



DEPARTMENT OF HEALTH & HUMAN SERVICES

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**STATEMENT OF**

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**FOOD AND DRUG ADMINISTRATION**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**BEFORE THE**

**SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS**

**COMMITTEE ON ENERGY AND COMMERCE**

**U.S. HOUSE OF REPRESENTATIVES**

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## INTRODUCTION

Good morning Mr. Chairman and members of the Subcommittee. I am Dr. Stephen Sundlof, Director of the Center for Food Safety and Applied Nutrition at the U.S. Food and Drug Administration (FDA or the Agency), which is part of the Department of Health and Human Services (HHS). FDA appreciates the opportunity to provide you with information on our ongoing investigation of the foodborne illness outbreak associated with *Salmonella* Typhimurium, which has been found in peanut products produced by the Peanut Corporation of America (PCA). Because our investigation and the accompanying recall of suspect product continue as we speak, our final conclusions and recommendations are necessarily pending the outcome of our investigation.

Let me begin by expressing the Agency's concern for people harmed in this outbreak of foodborne illness. This outbreak highlights a number of shortcomings with our nation's food safety systems, and underscores the need for greater Federal oversight, more effective industry practices, and stronger safeguards for the American people. A good day at the FDA is when avoidable outbreaks do not occur – and that did not happen here. We can, and will, learn from the outbreak what we can do to better assure the safety of our food supply moving forward. It bears noting that manufacturers play a critical role in ensuring the safety of the foods they introduce into commerce. Strong food safety programs in food manufacturing facilities begin with the commitment and strong oversight of management and the promotion of a strong food safety culture throughout the company.

This testimony will review the facts of this outbreak – as we know those facts today – and FDA’s investigation.

## **TRACEBACK PROCESS**

The first step in a foodborne outbreak response is to identify that an outbreak resulting from a food vehicle is occurring. When the Centers for Disease Control and Prevention (CDC) receive information from state and local health departments that identify clusters of illnesses, CDC pursues an epidemiological investigation, which involves working with those state and local agencies to identify the possible food(s) associated with a foodborne illness outbreak. Upon making that identification, CDC notifies FDA. At that point, FDA considers the strength of the evidence implicating the suspect food or foods and determines the appropriate level of regulatory response. Early in our traceback investigation to identify the source of the contamination, we work with the food industry and with state and local regulatory partners, and, when needed, with foreign governments. We trace the food suspected of being the vehicle for transmitting the pathogen back through the supply chain from the retailer, restaurant or institutional setting as far back as the manufacturer or grower, and inspect or investigate points throughout the supply chain to determine where the contamination most likely occurred. Tracing food requires us to find and examine documentation (such as bills of lading and invoices) for the product throughout the supply chain. We also obtain information on the practices and conditions under which the product was stored and handled at each point to help identify shipments of interest and determine whether contamination may have occurred at each point. The records we need are not always in

an electronic format, and records review often can be a time-consuming, resource-intensive process.

In the present case, FDA began its investigation prior to the establishment of a strong epidemiological link to a particular food, both to inform the epidemiological study and to shorten the time required to remove potentially contaminated foods from the market. Because institutionally-served peanut butter, in five-pound containers, was identified by the state of Minnesota as a potential vehicle, our investigation began with a strong lead: the brand name of a company and the address to begin our trace. But allow me to explain a few components of the epidemiological process, the critical first step in our collaborative efforts.

## **EPIDEMIOLOGICAL INVESTIGATION**

In early December 2008, FDA began collaborating with CDC, the Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA), and public health officials in various states to investigate the multi-state outbreak of human infections caused by *Salmonella* Typhimurium. Early epidemiological efforts to identify a likely food vehicle were inconclusive. While initial efforts focused on the potential for chicken to be the illness vehicle, peanut butter was first identified as a possible source in mid-December. On January 7 and 8, after conversations with CDC, FSIS, and the Minnesota Department of Health about the strength of association between illness and exposure to chicken or peanut butter, FDA decided to investigate institutional food service sources of peanut butter despite the inconclusive epidemiological data.

On January 8, based on preliminary information from CDC's multi-state case control study that explored other possible food sources in addition to peanut butter, and before Minnesota had identified the *Salmonella* strain, FDA visited the King Nut Company in Ohio. King Nut distributes peanut butter manufactured by the Peanut Corporation of America (PCA) at its Blakely, Georgia plant to institutional facilities, food service industries, and private label food companies in several states. On January 9, FDA initiated an inspection of the PCA plant in Blakely, and Minnesota reported that they had isolated *Salmonella* from the open container, although the type of *Salmonella* was not yet known.

As part of its epidemiological investigation, the Minnesota Department of Health tested an open five-pound container of King Nut peanut butter obtained at a nursing home where three patients were sickened by the outbreak strain of *Salmonella* Typhimurium. By January 10, Minnesota health officials had determined that the peanut butter contained the same strain of *Salmonella* Typhimurium associated with the illnesses linked to the outbreak. However, because it is always possible that an open container could have been contaminated by someone or something else in the environment, these results did not definitively confirm PCA as the source. FDA and other state health departments expanded the testing of unopened containers of the King Nut brand of peanut butter.

On January 19, testing by the Connecticut Department of Health of an unopened container of King Nut peanut butter showed that it contained the same strain of *Salmonella* Typhimurium that was associated with illnesses linked to the outbreak. The fact that the *Salmonella* Typhimurium

was confirmed in an unopened container of peanut butter indicated that the peanut butter was contaminated before it left the Blakely processing plant.

PCA sold peanut butter in bulk containers ranging in size from five to 1,700 pounds and peanut paste in sizes ranging from 35-pound containers to tanker trucks. In addition, peanut meal, granulated peanuts, and oil and dry roasted peanuts were sold by PCA in bulk containers of various sizes and, in some instances, in retail-sized containers. Through its investigation, FDA determined that PCA distributed potentially contaminated products to more than 300 consignee firms, many of whom then further distributed products for consumption as peanut butter or for use as ingredients in hundreds of different products, such as cookies, crackers, cereal, candy and ice cream.

As of February 9, CDC is reporting that 600 persons had been infected with the outbreak strain of *Salmonella* Typhimurium from 44 states, plus one person from Canada, and that the infection may have contributed to eight deaths.

## **PLANT INSPECTION**

After visiting King Nut on January 8 to determine where its peanut butter was manufactured and to collect samples, FDA initiated an inspection of PCA's Blakely plant on January 9, shortly after preliminary information indicated that this firm might be linked to the ongoing *Salmonella* Typhimurium outbreak. FDA completed its inspection on January 27. The inspection involved

sampling, documentation collection, and included a heavy focus on information needed to document and support product recall activities.

A document listing observations by FDA's investigators during their inspection of the Blakely plant, known as a List of Inspectional Observations, or FDA Form 483, has been posted on FDA's web site at [www.fda.gov/ora/frequent/default.htm](http://www.fda.gov/ora/frequent/default.htm). This list is not a final Agency determination regarding compliance by the firm. The list of observations includes matters relating to cleaning programs and procedures as well as failure to implement steps to mitigate *Salmonella* contamination in the facility. This document was initially issued to the firm on January 27 at the conclusion of the inspection. After a more detailed review of the many records obtained during this inspection, FDA determined that certain information provided by PCA management during the inspection was not consistent with FDA's subsequent analysis of the company's records. Therefore, on February 5, 2009, FDA issued an amended Form 483 to present the variety of testing and shipping circumstances reflected by the firm's records.

FDA's environmental sampling at the plant found two *Salmonella* strains, neither of which were *Salmonella* Typhimurium, the outbreak strain. Presently, CDC is not aware of any illnesses definitely connected to these other *Salmonella* strains. Although these samples did not match the outbreak strain, state sampling and analysis of unopened finished products indicate that PCA products shipped from the Blakely plant were contaminated with the *Salmonella* outbreak strain.

Further, FDA's review of the firm's testing records -- which were not disclosed to FDA and state inspectors during earlier routine inspections -- revealed that there were instances in 2007 and 2008 in which the firm distributed product in commerce that tested positive for *Salmonella*. FDA has recently confirmed that our Office of Criminal Investigations (OCI) is conducting an ongoing criminal investigation.

## **PRODUCT RECALLS**

After discussions with FDA, the first product recall related to the outbreak was initiated on January 10, 2009, by the King Nut Company of peanut butter distributed under the King Nut and Parnell's Pride labels. On January 13, PCA initiated a voluntary recall of certain lots of peanut butter produced on or after July 1, 2008, due to the risk of *Salmonella* contamination. PCA expanded this recall on January 16 to include all peanut butter produced on or after August 8, 2008, and all peanut paste produced on or after September 26, 2008. This was followed by yet another expansion on January 18, 2009, when PCA announced it was recalling all peanut butter and peanut paste manufactured on or after July 1, 2008, at its Blakely processing plant.

On January 28, PCA expanded the recall again to include all peanuts and peanut products, including all peanuts (dry and oil roasted), granulated peanuts, peanut meal, peanut butter and peanut paste processed in its Blakely facility since January 1, 2007. All of these recalled peanuts and peanut products were produced only at the company's Blakely facility.

Many companies that received peanuts and peanut products manufactured by PCA's Blakely facility have, in turn, conducted voluntary recalls. The recalled peanuts and peanut products were used as ingredients in many additional products, exponentially increasing the scope of the recall. To help consumers and others identify affected products, FDA has placed a user-friendly, searchable list of the products being recalled, with corresponding photographs, when available, on its web site at [www.accessdata.fda.gov/scripts/peanutbutterrecall/index.cfm](http://www.accessdata.fda.gov/scripts/peanutbutterrecall/index.cfm). The searchable list currently includes approximately 1,800 entries in 17 categories, representing products that have been recalled by nearly 200 companies. FDA is updating this list on a daily basis, as new information becomes available.

FDA has been working with purchasers of PCA's peanuts and peanut products to identify affected products and facilitate their removal from the market. FDA initiated inspections at the direct consignees of PCA and King Nut and continues to follow the distribution points for products. FDA and state officials have contacted thousands of firms throughout the entire distribution chain that may have purchased or further distributed PCA products. This work is continuing and includes the additional products in the expanded recall.

As FDA gathers additional information about these "downstream" products, the list of recalled products has expanded, and will likely continue to do so. FDA urges all affected retailers to immediately stop selling recalled products. Directors of institutions and food service establishments also are strongly urged to ensure that they are not serving recalled products.

We would like to emphasize, as we have stated numerous times, that major national brands of jarred peanut butter found in grocery stores are not affected by the PCA recall.

## **RECOMMENDATIONS FOR CONSUMERS**

FDA has created a web page to provide constantly updated information on the contamination and recall at [www.fda.gov/oc/opacom/hottopics/salmonellatyph.html](http://www.fda.gov/oc/opacom/hottopics/salmonellatyph.html). This web page has already been viewed more than 28 million times. The web page includes a searchable database, noted earlier, which can be found at [www.accessdata.fda.gov/scripts/peanutbutterrecall/index.cfm](http://www.accessdata.fda.gov/scripts/peanutbutterrecall/index.cfm), to assist consumers in quickly identifying recalled products. In addition to FDA's traditional consumer outreach through press releases and media briefings, we have initiated outreach through so-called "social media" such as Podcasts, Twitter, blogs and MySpace postings.

Consumers are urged to check FDA's web page to determine which products have been recalled and to learn of new recalls as they are announced. Any product that is on the recall list should be disposed of in a manner that will prevent others from consuming it. Consumers also are urged to wash their hands after handling potentially contaminated products. If consumers are unsure whether a peanut-containing product is potentially contaminated, they should avoid consuming it until they obtain more information about the product. Persons who think they may have become ill from eating peanuts or peanut products are advised to consult their health care providers.

Product recalls include some pet food products that contain peanut products made by PCA. In addition to the risk of animals contracting salmonellosis, there is risk to humans from handling

these products. It is important for people to wash their hands -- and make sure children wash their hands -- before and, especially, after feeding pets. Further information for consumers is located in the Frequently Asked Questions section located on FDA's web site. The pet food products are also included in the searchable data base of recalled products.

For information on products containing peanuts or peanut products from companies not reporting recalls, consumers may wish to consult the company's web site or call the toll-free number listed on most packaging. We note that information consumers may receive from the companies has not been verified by FDA.

## **PRODUCT MANUFACTURERS AND DISTRIBUTORS**

FDA urges manufacturers and distributors of products containing peanuts or peanut products to inform consumers about whether their products could contain peanuts or peanut products from PCA's Blakely plant. If a manufacturer knows its products do not contain peanuts or peanut products from PCA, it may wish to provide this information to consumers.

FDA is continuing to work with firms on the details of their actions, conducting follow-up audits and inspections, monitoring the progress of firms' actions, working with state and local regulatory authorities, and notifying our foreign regulatory counterparts of affected products that have now been confirmed as having been distributed internationally. Further, FDA is continuing its work to identify products that may be affected, and to track the ingredient supply chain of those products to facilitate their removal from the marketplace.

## CONCLUSION

FDA is working hard to ensure the safety of food, in collaboration with its Federal, state, local, and international food safety partners, and with industry, consumers, and academia. Although the *Salmonella* Typhimurium foodborne illness outbreak underscores the challenges we face, the American food supply continues to be among the safest in the world. Food safety is a priority for the new Administration.

The Agency will continue to review its actions both before and in response to this outbreak to identify lessons learned and areas for improvement. Although we responded to the available epidemiological information and quickly identified PCA's products as the source of the outbreak, we would prefer to prevent contamination from occurring or at minimum to identify it and take action before consumers become ill. It bears repeating that manufacturers play a critical role in ensuring the safety of the foods they introduce into commerce.

The facts of this outbreak, as well as our experience with other outbreaks, highlight the need to enhance FDA's statutory authority to protect consumers from foodborne outbreaks. We are reviewing with HHS, as well as other Federal and state food safety partners, prior requests to strengthen the Agency's ability to protect Americans from foodborne illness to determine whether those requests should be updated in light of our experience with this outbreak. At this time, we want to highlight the previously-identified need for new or enhanced authority in several areas:

- (1) Authority for FDA to issue preventive controls for high-risk foods;

- (2) Authority for enhanced access to food records during routine inspections to ensure that inspectors have access to all information that bears on product safety; and
- (3) Authority for FDA to require food facilities to renew their registrations every two years, and allow FDA to modify the registration categories.

In addition, we note that mandatory recall authority would be a useful tool that in some circumstances could result in faster removal of implicated products from commerce.

Over the last year and a half, FDA has made significant progress in identifying food vulnerabilities and mitigation strategies. For example, we have strengthened our response to food safety threats by providing incident command system training to our FDA offices around the country, and to states, and by enhancing communication during a food recall. We are proud of the collaborative efforts among Federal and state agencies to investigate, analyze samples, monitor the effectiveness of the current recall, and communicate with the public to protect public health. We will continue to strive to reduce the incidence of foodborne illness to the lowest level possible.

Thank you for the opportunity to discuss FDA's response to the recent *Salmonella* outbreak. I would be happy to answer any questions you may have.