



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

STATEMENT OF

STEPHEN F. SUNDLOF, D.V.M., PH.D.

DIRECTOR

CENTER FOR FOOD SAFETY AND APPLIED NUTRITION

FOOD AND DRUG ADMINISTRATION

DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE THE

COMMITTEE ON AGRICULTURE, NUTRITION AND FORESTRY

UNITED STATES SENATE

FEBRUARY 5, 2009

FOR RELEASE ONLY UPON DELIVERY

INTRODUCTION

Good morning Mr. Chairman and members of the Committee. 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. 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 continues as we speak, our final conclusions and recommendations are necessarily pending the outcome of our investigation.

Let me begin by providing a brief description of the typical traceback process employed by FDA and our sister agency, the Centers for Disease Control and Prevention (CDC). Once CDC, through its epidemiological investigation which involves working with state and local health departments, identifies the possible food(s) associated with a foodborne illness outbreak, 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. To start 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 do this by tracing the food suspected of being the vehicle for transmitting the pathogen back through the supply chain from the retailer, restaurant or institutional setting and inspecting or investigating 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 better determine shipments of interest and 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 current case, FDA began its investigation prior to having a strong epidemiological link to a particular food, both to inform the epidemiological study and to shorten the time required to get potentially contaminated foods off the market. Because institutionally-served peanut butter, in five-pound containers, was identified by the state of Minnesota as a potential vehicle, our investigation had 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 work, the first step in our collaborative efforts.

EPIDEMIOLOGICAL INVESTIGATION

Since early December 2008, FDA has collaborated 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 due to *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 begin to investigate institutional food service sources of peanut butter despite the inconclusive epidemiological data.

On January 7, 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 made its initial contact with 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, though 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 the open container was 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 same 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 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 when it left the Blakely processing plant.

Peanut butter is sold by PCA in bulk containers ranging in size from five to 1,700 pounds. The peanut paste is sold in sizes ranging from 35-pound containers to tanker trucks. However, through its investigation, FDA has 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 1, CDC reported that 550 persons infected with the outbreak strain of *Salmonella* Typhimurium have been reported from 43 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* outbreak. FDA completed its inspection on January 27.

A document listing observations by FDA investigators during their inspection, known as a List of Inspectional Observations, or Form 483, has been posted on FDA's website at www.fda.gov/ora/frequent/default.htm. This list is not a final Agency determination regarding compliance. 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.

FDA's environmental sampling at the plant found two *Salmonella* strains, neither of which were *Salmonella* Typhimurium, the outbreak strain. As of now, CDC is not aware of any illnesses definitely connected to these other *Salmonella* strains. We are confident, however, based on the investigations by the states, CDC and FDA, including product testing, that the Blakely plant is the source of the contaminated foods related to the current *Salmonella* Typhimurium outbreak. State sampling and analysis of unopened finished products indicate that PCA-shipped product from the Blakely plant was contaminated with the 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 where the firm distributed product in commerce which tested positive for *Salmonella*.

As you may be aware, 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 and peanut paste produced on or after July 1, 2008, due to the risk of *Salmonella* contamination. PCA expanded this recall on January 16 to include peanut butter produced on or after August 8, 2009, and peanut paste produced on or after September 26, 2008. This was followed by yet another expansion on January 18, 2008, 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 issued another expanded voluntary recall of 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 made 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. A user-friendly, searchable list of the products being recalled, with corresponding photographs, when available, can be found at www.accessdata.fda.gov/scripts/peanutbutterrecall/index.cfm. The searchable list currently includes approximately 1,000 entries in 16 categories representing products that have been

recalled by more than 75 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 hundreds 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.

Companies nationwide that received product made by PCA have issued voluntary recalls of their products. As FDA gathers additional information about these 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 are also 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. Further, FDA has no evidence to suggest that the *Salmonella* Typhimurium contamination originated with any manufacturing facility other than PCA's Blakely plant. The facility is not operating at this time.

RECOMMENDATIONS FOR CONSUMERS

FDA has established a web page to provide constantly updated information on the contamination and recall at www.fda.gov/oc/opacom/hottopics/salmonellatyph.html. This web page has already been viewed more than 19 million times. The web page includes a searchable database to assist consumers in quickly identifying recalled products, found at www.accessdata.fda.gov/scripts/peanutbutterrecall/index.cfm.

Consumers are urged to check this web page to determine which products have been recalled and to become aware of new recalls as they are announced. Any product that is on the recall list should be disposed of in a safe manner. Consumers are also 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 peanut products are advised to consult their health care providers.

Product recalls include some pet food products that contain peanut products made by PCA. Although the risk of animals contracting salmonellosis is minimal, 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 this web site. The pet food products are also included in the searchable data base of recalled products.

For information on products containing peanut butter from companies not reporting recalls, consumers may wish to consult the company's website 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 peanut-based ingredients to inform consumers about whether their products could contain peanuts or peanut products from PCA Blakely. 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 the firms on the details of their actions, conducting follow-up audits and inspections, monitoring the progress of the firms' actions, working with state and local regulatory authorities, and notifying our foreign regulatory counterparts of products that have now been confirmed as having been distributed internationally. 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.

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 developing templates to enhance 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.