



**STATEMENT OF**

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**OFFICE OF REGULATORY AFFAIRS**

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**BEFORE THE**

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## INTRODUCTION

Good morning, Madam Chairwoman and Members of the Subcommittee. I am Dr. Steven Solomon, Assistant Commissioner for Compliance Policy in the Office of Regulatory Affairs 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 about how we manage the recall of FDA-regulated products that can harm consumers, including the ongoing recalls related to peanuts and peanut-containing products made by the Peanut Corporation of America (PCA). As you know, these products have been the source of a foodborne illness outbreak caused by the *Salmonella* Typhimurium bacterium which, as of March 3, has infected 677 people in 45 states and may have contributed to nine deaths.

When a product on the market presents a public health hazard, promptly recalling that product usually is the most effective means of protecting the public. As illustrated by recent events, however, a recall initiated by one company can sometimes have repercussions for a very large number of businesses that receive those products or ingredients for further processing, distribution, or retail sale.

It is important to understand 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 promotion of a strong culture of food safety throughout the company, including the need for preventive measures to detect and prevent problems before they occur.

Establishing this culture requires a strong sense of corporate responsibility and continuous management oversight.

One of the key messages that FDA has been emphasizing over the last few years is that all food companies, both large and small, must know their suppliers. It is critically important for firms to know the supply chain for the ingredients they use in their products and to be sure that their suppliers provide accurate information about their food safety and defense controls and the products they supply. In a complex, global market, this may require close interaction with many critical components throughout the food supply chain, including growers, manufacturers, distributors, retailers, food service providers, and importers.

## **RECALL POLICIES AND PROCEDURES**

Various statutory provisions authorize FDA to require recalls of certain products in particular circumstances. However, in the food arena, with the exception of infant formula, FDA does not have the authority to order a recall of a food or dietary supplement.

Subpart C of Part 7 of FDA's regulations (Title 21, *Code of Federal Regulations*, 7.40-59) provides general guidance for the voluntary recall of products, including those recalls initiated by a firm on its own and those initiated at FDA's request. In addition, FDA has published guidance for recalling firms which can be found at:

*[http://www.fda.gov/ora/compliance\\_ref/recalls/ggp\\_recall.htm](http://www.fda.gov/ora/compliance_ref/recalls/ggp_recall.htm)*.

FDA's recall guidance describes actions that FDA and the industry can take to carry out their respective recall responsibilities. The underlying premise of FDA's recall guidance is that firms producing and marketing FDA-regulated products assume a responsibility to timely remove violative products from the marketplace when removal is necessary to protect the public health.

FDA assigns recalls to one of three categories according to the level of hazard associated with the violative product that is being recalled:

- Class I recalls are those where there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death. Examples of products that could fall into this category are a food found to contain botulinum toxin or *Salmonella*, or a food with undeclared allergens.
- Class II recalls are those in which use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote. One example is a drug that is under strength but that is not used to treat life-threatening situations.
- Class III recalls are those in which use of, or exposure to, a violative product is not likely to cause adverse health consequences. One example is a food sold at retail with a label that does not contain the required information in English.

A recall is intended to achieve the orderly and prompt removal or correction of a violative product. As previously mentioned, almost all recalls are conducted voluntarily since FDA has mandatory recall authority in very limited circumstances. A formal FDA “request” for a recall, although still voluntary, is reserved for urgent situations, i.e., those violative distributed products that pose a hazard to the consumer. In most instances, companies are willing either to conduct voluntary recalls of their own accord or after a formal request from FDA. If a firm refuses to recall violative product, FDA may pursue a remedy in Federal court, such as a seizure or injunction. FDA also may choose to issue press releases to warn the public about violative products that are in the marketplace.

## **ROLE OF FDA AND FIRMS IN CONDUCTING RECALLS**

The cooperation of industry in expediting recall activities is vital to ensuring that recalled products are removed from the marketplace swiftly, efficiently, and effectively. Recalling firms are urged to notify FDA as soon as they determine that the recall of a violative product is appropriate. Firms also are asked to provide certain information about the recall to FDA, including: the reason for the recall; why the product is violative; how the problem occurred; the extent of the problem; how and when the problem was discovered; where the product was distributed; and any consumer or supplier complaints.

Following notification, in most cases the recalling firm and FDA work collaboratively to develop a recall strategy. This early communication helps to ensure the orderly and prompt removal or correction of a violative product to the extent necessary to protect the public health. Likewise, it

allows FDA to determine the steps it must take to address the specific circumstances, which may include: making certain that all products that need to be recalled are, in fact, recalled; helping to locate the product subject to the recall; assisting in identifying the cause of the problem; and checking similar firms and/or products to determine if the problem could be more widespread. FDA uses information it learns during recalls to help prevent future problems and to identify similar problems if they arise in the future.

Throughout the course of the recall, it is the recalling firm's responsibility to determine whether the recall is progressing satisfactorily by performing effectiveness checks. These checks help to verify that all known, affected consignees have received notification about a recall and have taken appropriate action. At the same time, FDA conducts "audit checks" to assess the effectiveness of a firm's recall efforts.

Even though the firm recalling the product may issue a press release, FDA will further publicize a recall when it believes the public needs to be alerted about a serious hazard. For example, if a canned food product, purchased by a consumer at a retail store, was found by FDA to contain botulinum toxin, the recall strategy would include an effort to retrieve all cans in circulation, including those in the hands of consumers. As part of this effort, the Agency also could issue a public warning via the news media to alert as many consumers as possible to the potential hazard. The news media is a very effective way to inform large numbers of people that a widely distributed product has been recalled.

## **HOW FDA WORKS WITH FIRMS DURING RECALLS**

FDA is committed to working with recalling firms to effect the orderly and prompt removal of a violative product from the marketplace and has a variety of mechanisms in place to achieve this goal. For example, FDA has field recall coordinators located throughout the country to act as the point of contact for a recalling firm and to assist firms with a recall. The recall coordinators provide a recalling firm with information about the recall process and are available to work closely with the firm throughout the course of the recall. For example, recall coordinators assist the firm in determining an appropriate recall strategy, review the recalling firm's notification letter to customers affected by the recall, and coordinate the appropriate destruction, reconditioning, or disposition of recalled product. A list of the recall coordinators can be found at: <http://www.fda.gov/oc/opacom/hottopics/salmonellatyph/recallcoordlist.html>.

In addition, FDA has developed "model" press releases available for use by a recalling firm that needs to issue press to inform the public about its recall. These model press releases help ensure that all appropriate information about the recalled product is accurately and appropriately conveyed to the public. Further, FDA encourages recalling firms to consult with their local recall coordinators before issuing press releases.

To assist firms in communicating their recall actions, and to help ensure that the public is informed, FDA posts firms' press releases on its Web site. In the case of a Class I recall, FDA also will post photos of the recalled food product if provided by the firm. The use of product

photographs for food recalls has proven to be so successful and useful to consumers that FDA plans to expand it to include other Class I recalled products, such as drugs or medical devices.

For recalls of widely distributed products, such as pet food contaminated with melamine, and the current recall of peanuts and peanut-containing products that may be contaminated with *Salmonella* Typhimurium, FDA also has posted a searchable database on its Web site to help the public and recalling firms identify recalled products. FDA updates the database daily and includes descriptive information about the recalled products such as brand name, recalling firm, UPC code, size, and description of the product. In at least one instance during the current peanut-related outbreak, FDA learned that a small business, using the searchable database, was able to identify a recalled peanut product it had used in its finished product and initiate a recall of its own products even before receiving notification from its supplier.

## **THE IMPACT OF FOODBORNE OUTBREAKS ON BUSINESS**

FDA has a duty to protect the public health. At the same time, FDA is aware that foodborne outbreaks can adversely impact businesses, which bear the cost of the recall and may suffer from negative consumer perception of their products. FDA believes that responding quickly to remove misbranded and adulterated products from shelves through effective recalls is in industry's and the public's best interest.

Preventing such outbreaks from occurring is the most desirable goal, from the perspectives of both public health and industry. Businesses should take measures to ensure the quality of the

ingredients they use in their products. To protect against contamination, food manufacturing facilities are required to follow FDA's current Good Manufacturing Practices regulation. FDA remains committed to working with industry at all levels to prevent foodborne outbreaks.

In addition, there are actions that firms can take to be prepared if a recall becomes necessary. For example, FDA recommends in its recall guidance that firms prepare and maintain a current written contingency plan for use in initiating and effecting a recall. FDA also recommends that firms take steps to enable them to trace their inventory in the event of a recall to limit the amount of product affected.

## **PCA INVESTIGATION**

On January 7, 2009, FDA discussed peanut butter as a possible source of the outbreak with the Centers for Disease Control and Prevention (CDC) and the Minnesota Department of Health. On January 8, based on preliminary data from CDC and Minnesota's investigation, FDA initiated an inspection and collected samples at a peanut butter distributor, King Nut Company. King Nut distributed peanut butter manufactured by 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.

By January 19, tests 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, PCA sold peanut meal, granulated peanuts, and oil and dry roasted peanuts 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 in 2007 and 2008, many of which then further distributed products for consumption or for use as ingredients in hundreds of different products, such as cookies, crackers, cereal, candy, and ice cream.

Because of public health concerns related to PCA's plant in Blakely, Georgia, FDA expanded the scope of its inspections to include the PCA plant in Plainview, Texas, where FDA found additional problems relating to filth and Salmonella contamination.

## **PEANUT AND PEANUT PRODUCT RECALLS**

After discussions with FDA, the first product recall related to the outbreak was initiated on January 10, 2009, by King Nut 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 processed peanuts and peanut products, including all dry and oil roasted peanuts, granulated peanuts, peanut meal, peanut butter and peanut paste processed in its Blakely facility since January 1, 2007.

On February 12, the State of Texas issued an emergency order directing PCA's Texas facility to cease the manufacture and distribution of all food products at the facility and issued a mandatory recall order requiring PCA to recall all products manufactured at the plant. On February 20, PCA issued a statement indicating it earlier had filed for Chapter 7 bankruptcy and that it was no longer able to communicate with customers regarding recalled products. As a result, FDA and Texas officials are now coordinating their efforts to notify companies that received product from PCA's Plainview, Texas facility from January 1, 2007, forward.

Many companies that received recalled peanuts and peanut products from PCA 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 3,200 product entries in 18 categories, representing

products that have been recalled by approximately 300 companies. FDA is updating this list on a daily basis, as new information becomes available.

FDA has been working with companies that purchased PCA's peanuts and peanut products to identify affected products and facilitate their removal from the market. FDA and state officials have contacted more than 14,000 firms throughout the distribution chain, including direct accounts, sub-accounts, and retail accounts.

FDA is continuing to work closely with firms, conduct follow-up audits and inspections, monitor the progress of firms' actions, work with state and local regulatory authorities, and notify our foreign regulatory counterparts of affected products that have 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**

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 currently reviewing with HHS the Agency's prior legislative requests to strengthen our ability to protect Americans from foodborne illness.

One of the areas under discussion is mandatory recall authority, which would be a useful tool that in some circumstances could result in faster removal of implicated products from commerce.

We are also discussing the need for new or enhanced authority in several other areas:

- (1) Authority for FDA to require preventive controls;
- (2) Authority for enhanced access to food records during routine inspections; and
- (3) Authority for FDA to require food facilities to renew their registrations more frequently, and for FDA to modify the registration categories.

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. We can, and will, learn from the outbreak what we can do to better ensure the safety of our food supply moving forward.

Thank you for the opportunity to discuss FDA's recall process and its application to the ongoing recalls of contaminated peanuts and peanut products. I would be happy to answer any questions you may have.