AUG 1 2 2009

TO: Margaret A. Hamburg, M.D.
Commissioner
Food and Drug Administration

FROM: Daniel R. Levinson *for DRL*
Inspector General

SUBJECT: Review of the Food and Drug Administration's Monitoring of Pet Food Recalls (A-01-07-01503)

The attached final report provides the results of our review of the Food and Drug Administration's (FDA) monitoring of pet food recalls. The Chairman of the Senate Committee on Agriculture, Nutrition, and Forestry requested this review.

When a problem arises with a particular food, the manufacturer or importer is responsible for voluntarily recalling the product, and FDA works with the firm to develop and oversee a recall strategy. FDA established regulations (21 CFR part 7) as nonbinding guidance (referred to as "recall guidance") that FDA and the recalling firm should consider in planning and implementing a recall.

From March 16 to April 26, 2007, firms initiated and FDA oversaw 16 Class I recalls of pet food contaminated with melamine. Three recalls by one manufacturer, Menu Foods Limited (Menu Foods), accounted for approximately 89 percent of the products in the 16 recalls. Our review focused on one small recall each by an import firm and an import broker and on the three Menu Foods recalls.

Our objective was to determine (1) what authority FDA has with respect to recalls of pet food and (2) what procedures FDA has developed to implement its authority, whether FDA followed its procedures, and whether the procedures were adequate.

The results of our audit follow:

- FDA does not have statutory authority to require manufacturers to initiate pet food recalls. Therefore, the initiation of such recalls on the part of manufacturers or importers is voluntary. Furthermore, FDA issued its regulations as nonbinding recall guidance. Even if FDA were to require firms to follow certain procedures, FDA has no statutory authority to assess penalties for recall violations. However, when FDA believes that an

article of food presents a serious health threat, the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 provides additional authority to FDA to administratively detain food and obtain certain food records. Several bills proposed in the 110th session of Congress would have provided FDA with authority to mandate recalls and to dictate and enforce the terms of a recall.

- FDA has developed procedures for monitoring recalls and assessing a firm's recall effectiveness. The procedures cover, among other activities, reviewing the firm's recall strategy and recommending changes, inspecting the firm, conducting audit checks at selected distributors and retailers, and reviewing the firm's status reports and assessing the results of the firm's effectiveness checks of distributors and retailers as shown in the status reports. Although FDA's oversight of the two small pet food recalls by an import firm and an import broker was generally adequate, FDA did not always follow its procedures in overseeing the Menu Foods recalls. Furthermore, FDA's procedures were not always adequate for monitoring recalls as large as those of Menu Foods.

The ultimate responsibility for removing the contaminated pet food rested with Menu Foods and its distributors and retailers. Nevertheless, FDA's lack of authority, coupled with its sometimes lax adherence to its recall guidance and internal procedures and the inadequacy of some of those procedures, limited FDA's ability to ensure that contaminated pet food was promptly removed from retailers' shelves.

Our report contains detailed recommendations for strengthening FDA's recall authority and improving its effectiveness in monitoring food recalls.

In comments on our draft report, FDA agreed or agreed in principle with all of our recommendations.

Pursuant to the Freedom of Information Act, 5 U.S.C. § 552, Office of Inspector General reports generally are made available to the public to the extent that information in the report is not subject to exemptions in the Act. Accordingly, this report will be posted on the Internet at http://oig.hhs.gov.

Please send us your final management decision, including any action plan, as appropriate, within 60 days. If you have any questions or comments about this report, please do not hesitate to call me, or your staff may contact Lori S. Pilcher at (202) 619-1175 or through email at Lori.Pilcher@oig.hhs.gov. Please refer to report number A-01-07-01503 in all correspondence.

Attachment

Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

REVIEW OF THE FOOD AND DRUG ADMINISTRATION'S MONITORING OF PET FOOD RECALLS

Daniel R. Levinson
Inspector General

August 2009
A-01-07-01503

Office of Inspector General

http://oig.hhs.gov

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OFFICE OF AUDIT SERVICES FINDINGS AND OPINIONS

The designation of financial or management practices as questionable, a recommendation for the disallowance of costs incurred or claimed, and any other conclusions and recommendations in this report represent the findings and opinions of OAS. Authorized officials of the HHS operating divisions will make final determination on these matters.

EXECUTIVE SUMMARY

BACKGROUND

The Food and Drug Administration (FDA) is responsible for safeguarding the Nation's food supply, including food given to animals. When a problem arises with a particular food, the manufacturer or importer is responsible for voluntarily recalling the product, and FDA works with the firm to develop and oversee a recall strategy. FDA established regulations (21 CFR part 7) as nonbinding guidance that FDA and the recalling firm should consider in planning and implementing a recall. This report refers to these regulations as "recall guidance."

From March 16 to April 26, 2007, firms initiated and FDA oversaw 16 Class I recalls of pet food contaminated with melamine, an unapproved substance. FDA designates a recall as Class I when it believes that the product being recalled presents a high health hazard. Three recalls by one manufacturer, Menu Foods Limited (Menu Foods), accounted for approximately 89 percent of the products in the 16 recalls. Menu Foods initiated its recalls in response to animal taste tests and consumer complaints that dogs and cats were becoming seriously ill or dying after consuming certain Menu Foods pet food products.

Our review focused on 5 of the 16 Class I pet food recalls: one small recall each by an import firm and an import broker and the three Menu Foods recalls. The Chairman of the Senate Committee on Agriculture, Nutrition, and Forestry requested this review.

OBJECTIVE

Our objective was to determine:

- what authority FDA has with respect to recalls of pet food and
- what procedures FDA has developed to implement its authority, whether FDA followed its procedures, and whether the procedures were adequate.

SUMMARY OF RESULTS

The results of our audit follow:

- FDA does not have statutory authority to require manufacturers to initiate pet food recalls. Therefore, the initiation of such recalls on the part of manufacturers or importers is voluntary. Furthermore, FDA issued its regulations as nonbinding recall guidance. Even if FDA were to require firms to follow certain procedures, FDA has no statutory authority to assess penalties for recall violations. However, when FDA believes that an article of food presents a serious health threat, the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 provides additional authority to FDA to administratively detain food and obtain certain food records. Several bills proposed in the 110th session of Congress would have provided FDA with authority to mandate recalls and to dictate and enforce the terms of a recall.

- FDA has developed procedures for monitoring recalls and assessing a firm's recall effectiveness. The procedures cover, among other activities, reviewing the firm's recall strategy and recommending changes, inspecting the firm, conducting audit checks at selected distributors and retailers, and reviewing the firm's status reports and assessing the results of the firm's effectiveness checks of distributors and retailers as shown in the status reports. Although FDA's oversight of the two small pet food recalls by an import firm and an import broker was generally adequate, FDA did not always follow its procedures in overseeing the Menu Foods recalls. Furthermore, FDA's procedures were not always adequate for monitoring recalls as large as those of Menu Foods.

The ultimate responsibility for removing the contaminated pet food rested with Menu Foods and its distributors and retailers. Nevertheless, FDA's lack of authority, coupled with its sometimes lax adherence to its recall guidance and internal procedures and the inadequacy of some of those procedures, limited FDA's ability to ensure that contaminated pet food was promptly removed from retailers' shelves.

RECOMMENDATIONS

We recommend that FDA:

- consider seeking statutory authority to mandate food recalls and to assess penalties for noncompliance with the terms of recalls;

- amend its regulations or, if necessary, seek additional legislative changes to establish mandatory requirements for firms to follow in conducting recalls, including:

  - a written recall strategy,

  - prompt initiation of effectiveness checks, and

  - periodic status reports that contain all specified information, including the number and results of the firm's effectiveness checks;

- comply with its procedures for monitoring recalls; and

- revise its procedures to require FDA staff to:

  - document the approved recall strategy, including the specified effectiveness check levels and target dates for initiating and completing effectiveness checks,

  - promptly determine the accuracy of the firm's recall list,

  - ensure that audit checks are performed as assigned and that the results are accurately and completely documented,

  - separately tabulate the results of audit checks for each recalling firm, and

- follow up with the firm to ensure that it has completed the specified level of effectiveness checks in a timely manner.

FOOD AND DRUG ADMINISTRATION COMMENTS

In comments on our draft report, FDA agreed or agreed in principle with all of our recommendations. FDA's comments are included in their entirety as Appendix B.

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INTRODUCTION

BACKGROUND

Food and Drug Administration

Pursuant to the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. § 301 et seq.), the Food and Drug Administration (FDA) is responsible for safeguarding the Nation's food supply by ensuring that all ingredients used in food are safe and that food is free of disease-causing organisms, chemicals, or other harmful substances. The Act defines food to include food given to pets, livestock, and other animals. When a problem arises with a particular food, the manufacturer or importer is responsible for voluntarily recalling the product, and FDA works with the firm to develop and oversee a recall strategy.

FDA established regulations (21 CFR part 7) as nonbinding guidance that FDA and the recalling firm should consider in planning and implementing a recall. This report refers to these regulations as "recall guidance." Recall guidance (21 CFR § 7.3(g)) defines a recall as a firm's removal or correction of a product that FDA considers to be a violation of the laws that it administers.

Within FDA, the Center for Veterinary Medicine and the Office of Regulatory Affairs are responsible for overseeing firm-initiated recalls of food for pets and livestock. The Office of Enforcement, which is part of the Office of Regulatory Affairs, is responsible for providing oversight of field activities and coordinating product recalls. The FDA district office in the recalling firm's geographical region is designated as the lead district and is responsible for providing guidance to the firm and for monitoring day-to-day recall activities. The Office of Enforcement and the FDA district offices consult and coordinate with the Center for Veterinary Medicine.

Recall Guidance

Health Hazard Evaluation and Recall Classification

Recall guidance (21 CFR § 7.41) states:

> An evaluation of the health hazard presented by a product being recalled or considered for recall will be conducted by an ad hoc committee of . . . [FDA] scientists and will take into account, but need not be limited to, the following factors: . . . Assessment of the degree of seriousness of the health hazard to which the populations at risk would be exposed . . . . On the basis of this determination, the Food and Drug Administration will assign the recall a classification, i.e., Class I, Class II, or Class III, to indicate the relative degree of health hazard of the product being recalled or considered for recall.

Class I indicates the highest degree of health hazard.

Recall Strategy

Recall guidance (21 CFR § 7.42) states: ". . . [a] recall strategy . . . will be developed by the agency for . . . [an FDA]-requested recall and by the recalling firm for a firm-initiated recall . . . . [FDA] will review the adequacy of a proposed recall strategy developed by a recalling firm and recommend changes as appropriate." The guidance recommends that a recall strategy address the following elements:

- *Depth of recall*. The recall strategy "will specify the level in the distribution chain [i.e., consumer level, retail level, or wholesale level] to which the recall strategy is to extend" based on the product's degree of hazard and extent of distribution.

- *Public warning.* The recall strategy "will specify whether a public warning is needed" to alert the public that a product being recalled presents a serious health hazard.

- *Effectiveness checks.* The recall strategy "will specify the method(s)" that the recalling firm should use to conduct effectiveness checks of consignees (distributors and retailers)[1] and the FDA-determined level of the checks. Effectiveness checks involve contacting distributors and retailers by visits, telephone calls, and/or letters to verify that they have received notification of the recall and have taken appropriate action. Effectiveness checks range from Level A (contacting 100 percent of the distributors and retailers) to Level E (conducting no effectiveness checks).

Recall Communications

Pursuant to 21 CFR § 7.49, a recalling firm is responsible for promptly notifying each of its affected distributors and retailers in writing about the recall. This recall communication should clearly identify the product being recalled; explain the reason for the recall; and instruct the distributor or retailer to immediately stop distributing any remaining product and, when appropriate, to notify its customers about the recall. The communication also should provide instructions on what the distributor or retailer should do with the recalled product. Distributors and retailers that receive a recall communication should immediately carry out its instructions.

Recall Status Reports

Pursuant to 21 CFR § 7.53, the recalling firm "is requested to submit periodic recall status reports to the appropriate . . . [FDA] district office so that . . . [FDA] may assess the progress of the recall." In general, the recalling firm should submit recall status reports every 2 to 4 weeks. The reports should include the number of distributors and retailers notified of the recall and the date and method of notification, the number of distributors and retailers that did and did not respond to the recall communication and the quantity of products on hand, the number of products that the distributors and retailers returned or corrected, and the number and results of the recalling firm's effectiveness checks.

[1]Recall guidance (21 CFR § 7.3) defines a consignee as any party that received, purchased, or used the product being recalled. This report refers to consignees as "distributors and retailers."

Recalls of Melamine-Contaminated Pet Food

From October 2006 through September 2007, FDA's Center for Veterinary Medicine oversaw 79 recalls, including 38 recalls of melamine-contaminated[2] pet food that began in March 2007. According to FDA, it received approximately 18,000 consumer complaints from March through May 2007 regarding melamine-contaminated pet food that was causing illness and death among pets. The melamine-related recalls involved 27 firms and more than 1,000 products. FDA classified 16 of these recalls as Class I recalls based on the toxic levels of melamine in the sampled pet food.

According to FDA, the melamine-related pet food recalls were unprecedented in size and scope and involved FDA's central office and all 19 district offices, as well as State health agencies in all 50 States and the District of Columbia. A total of approximately 400 FDA employees were involved in, among other activities, collecting samples of pet food for analysis, analyzing the contaminated pet food to determine the causative agents, monitoring the effectiveness of the recalls, preparing customer complaint reports, issuing press releases, and posting and updating consumer warnings on the FDA Web site.

Three recalls by one manufacturer, Menu Foods Limited (Menu Foods), accounted for approximately 89 percent of the 666 products in the 16 Class I pet food recalls. The first two recalls, which Menu Foods initiated on March 16, 2007, included almost 2.4 million cases of dog and cat food that had been distributed throughout the United States and Canada under various labels. The third recall, initiated on April 10, 2007, involved cat food that was not on the initial recall list.

Menu Foods initiated its recalls in response to animal taste tests and consumer complaints that dogs and cats were becoming seriously ill or dying after consuming certain Menu Foods pet food products. Menu Foods traced the illnesses and deaths to pet food products that it had manufactured with raw material from a new supplier. On March 23, 2007, FDA's investigation found the presence of melamine, an unapproved substance, in the pet food. On May 1, 2007, according to FDA, further FDA research found that the melamine in the pet food had combined with small quantities of cyanuric acid to form crystals that had been linked to acute renal failure in pets. FDA traced the melamine to wheat gluten and rice protein imported from two Chinese suppliers that used melamine to increase the apparent protein content of these products. Appendix A presents a timeline of the major events in the Menu Foods recalls.

Congressional Request

Concerned about FDA's handling of recent recalls of contaminated food and the increase in imports from countries that may have lower food safety standards than those of the United States, the Chairman of the Senate Committee on Agriculture, Nutrition, and Forestry requested this review.

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[2]Melamine is a triazine derivative that has various industrial uses, including as a binding agent and flame retardant. Melamine and its related compounds have no approved use as ingredients in animal or human food in the United States. For the purpose of this report, the term "melamine-contaminated pet food" refers to products contaminated with both melamine and its related compounds, including cyanuric acid, ammeline, and ammelide.

OBJECTIVE, SCOPE, AND METHODOLOGY

Objective

Our objective was to determine:

- what authority FDA has with respect to recalls of pet food and
- what procedures FDA has developed to implement its authority, whether FDA followed its procedures, and whether the procedures were adequate.

Scope

Our review focused on 5 of the 16 Class I pet food recalls involving imported products contaminated with melamine. These five recalls accounted for approximately 90 percent of the products in the Class I recalls of melamine-contaminated pet food during our review period (March through September 2007).

To gain an understanding of FDA's recall process, we conducted a limited review of FDA's internal controls as they related to our objective.

We performed our fieldwork at FDA's offices in Rockville, Maryland, and Lenexa, Kansas, from August 2007 through April 2008.

Methodology

To accomplish our objective, we:

- reviewed Federal laws, regulations, policies, and procedures related to FDA's recall authority;
- discussed with FDA personnel the information maintained in FDA's Recall Enterprise System database (recall database) and compared the number of all Class I recalls of pet food containing contaminated imported products in the recall database with the number of such recalls in the Center for Veterinary Medicine's records to ensure the completeness of the recall database;
- identified from the recall database 16 Class I recalls during our audit period that involved pet food that contained imported products contaminated with melamine and judgmentally selected for review five recalls: one small recall each by an import firm and an import broker and the three recalls by Menu Foods;
- evaluated the adequacy of FDA's procedures for monitoring the effectiveness of the recalls;
- evaluated the timeliness and completeness of FDA's recall monitoring activities;

- checked the accuracy and completeness of FDA's audit check forms and tabulated the results; and

- interviewed FDA officials involved in the recall process.

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objective.

RESULTS OF AUDIT

The results of our audit follow:

- FDA does not have statutory authority to require manufacturers to initiate pet food recalls. Therefore, the initiation of such recalls on the part of manufacturers or importers is voluntary. Furthermore, FDA issued its regulations as nonbinding recall guidance. Even if FDA were to require firms to follow certain procedures, FDA has no statutory authority to assess penalties for recall violations. However, when FDA believes that an article of food presents a serious health threat, the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act)[3] provides additional authority to FDA to administratively detain food and obtain certain food records. Several bills proposed in the 110th session of Congress would have provided FDA with authority to mandate recalls and to dictate and enforce the terms of a recall.

- FDA has developed procedures for monitoring recalls and assessing a firm's recall effectiveness. The procedures cover, among other activities, reviewing the firm's recall strategy and recommending changes, inspecting the firm, conducting audit checks at selected distributors and retailers, and reviewing the firm's status reports and assessing the results of the firm's effectiveness checks of distributors and retailers as shown in the status reports. Although FDA's oversight of the two small pet food recalls by an import firm and an import broker was generally adequate, FDA did not always follow its procedures in overseeing the Menu Foods recalls. Furthermore, FDA's procedures were not always adequate for monitoring recalls as large as those of Menu Foods.

The ultimate responsibility for removing the contaminated pet food rested with Menu Foods and its distributors and retailers. Nevertheless, FDA's lack of authority, coupled with its sometimes lax adherence to its recall guidance and internal procedures and the inadequacy of some of those procedures, limited FDA's ability to ensure that contaminated pet food was promptly removed from retailers' shelves.

[3]Title III, P.L. No. 107-188 (amending §§ 304 and 414 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. §§ 334(h) and 350(c)).

RECALL AUTHORITY

Authority for Mandatory Recalls

No statute authorizes FDA to require manufacturers to recall food except for infant formula. Pursuant to 21 U.S.C § 350a(e), FDA may mandate a recall of infant formula if it determines that an adulterated or misbranded infant formula "presents a risk to human health." In addition, FDA is authorized to require manufacturers to recall medical devices and biological products.

Federal requirements for infant formula recalls (21 CFR part 107, subpart E) state that when FDA determines that an adulterated or misbranded infant formula presents a risk to human health, the manufacturer will immediately take all actions necessary to recall the formula. The recalling firm must, among other requirements, provide FDA with an initial report on the recall within 14 days after the recall initiation and with a status report at least every 14 days thereafter. All status reports must include the number and results of the firm's effectiveness checks and describe the steps that the firm has taken since the prior status report (21 CFR § 107.240).

Authority for Voluntary Recalls

Recall guidance states that food recalls are voluntary. If a firm does not initiate a recall, FDA has the authority to request one. If a firm refuses FDA's request for a recall, FDA has no authority to order a recall or to impose sanctions on the firm. However, FDA may take legal action on the underlying violation that led to its recall request by, for example, seizing the product or obtaining an injunction against the firm (21 U.S.C. §§ 334 and 332).

Recall guidance (21 CFR § 7.40(a)) states:

> Recall is a voluntary action that takes place because manufacturers and distributors carry out their responsibility to protect the public health and well-being from products that present a risk of injury or gross deception or are otherwise defective. This section and §§ 7.41 through 7.59 recognize the voluntary nature of recall by providing guidance so that responsible firms may effectively discharge their recall responsibilities. These sections also recognize that recall is an alternative to . . . [an FDA]-initiated court action for removing or correcting violative, distributed products by setting forth specific recall procedures for the . . . [FDA] to monitor recalls and assess the adequacy of a firm's efforts in recall.

As established by FDA, the food recall procedures in 21 CFR part 7 are guidance, and FDA has no authority to require compliance. In the preamble to the 1978 final rule for 21 CFR part 7 (43 Fed. Reg. 26202, 26202-03 (June 16, 1978)), the Commissioner stated that FDA has the authority to prescribe mandatory procedures and requirements for firms and FDA to follow in carrying out voluntary recalls. At that time, however, the Commissioner chose not to fully exercise the authority and issued the recall procedures as guidance instead of legally binding regulatory requirements.

Bioterrorism Act

The Bioterrorism Act provides additional authority to improve the safety of the Nation's food supply when FDA believes that an article of food presents a serious health threat. Section 303 of the Bioterrorism Act (21 U.S.C. § 334(h)) authorizes an officer or qualified employee of FDA to order the detention of an article of food that is found during an inspection, examination, or investigation if the individual has credible evidence or information indicating that the article of food "presents a threat of serious adverse health consequences or death to humans or animals." This "administrative detention" period may not exceed 30 days. Section 306 (21 U.S.C. § 350c(a)) authorizes FDA to require certain food manufacturers, packers, and distributors, among others, to maintain specified records and to make the records available to FDA in a food emergency, such as a recall, no more than 24 hours after the receipt of an official request.

On April 16, 2007, FDA invoked section 306 of the Bioterrorism Act to ensure continued access to Menu Foods' records and information pertaining to its pet food recalls.

Government Accountability Office Report

An October 2004 Government Accountability Office (GAO) report[4] identified weaknesses in the U.S. Department of Agriculture's (USDA) and FDA's food recall programs. The report stated: "We believe that addressing the problems we have identified could raise the likelihood that recalled food will be removed from the marketplace more promptly and completely. However, these corrective steps, while necessary, will still leave fundamental vulnerabilities because the agencies lack specific recall authority available to other agencies with consumer safety responsibilities." The report recommended that Congress consider legislation that would give USDA and FDA the authority to issue mandatory recalls, to establish recall requirements, and to impose monetary penalties or seek fines or imprisonment for firms that do not follow food recall requirements.

Proposals To Increase Recall Authority

In the November 2007 "Action Plan for Import Safety," the Secretary of Health and Human Services outlined recommendations for improving import safety, including authorizing FDA to issue a mandatory recall of food products when a voluntary recall is not effective. In April 2008 testimony before the House Committee on Energy and Commerce, Subcommittee on Health, FDA requested both authority to mandate recalls and enhanced access to food records during emergencies.

Several bills introduced during the 110th session of Congress would have provided FDA, through the Secretary, with authority to mandate food recalls and to dictate and enforce the terms of recalls. As of September 2008, the proposed legislation included:

- The FDA Food Safety Modernization Act: Under this bill, the Secretary would allow a firm to voluntarily cease distribution and recall an adulterated or misbranded product before the Secretary would be authorized to issue an order to cease distribution and begin

[4] "USDA and FDA Need To Better Ensure Prompt and Complete Recalls of Potentially Unsafe Food" (GAO-05-51).

a recall. For a mandated recall, the Secretary would specify a timetable, set requirements for periodic status reports from the firm, and notify consumers. Any firm that did not comply with a recall order would be subject to civil monetary penalties.

- The Food and Drug Import Safety Act of 2007: This bill would authorize the Secretary to order a firm to stop distributing a food product that caused serious adverse health consequences or death and to implement a recall of the food involved. The Secretary would set a timetable for the recall and require progress reports. Any person who introduced adulterated food into interstate commerce would be subject to civil monetary penalties.

- The SAFER Meat, Poultry, and Food Act of 2007: This bill would authorize the Secretary to mandate a food recall after first allowing the firm to take voluntary action to cease distribution and recall the adulterated or misbranded items. For mandatory recalls, the Secretary would set a timetable and require the firm to submit progress reports and to notify the public. Any firm that did not comply with these requirements would be subject to civil monetary penalties.

RECALL PROCEDURES

FDA's recall procedures are generally limited to monitoring recalls and assessing a firm's overall recall effectiveness. These procedures, which are based on the recall guidance in 21 CFR part 7, are detailed in FDA's "Regulatory Procedures Manual" (Procedures Manual) and "Investigations Operations Manual" (Operations Manual). FDA has also developed the publication "Product Recalls, Including Removals and Corrections" to assist firms in handling recalls. This publication includes a checklist of documentation and other information that FDA uses to evaluate, classify, monitor, and audit recalls.

FDA's monitoring and assessment activities include (1) reviewing the firm's recall strategy and recommending changes, (2) inspecting the firm, (3) conducting audit checks at selected distributors and retailers, and (4) reviewing the firm's status reports and assessing the results of its effectiveness checks. Our review of the three Menu Foods recalls found that FDA did not always follow its procedures for carrying out these activities and that FDA's procedures sometimes were inadequate for monitoring and assessing the effectiveness of recalls.

Reviewing the Recall Strategy and Recommending Changes

Food and Drug Administration Procedures

The Procedures Manual, chapter 7-6-4, states: "Each recall is unique and requires its own recall strategy . . . . [FDA] will review the firm's recall strategy for voluntary recalls . . . . The recall strategy includes the type [of] notification and depth of the recall. It also contains the depth and level of . . . [effectiveness] checks and the need for public warning. Recall strategies are based on the individual recall circumstances and are not necessarily dependent on the recall classification."

The Procedures Manual, chapter 7-6-4-2, states that in reviewing or developing a recall strategy, FDA should consider the health hazard evaluation, type or use of the product, ease in identifying the product, degree to which the product's deficiency is obvious to the consumer or user, amount of product remaining unused in the marketplace, product distribution pattern, and continued availability of essential products. For firm-initiated recalls, FDA should review the firm's recall strategy and recommend changes as necessary.

The Procedures Manual, chapter 7-7-1, states that when FDA has assigned the recall identification number, classified the recall, and reviewed the firm's recall strategy, the FDA lead district should promptly send the firm a notification letter specifying the depth and level of the effectiveness checks (from 0 percent to 100 percent of distributors and retailers) that the firm should conduct to ensure that distributors and retailers have removed all contaminated products from their shelves.

Adherence to Procedures

FDA generally followed its procedures for obtaining the information needed to evaluate a recall strategy. Although Menu Foods did not provide (and was not required to provide) FDA with a written recall strategy, FDA obtained most of the recommended recall information from Menu Foods orally and through other means, such as emails and handwritten notes. FDA also worked with Menu Foods to develop public warnings and to determine the depth of the recall (i.e., the level of the distribution chain to which the recall would extend).

Contrary to its procedures, however, FDA did not ensure that Menu Foods' recall strategy included the FDA-assigned depth and level of effectiveness checks that Menu Foods would conduct. In addition, FDA did not promptly send Menu Foods a notification letter specifying the level of the effectiveness checks. According to FDA, it confirmed its understanding that Menu Foods would conduct effectiveness checks in a March 23, 2007, email to Menu Foods. However, this email did not specify that FDA expected Menu Foods to conduct effectiveness checks of 100 percent of its distributors and retailers. FDA did not send Menu Foods a notification letter containing this information until September 21, 2007, 6 months after the recalls began.

Adequacy of Procedures

FDA's procedures did not ensure that Menu Foods submitted a written recall strategy. We acknowledge that because FDA issued its regulations as guidance, FDA cannot require a firm to comply with any of its recall procedures. However, FDA could not provide evidence that it had requested a written recall strategy from Menu Foods. The lack of a formal, written recall strategy containing agreed-upon deadlines and targets limited FDA's ability to review and comment on Menu Foods' proposed recalls and to monitor the recalls throughout their course. For example, although FDA stated that it had orally instructed Menu Foods to conduct effectiveness checks at the 100-percent level, it had no written documentation that Menu Foods had incorporated this level of checks into its recall strategy.

Inspecting the Firm

Food and Drug Administration Procedures

The Operations Manual, chapter 7.2, states that if FDA determines that a recalled product has a reasonable probability of causing serious illness or death, it should inspect the recalling firm. The inspection should include a review of the firm's batch records, processing logs, and other types of production records to identify contaminated lots and associated lots (7.2.1.5). FDA also should obtain a complete list of all shipments of the contaminated lots being recalled (7.2.1.1.5).

Adherence to Procedures

FDA generally followed its procedures for inspecting Menu Foods and for collecting the required information. On March 15, 2007, Menu Foods first notified FDA that it was recalling pet food because of the death and illness of pets that participated in taste tests of food made with ingredients from a new supplier. The next day, FDA began its inspection at a Menu Foods plant that received the contaminated ingredient (wheat gluten). As part of the inspection process, FDA performed a comprehensive plant inspection; obtained samples of pet food for testing; and obtained detailed product information, including information on manufacturing processes, production records (e.g., batch logs, production dates, and product labels), raw material listings, names of ingredient suppliers and related manufacturing plants, and Menu Foods' laboratory test results.

Adequacy of Procedures

FDA's inspection procedures did not ensure that FDA verified the accuracy and completeness of Menu Foods' recall list.[5] Specifically, FDA's procedures did not require that FDA promptly reconcile the firm's production records to its raw material lists to ensure that the recall list covered all contaminated lots.

Because FDA did not perform a detailed reconciliation of Menu Foods' production records and raw material lists at the time of the March 2007 inspection, FDA was unaware that the production records did not document the transfer of 11,000 pounds of contaminated wheat gluten to a Canadian plant before the recalls began. FDA remained unaware of the transferred wheat gluten until April 9, 2007, when FDA learned that the University of California at Davis had traced the death of a pet to a brand of Menu Foods pet food that was not on the recall list. On April 11, 2007, FDA began an indepth reconciliation of Menu Foods' records and confirmed that the Canadian plant had produced melamine-contaminated pet food that was not on the recall list.

Although Menu Foods was responsible for providing FDA with accurate and complete records, a timely reconciliation of Menu Foods' records would have helped FDA determine that the records provided were not complete and that not all contaminated pet food lots had been recalled.

[5]A firm's recall list contains product descriptions, expiration dates, container types and sizes, and Universal Product Codes.

Conducting Audit Checks To Determine Recall Effectiveness

Food and Drug Administration Procedures

The Procedures Manual, chapter 7-8-1, states that FDA will conduct audit checks of distributors and retailers to assess the effectiveness of a firm's recall effort. The Operations Manual, chapter 7.3.2.1, defines an audit check as a visit, telephone call, or letter (or a combination thereof) from FDA staff to a distributor or retailer to verify that the distributor or retailer has been notified of the recall and has taken appropriate action. The Procedures Manual, chapter 7-8-2-1, states that FDA determines the type of contact. In addition, chapter 7-7-2-1 states that district offices should consider notifying State and local officials of recall actions that may be pertinent to them and requesting assistance from State and local officials as needed in conducting or auditing recalls.

The Operations Manual, chapter 7.3.2.4, states that inspectors should obtain 10 specific items of information and any additional information that the lead district or home district requests. The specific information to obtain includes the amount of recalled product on hand when the retailer was notified of the recall, the amount returned and method of return, the amount destroyed and method of destruction, and the amount presently on hand.[6] If FDA specifies that audit checks should be accomplished through visits, inspectors should visit the storage sites and check the shelf stock to ensure that all recalled products have been identified, removed, and quarantined. Inspectors should record this information on a store visit form (7.3.2.5).

The Procedures Manual, chapter 7-8-2-4, states that the district office will evaluate audit check reports to ensure that they are adequate. If the reports contain insufficient information, the district office will advise the supervisory investigator.

The Procedures Manual, chapter 7-8-2-6, states that if FDA determines at any time during its audit of a recall that the recall effort is ineffective, FDA should discuss its findings with the recalling firm. The Operations Manual, chapter 7.3.2.6, states: "If your audit check discloses recalled product being held for sale, . . . document the responsibility for failure to follow recall instructions. This is particularly important if the account received the recall notice and ignored it."

Audit Checks of the Menu Foods Recalls

For the Menu Foods recalls, FDA conducted one round of audit checks (the first round) followed by an expanded round of audit checks that FDA termed a "national audit blitz" (the blitz).

During the first round, 6 of the 19 FDA district offices visited a total of 64 retail stores. According to FDA officials, FDA decided to expand the first round of audit checks because of continuing consumer complaints. FDA officials stated that the blitz was an innovative attempt to

[6]The other specific information consists of the name and title of the person interviewed; whether the store received, understood, and followed the notification instructions; the date and method of notification; the date of anticipated return or destruction; whether a subrecall was conducted and, if so, a list of retailers from which the subrecall check locations were selected; and whether injury complaints had been received and, if so, details of the complaints.

supplement traditional audit checks prompted by the unprecedented size and scope of the pet food recalls.

The blitz covered the melamine-contaminated pet food recalled by six firms, including Menu Foods. The methodology for the blitz involved requesting the health agencies of the 50 States and the District of Columbia to randomly select and visit 20 retail stores each. FDA also required its 19 district offices to select and visit 20 retail stores each. The blitz covered a total of 1,407 stores. FDA requested that both the State health agencies and the district offices "generally" follow the audit check instructions in the Operations Manual, chapter 7.

Adherence to Procedures

During the first round, FDA did not always adhere to its procedures when conducting audit checks at the 64 retail stores:

- Of the 64 store visit forms, 40 were missing one or more pieces of required information, such as the amount of product that the store had removed from its shelves and the amount still remaining on its shelves.

- FDA did not tabulate the results of the 64 store visits and therefore could not adequately assess the effectiveness of the recall effort as required. Our tabulation of the first round of audit checks, based on the information available on the store visit forms, indicated that 20 percent of the stores visited still had recalled products on their shelves.

FDA appeared to have adhered to its "general" procedures for carrying out the blitz.

Adequacy of Procedures

Although FDA's procedures were generally adequate for carrying out the first round of audit checks, they were not always adequate for carrying out the blitz:

- FDA's procedures did not ensure that the blitz covered all States. Specifically, 16 State health agencies did not participate in the blitz. Although FDA's district offices included retail stores in 12 of these States in their samples, four States were not covered by a State health agency or by an FDA district office.

- FDA's procedures did not ensure the accuracy or utility of the effectiveness rate that FDA calculated based on the results of the blitz. FDA officials concluded from the store visit forms that the pet food recalls by the six firms included in the blitz were 95 percent effective. However, we were unable to substantiate this rate or to determine the specific rate applicable to the Menu Foods recalls because:

    - FDA's procedures did not require FDA to follow up with State health agencies that did not submit or did not accurately complete store visit forms. State health agencies did not submit store visit forms to document the results of their audit

checks at 204 of the 1,407 stores included in the blitz.[7] In addition, some of the 1,195 store visit forms that inspectors submitted did not contain all requested information or contained misclassified results. For example, the store visit forms for 31 stores classified the recalls as effective even though the stores (1) had not received notice of the recalls or (2) said that they had received notice of the recalls but had not removed the products from their shelves.

- FDA's procedures did not require FDA to separately tabulate the audit check results for the six firms included in the blitz. Because FDA commingled the results for the six firms in calculating a 95-percent effectiveness rate, we were unable to determine what percentage of the rate was attributable to Menu Foods.

Reviewing Status Reports and Assessing the Results of Effectiveness Checks

Food and Drug Administration Procedures

The Procedures Manual, chapter 7-6-4-1, states that the firm's recall strategy should include conducting effectiveness checks. Chapter 7-8-2 specifies that FDA should closely monitor recalls and assess the firm's recall efforts. FDA district office personnel are responsible for the timely receipt and review of the firm's monthly status reports, which should include the results of the firm's effectiveness checks, and for the timely completion of the recall.

Adherence to Procedures

FDA did not always follow its procedures for monitoring Menu Foods' status reports and effectiveness checks. Had FDA done so, it would have noticed that the status reports for the first 3 months of the recalls (April−June 2007) did not include information about the firm's effectiveness checks. In fact, Menu Foods did not begin conducting effectiveness checks until June 22, more than 3 months after initiating the recalls. The following examples illustrate the importance of conducting and monitoring effectiveness checks in a timely manner:

- A retail store that was first notified of the recall on March 18, 2007, still had 185 cans of recalled pet food on its shelves when FDA conducted its audit check on April 16, almost a month after the store was notified. FDA's records did not indicate why the store did not remove the product until FDA conducted its audit check.

- A retail store that was part of a large national chain had 470 pouches and cans of recalled pet food on its shelves when, as part of the blitz, the District of Columbia's health agency conducted an audit check on April 13, 2007, almost 4 weeks after the recalls began. Although the health agency confirmed that Menu Foods had sent a recall notice to the store's national headquarters, the store manager stated that the store had not received the notice. The store removed the products from its shelves during the health agency's audit check.

[7]In addition, FDA inspectors did not submit store visit forms for 8 of the 1,407 stores in the blitz.

Adequacy of Procedures

FDA's procedures did not ensure that Menu Foods conducted effectiveness checks in a timely manner and completed the specified level of checks. Although FDA's procedures state that effectiveness checks should be part of a firm's recall strategy, the procedures do not specify when the firm should begin and complete the effectiveness checks. FDA's procedures also offer no guidance as to when and how FDA should follow up with the firm to ensure that it has completed the specified level of effectiveness checks.

Menu Foods' status report for July 2007 indicated that a third-party contractor conducted 2,937 effectiveness checks from June 22 to July 12. Menu Foods' monthly status reports through October 2007 indicated that Menu Foods did not conduct any additional effectiveness checks after July 2007. According to FDA officials, FDA had specified during recall strategy discussions that Menu Foods should conduct effectiveness checks at 100 percent of its affected distributors and retailers, which FDA estimated to total more than 10,000. Thus, Menu Foods conducted effectiveness checks at fewer than 30 percent of its distributors and retailers. We found no evidence that FDA had followed up with Menu Foods to determine why the firm had not promptly initiated and completed the specified level of effectiveness checks.

CONCLUSION

According to FDA staff, FDA's lack of statutory authority limited the quantity and timeliness of the information that it received from Menu Foods during the pet food recalls. In the 110th session of Congress, several bills were proposed that would have provided FDA with authority to mandate recalls and to dictate and enforce the terms of a recall. Although FDA currently lacks authority to order a recall, it could issue mandatory requirements to improve the efficiency and effectiveness of recalls that firms voluntarily initiate. However, FDA has thus far chosen not to make its recall guidance mandatory.

Menu Foods and its distributors and retailers were ultimately responsible for the timely completion of the recalls. Nevertheless, FDA's inability to enforce its recall guidance, along with its sometimes lax adherence to its recall guidance and internal procedures and the inadequacy of some of those procedures, limited FDA's ability to ensure that contaminated pet food was promptly removed from retailers' shelves.

RECOMMENDATIONS

We recommend that FDA:

- consider seeking statutory authority to mandate food recalls and to assess penalties for noncompliance with the terms of recalls;

- amend its regulations or, if necessary, seek additional legislative changes to establish mandatory requirements for firms to follow in conducting recalls, including:

    - a written recall strategy,

- prompt initiation of effectiveness checks, and

- periodic status reports that contain all specified information, including the number and results of the firm's effectiveness checks;

- comply with its procedures for monitoring recalls; and

- revise its procedures to require FDA staff to:

  - document the approved recall strategy, including the specified effectiveness check levels and target dates for initiating and completing effectiveness checks,

  - promptly determine the accuracy of the firm's recall list,

  - ensure that audit checks are performed as assigned and that the results are accurately and completely documented,

  - separately tabulate the results of audit checks for each recalling firm, and

  - follow up with the firm to ensure that it has completed the specified level of effectiveness checks in a timely manner.

FOOD AND DRUG ADMINISTRATION COMMENTS

In comments on our draft report, FDA agreed with our recommendation to consider seeking statutory authority to mandate food recalls and to assess penalties for noncompliance with the terms of recalls. FDA also agreed to amend its regulations or, if necessary, seek additional legislative changes to establish mandatory requirements for firms to follow in conducting recalls. FDA agreed in principle with our recommendations to comply with its procedures for monitoring recalls and to revise its recall procedures.

FDA's comments are included in their entirety as Appendix B.

APPENDIXES

TIMELINE OF RECALL EVENTS
March−November 2007

March 15
Menu Foods Limited (Menu Foods) notifies the Food and Drug Administration (FDA) of a potential pet food problem.

↓

March 16
FDA begins an inspection of a Menu Foods facility.

Menu Foods initiates the first two recalls of pet food.

↓

March 23
FDA begins the first round of audit checks.

FDA finds melamine in wheat gluten used in pet food.

↓

March 28
The FDA district office recommends a Class I designation.

↓

April 6
FDA begins the second round of audit checks (the blitz).

↓

April 10
Menu Foods issues a third recall of pet food manufactured at a different facility.

↓

April 11
FDA begins a detailed reconciliation of the contaminated wheat gluten.

↓

April 16
FDA completes the first round of audit checks and the blitz.

↓

May 1
FDA finds that the combination of melamine and cyanuric acid has been linked to acute renal failure in pets.

↓

June 22 – July 12
Menu Foods performs effectiveness checks.

↓

September 21
FDA classifies the Menu Foods recalls as Class I.

↓

November 17
FDA issues the health hazard evaluation report on contaminated wheat gluten.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

Date: June 16, 2009

To: Inspector General

From: Principal Deputy Commissioner

Subject: FDA's General Comments to OIG Draft Report, *Review of Food and Drug Administration's Monitoring of Pet Food Recall (A-01-07-01503)*

FDA is providing the attached general comments to the Office of Inspector General's draft report entitled, *Review of Food and Drug Administration's Monitoring of Pet Food Recall (A-01-07-01503).*

FDA appreciates the opportunity to review and comment on this draft report before it is published.

Joshua M. Sharfstein, M.D.

Attachment

FDA's General Comments to OIG Draft Report, *Review of Food and Drug Administration's Monitoring of Pet Food Recall (A-01-07-01503)*

FDA encountered one of the largest recalls in its history during the pet food crisis in 2007. This was a complex and multi-faceted investigation that involved not only recalls, but also development of new regulatory science and novel approaches to public health protection efforts. FDA's priority during this recall was the protection of the public health, and its actions reflected this foremost priority. Because of the unprecedented size and scope of the recall, FDA deemed it necessary and appropriate to seek the voluntary assistance of the states as a leveraged approach to more broadly audit the recalls. These measures, of necessity, went beyond the Agency's existing procedures to enable the Agency to focus its limited resources to effectively and efficiently address the public health threat that this extraordinary outbreak presented. FDA's experience in this incident also has provided the Agency with important lessons that it will apply in the future, including implementing processes to improve its coordination with states in the context of large recalls.

OIG Recommendation

That FDA consider seeking statutory authority to mandate food recalls and to assess penalties for noncompliance with the terms of recalls and amend its regulations or, if necessary, seek additional legislative changes to establish mandatory requirements for firms to follow in conducting recalls, including:

- *a written recall strategy;*
- *prompt initiation of effectiveness checks; and*
- *periodic status reports that contain all specified information, including the number and results of the firm's effectiveness check.*

FDA Response

FDA agrees with these recommendations and has testified to this effect at Congressional hearings.

OIG Recommendation

That FDA comply with its procedures for monitoring recalls; and revise its procedures to require FDA staff to:

- *document the approved recall strategy, including the specified effectiveness check levels and target dates for initiating and completing effectiveness checks;*
- *promptly determine the accuracy of the firm's recall list;*
- *ensure that audit checks are performed as assigned and that the results are accurately and completely documented; and*

- *separately tabulate the results of audit checks for each recalling firm, and follow up with the firm to ensure that it has completed the specified level of effectiveness checks in a timely manner.*

FDA Response

FDA agrees in principle with this recommendation. In addition, the Agency believes that in the interest of protecting the public health, it must have the latitude and discretion to address the complexities of a globalized food supply chain with innovative and resourceful approaches, and to use its experiences to further design and implement new procedures as appropriate.