards and the 483 will certainly be very specific about that.

This is a practice that the firm should not have engaged in. And again, we rely on the companies to have in place quality systems that will ensure the safety of food as they do not - as occurred in this case and that is a violation of the law.

George Strait: It's really quite simple. Inspectors and regulators can't actually on information that they don't have. Next question please.

Coordinator: Your next question comes from Miriam Falco with CNN Medical News. You may ask your question.

Miriam Falco: Hi, thanks. I'm going to ask for a clarification too before I ask my question. Just to be clear, four strains of Salmonella. Does that include the one that was found in Minnesota, which is linked to the sick people, which was in the open container, one strain that was found in Connecticut in the unopened container? Plus the two that you guys found on the floor and in the crack which you told us about in the last debriefing?

Stephen Sundlof: The one, the Minnesota one and the Connecticut one were the same strain. The ones that we found in the plant were two different strains.

Miriam Falco: So where's the fourth one then?

Stephen Sundlof: I don't at this point. I mean there - we - again there - you will see in the 483 that we will be naming some Salmonella.

Miriam Falco: Okay then what is Dr. Tauxe talking about then?

Stephen Sundlof: I refer to Dr. Tauxe.

Robert Tauxe: Yes, thank you. Actually the strain of types of Typhimurium that is part of the outbreak and has caused all the human illness has been found in the open container in Minnesota, a closed container in Connecticut and I believed I mentioned the close containers of the crackers in Canada. There is - there are the two strains then that were found on the floor of the plant and there was no uptake in human illnesses associated with those.

And there is - there is another strain which is different from either the two strains found in the plant or the initial outbreak strain itself which has also been identified in the peanut butter. And that additional strain, as I mentioned, there is no uptake in human illness associated with that strain either.

George Strait: Next question.

Coordinator: The next question comes from Mariam McVeen with LA Times. You may ask your question.

Mary MacVean: (unintelligible) that didn't cause any human illness. Where was that found?

George Strait: I think we lost the first part of your question. Could you repeat it please?

Mary MacVean: Oh, I'm sorry. I just wanted to clarify that - what Dr. Tauxe just said. The last thing he mentioned, the different strain identified in the peanut butter that had no associated human illness. Where was that found? Where was the peanut butter, not where is the bacteria.

Robert Tauxe: Yes, this is Dr. Tauxe. That was - it was isolated from the King Nut Brand peanut butter actually tested in more than one location. And those locations are in State Health Department or Agriculture facilities.

Mary MacVean: In which state?

Robert Tauxe: I like to encourage you to talk with the states that have been sampling the product and they can provide further details.

Mary MacVean: Will that be in the 483 as well?

Michael Rogers: No.

George Strait: And the next question.

Coordinator: Your next question comes from Rob Waters of Bloomberg News. You may ask your question.

Woman: Hold on just a moment please.

Robert Tauxe: I'm sorry, this is Dr. Tauxe again. I think it would be useful to talk to the Minnesota State Health Department. Sorry there was a cough. With the Minnesota State Health Department and with the Georgia Department of Agriculture.

George Strait: And the next question.

Coordinator: Mr. Waters you may ask your question.

Rob Waters: Okay. Yes, I'm wondering during this period in 2007 and 2008, you know prior to the identification of the outbreak, how many times did FDA visit the Blakely plant for inspections? And what obligation did PCA have to inform FDA at the time of those inspections about, you know negative test or positive tests I guess you would say, that it found?

Michael Rogers: This is Michael Rogers. I previously mentioned that this firm was under state contract and was covered by the State of Georgia. There is no requirement presently that a firm inform FDA of a positive internal testing of their finished product.

Rob Waters: So when you say they were covered by the State of Georgia, under a state contract, you mean the inspections were performed by the - any inspections were performed by the State and not by FDA?

Michael Rogers: Yes. Under state contract but those contracts are negotiated between FDA and the state. It involves a level of training and coordinated inspectional approach. As well as some discussion about what the work product looks like coming back to FDA. But they were state inspections, that's correct.

George Strait: We've got time for three more questions.

Coordinator: Your next question comes from Tom Costello with NBC News. You may ask your question.

Tom Costello: I'll give my question to somebody else. Min's been answered, thank you.

Coordinator: Thank you. The next question comes from Lyndsey Layton with the Washington Post. You may ask your question.

Lyndsey Layton: Tom Costello, thanks very much I appreciate that. I wanted to ask about this contract with the State of Georgia because in October 2008 after the contaminated product was being shipped around the country and consumed the state inspectors didn't check for Salmonella at that plant. And so I wonder what you all think of the quality of the inspection that you're getting? And I have a second question as well.

Michael Rogers: The issue - this is Michael Rogers. This issue was under review. At this time I have not seen the inspection report done by the state. I can tell you that all inspections are a snap shot in time. And they only reveal what is happening at the firm at that particular time. And so the issue is under review is all I can say.

Lyndsey Layton: Okay. The other - thank you. The other question I had and I don't, I'm sorry I don't know who referred to this, but somebody had mentioned that the firm

behavior was a violation of the law. Can somebody elaborate on that? The fact that they were shipping contaminated product. What law does that violate? And are we talking about a criminal violation here?

Stephen Sundlof: This is Steve Sundlof. I think I was the one that said that. Foods are supposed to be produced under conditions which will not render them injurious to health. And in order to make sure that that happens, food companies are supposed to be producing foods in accordance with good manufacturing practice standards, those are regulations. They have the force of law.

Whether or not there was any criminal activity involved is a different issue. We're looking - but this is a matter of producing food in accordance with the Food, Drug and Cosmetic Actually and where there are violations of those laws and regulations that apply to those laws then that is technically a violation of the law.

George Strait: Next one please, the next question please.

Coordinator: Your next question comes from David Schaffer with Minneapolis Star Tribune. You may ask your question.

David Schaffer: Yes. I'd like to go back to those 12 resample and shipped matters. What - were any of those shipments that went out later subject to the recall that you're doing now?

Stephen Sundlof: We're still evaluating the scope of the present recall. And what these observations actually relate to. That's under review. This inspection just closed. And the purpose of this call was to update the public on what those findings were.

David Schaffer: And a follow up question. Could you tell us were those samples taken from products that had been put in containers or were they from a production line? And if they were in containers what size they were?

Stephen Sundlof: This is the firm's internal testing program that these observations relate to and those samples included both finished product as well as starting material and in process materials.

George Strait: Thank you. And the final question.

Coordinator: The last question comes from Jane Zhang with Wall Street Journal. You may ask your question.

Jane Zhang: Hi and thanks for taking my call. Dr. Tauxe the two strains that the FDA found on the floor of the plant, did you ever find any patients sick with that strain or those two strains?

Robert Tauxe: Yes, thank you for your question. This is Dr. Tauxe. Those two strains are - do not have any uptake in human illness and so we are not seeing any increase in human illness associated with those two strains. I think we had a total in review of since September 1st of one single person who had one of the strains and that person is being - we're attempting to interview that person but so far there's no reason to believe they're related.

Jane Zhang: Okay. What about the first strain you guys found at Minnesota and in Connecticut? Did the FDA find that in the plant?

Man: We previously reported on the environmental samples and they were not Salmonella Typhimurium.

Jane Zhang: So will you report tomorrow saying that you found the strain in the plant or no?

Michael Rogers: I think the 483 will show what the firm was able to find as part of their own internal sampling and testing program. And there are subspecies of Salmonella that are specifically identified on the 483. It will be remarkable to.

Robert Tauxe: This is Dr. Tauxe again. This is going to be confusing isn't it because there are several different strains of Salmonella? The dominate - the strain that has caused this outbreak, the Typhimurium strain that has been isolated from foods in several states and Canada now, that is clearly the cause of the outbreak.

There are these other strains that have been identified that are not associated with human illness that indicate there is certainly a Salmonella problem in the plant even though they are not associated with human illness.

Stephen Sundlof: Yes this is Steve Sundlof. Just to - the question was did we find the outbreak strain in the plant or did the company find the outbreak strain in the plant and the answer is we - there's no way of knowing because what the outbreak strain identified by is its post field gel electrophoresis fingerprint, its DNA fingerprint.

None of the testing that the firm did got down to that specific level. So that's not, it's impossible to say. However, finding the outbreak strain in closed containers of peanut butter produced by that plant is an indication, I mean that's clear proof that the organism was in the plant.

George Strait: Okay, thank you all. That concludes today's media teleconference. Thanks for your participation. Remember the replay will be available in about an hour,

hour and a half and will be available until January 28. If you have follow up questions, please don’t hesitate to call the respective agencies and also check with both the FDA and CDC websites for the updated information that was discussed here today. Thank you all.

#