DEPARTMENT OF HEALTH & HUMAN SERVICES **Office of Inspector General**

Washington, D.C. 20201

June 21, 2011

TO: Margaret A. Hamburg, M.D.
Commissioner of Food and Drugs

FROM: /Daniel R. Levinson/
Inspector General

SUBJECT: Review of the Food and Drug Administration's Monitoring of Imported Food Recalls (A-01-09-01500)

The attached final report provides the results of our review of Food and Drug Administration's monitoring of imported food recalls.

Section 8L of the Inspector General Act, 5 U.S.C. App., requires that the Office of Inspector General (OIG) post its publicly available reports on the OIG Web site. Accordingly, this report will be posted at http://oig.hhs.gov.

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, Assistant Inspector General for Grants, Internal Activities, and Information Technology Audits, at (202) 619-1175 or through email at Lori.Pilcher@oig.hhs.gov. We look forward to receiving your final management decision within 6 months. Please refer to report number A-01-09-01500 in all correspondence.

Attachment

Department of Health & Human Services

OFFICE OF INSPECTOR GENERAL

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

Daniel R. Levinson
Inspector General

June 2011
A-01-09-01500

Office of Inspector General

http://oig.hhs.gov

The mission of the Office of Inspector General (OIG), as mandated by Public Law 95-452, as amended, is to protect the integrity of the Department of Health & Human Services (HHS) programs, as well as the health and welfare of beneficiaries served by those programs. This statutory mission is carried out through a nationwide network of audits, investigations, and inspections conducted by the following operating components:

Office of Audit Services

The Office of Audit Services (OAS) provides auditing services for HHS, either by conducting audits with its own audit resources or by overseeing audit work done by others. Audits examine the performance of HHS programs and/or its grantees and contractors in carrying out their respective responsibilities and are intended to provide independent assessments of HHS programs and operations. These assessments help reduce waste, abuse, and mismanagement and promote economy and efficiency throughout HHS.

Office of Evaluation and Inspections

The Office of Evaluation and Inspections (OEI) conducts national evaluations to provide HHS, Congress, and the public with timely, useful, and reliable information on significant issues. These evaluations focus on preventing fraud, waste, or abuse and promoting economy, efficiency, and effectiveness of departmental programs. To promote impact, OEI reports also present practical recommendations for improving program operations.

Office of Investigations

The Office of Investigations (OI) conducts criminal, civil, and administrative investigations of fraud and misconduct related to HHS programs, operations, and beneficiaries. With investigators working in all 50 States and the District of Columbia, OI utilizes its resources by actively coordinating with the Department of Justice and other Federal, State, and local law enforcement authorities. The investigative efforts of OI often lead to criminal convictions, administrative sanctions, and/or civil monetary penalties.

Office of Counsel to the Inspector General

The Office of Counsel to the Inspector General (OCIG) provides general legal services to OIG, rendering advice and opinions on HHS programs and operations and providing all legal support for OIG's internal operations. OCIG represents OIG in all civil and administrative fraud and abuse cases involving HHS programs, including False Claims Act, program exclusion, and civil monetary penalty cases. In connection with these cases, OCIG also negotiates and monitors corporate integrity agreements. OCIG renders advisory opinions, issues compliance program guidance, publishes fraud alerts, and provides other guidance to the health care industry concerning the anti-kickback statute and other OIG enforcement authorities.

Notices

THIS REPORT IS AVAILABLE TO THE PUBLIC

at http://oig.hhs.gov

Section 8L of the Inspector General Act, 5 U.S.C. App., requires that OIG post its publicly available reports on the OIG Web site.

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 by ensuring that all ingredients are safe and free from disease-causing organisms, chemicals, or other harmful substances. No statute existed prior to 2011 to authorize FDA to require manufacturers/processors or importers to recall food except for infant formula. When a problem arises with a particular food, the manufacturer/processor or importer may voluntarily recall the product.

FDA established regulations (21 CFR part 7) that are explicit in that the regulations are 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." The recall guidance specifies that when a firm initiates a recall, FDA should assess the seriousness of the health hazard that the recalled product poses and assign a recall classification of Class I, II, or III. Class I indicates the greatest health hazard. The recall guidance also specifies the elements of the firm's recall process that FDA should monitor and assess in determining the adequacy of the firm's recall. These elements include recall initiation, recall strategy, recall communications, recall status reports, and product disposal.

From July 1, 2007, through June 30, 2008, FDA oversaw 40 Class I recalls of imported food products contaminated with pathogens and other harmful substances that can cause serious illnesses. We reviewed FDA's monitoring of 17 of the 40 recalls. Of the 17 recalls, 7 were for *Salmonella*, 5 were for *Listeria monocytogenes*, 4 were for *Clostridium botulinum*, and 1 was for unacceptable lead levels in beverage pitchers.

In January 2011, the President signed the FDA Food Safety Modernization Act. This law gives the Secretary of Health & Human Services authority to conduct mandatory recalls and assess and collect fees related to food facility reinspections and food recall orders.

OBJECTIVES

Our objectives were to determine whether (1) FDA's guidance for developing and implementing food recalls was adequate to ensure the safety of the Nation's food supply and (2) FDA followed its own procedures for ensuring that the recall process operated efficiently and effectively.

SUMMARY OF FINDINGS

FDA's guidance for developing and implementing food recalls was not adequate to ensure the safety of the Nation's food supply because it was not enforceable. In addition, FDA did not always follow its own procedures for ensuring that the recall process operated efficiently and effectively.

Our review of FDA's records relating to 17 recalls found the following problems:

- Firms did not promptly initiate recalls. Two of the seventeen recalls were not initiated until 28 and 102 days, respectively, after FDA became aware of the contamination.

- Firms did not submit recall strategies or strategies did not contain complete information. For 3 of the 17 recalls, firms did not submit any recall strategies. For the 14 other recalls, the strategies submitted did not contain complete information.

- Firms did not issue accurate and complete recall communications to their consignees. For 13 of the 17 recalls, firm communications did not contain essential information on the contaminated products or contained inaccurate information.

- Firms did not submit timely and complete recall status reports. Of the 17 recalling firms, 5 firms did not submit any reports, 10 firms submitted untimely and incomplete reports, and 2 firms submitted timely but incomplete reports.

Because FDA's food recall guidance is nonbinding on the industry, FDA cannot compel firms to follow it and therefore FDA cannot ensure the safety of the Nation's food supply.

FDA did not always follow its own procedures to ensure that the recall process operated efficiently and effectively. Specifically, FDA:

- did not conduct firm inspections or obtain complete information on the contaminated products in 14 of the 17 recalls,

- did not conduct any audit checks of consignees in 5 of the 17 recalls and conducted untimely and incomplete audit checks in the remaining 12 recalls,

- did not review recall strategies and promptly issue notification letters to firms conveying the review results and essential instructions in all 17 recalls, and

- did not witness the disposal of the products or obtain the required documentation showing that the products had been properly disposed of in 13 of the 17 recalls.

RECOMMENDATIONS

We recommend that FDA:

- consider the results of this review in implementing the FDA Food Safety Modernization Act and

- follow its procedures for monitoring recalls.

FOOD AND DRUG ADMINISTRATION COMMENTS

In its written comments on our draft report, FDA agreed with our recommendations and described actions it has taken to improve how recalls are conducted and monitored. FDA's comments are included in their entirety as Appendix C.

TABLE OF CONTENTS

INTRODUCTION

BACKGROUND

Food and Drug Administration Recall Authority

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 are safe and free from disease-causing organisms, chemicals, or other harmful substances.

No statute existed prior to 2011 to authorize FDA to require manufacturers/processors or importers to recall food except for infant formula. When a problem arises with a particular food, the manufacturer/processor or importer may voluntarily recall the product. Within FDA, the Center for Food Safety and Applied Nutrition (CFSAN) and the Office of Regulatory Affairs (ORA) are responsible for overseeing firm-initiated recalls of food. 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.

Recall Guidance and Related Procedures

FDA established regulations (21 CFR part 7) that are explicit in that the regulations are 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." The 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 in violation of law. The recall guidance specifies that when a firm initiates a recall, FDA should assess the seriousness of the health hazard that the recalled product poses and assign a recall classification of Class I, II, or III. Class I indicates the greatest health hazard. The recall guidance also specifies the elements of the firm's recall process that FDA should monitor and assess in determining the adequacy of the firm's recall. These elements include recall initiation, recall strategy, recall communications, recall status reports, and product disposal.

FDA's recall procedures, which are based on the recall guidance, generally include classifying, publicizing, and monitoring firm recalls and assessing their effectiveness. These procedures are detailed in FDA's *Regulatory Procedures Manual* (Procedures Manual) and *Investigations Operations Manual* (Operations Manual). Included in these manuals are procedures for FDA to follow when inspecting firms and conducting audit checks of the firms' consignees (primarily distributors and retailers). FDA has also developed the publications *Guidance for Industry: Product Recalls, Including Removals and Corrections* (Industry Guidance) and *Methods for Conducting Effectiveness Checks* to assist firms in handling recalls. These publications include a checklist and other information that FDA uses to monitor and evaluate recalls.

Recent Recalls of Imported Food

From July 1, 2007, through June 30, 2008, FDA oversaw 40 Class I recalls of imported food products contaminated or potentially contaminated with pathogens and other harmful substances that can cause serious illnesses, such as salmonellosis, listeriosis, and botulism.[1] The imported food products included beverage pitchers containing unsafe levels of lead.

Initiatives To Better Protect the Food Supply and Increase Recall Authority

In the *Action Plan for Import Safety* (action plan), which was issued in November 2007, the Interagency Workgroup on Import Safety, consisting of 12 departments and agencies and chaired by the Secretary of Health & Human Services, outlined recommendations for improving the safety of imported products. In conjunction with the action plan, FDA issued its *Food Protection Plan*. The *Food Protection Plan* addresses prevention (building in safety from the start), intervention (using risk-based inspections and tests), and response (responding rapidly and communicating effectively when problems are identified).

Several bills were introduced during the 111th session of Congress to authorize FDA, through the Secretary, to mandate food recalls and to dictate and enforce the terms of recalls. In January 2011, the President signed the FDA Food Safety Modernization Act (P.L. No. 111-353 (Jan. 4, 2011)). This law gives the Secretary of Health & Human Services authority to conduct mandatory recalls and assess and collect fees related to food facility reinspections and food recall orders. The Secretary will identify preventive programs and practices to promote the safety and security of food and is authorized to order an immediate cessation of distribution and recall of food. The law provides for foreign supplier verification activities and the inspection of foreign facilities registered to export food.

Prior Office of Inspector General Reviews

The Office of Inspector General has conducted several recent reviews that have raised questions about FDA's ability to protect the Nation's food supply. The recommendations in those reports generally called for strengthening FDA's recall authority through legislative and regulatory change. Appendix A summarizes the results of these reviews.

OBJECTIVES, SCOPE, AND METHODOLOGY

Objectives

Our objectives were to determine whether (1) FDA's guidance for developing and implementing food recalls was adequate to ensure the safety of the Nation's food supply and (2) FDA followed its own procedures for ensuring that the recall process operated efficiently and effectively.

[1] The pathogens that cause salmonellosis, listeriosis, and botulism are *Salmonella*, *Listeria monocytogenes*, and *Clostridium botulinum*, respectively.

Scope

We reviewed FDA's monitoring of 17 of the 40 Class I recalls of imported food products. These recalls were initiated by 17 firms from July 1, 2007, through June 30, 2008. Of the 17 recalls, which are listed in Appendix B, 7 were for *Salmonella*, 5 were for *Listeria monocytogenes*, 4 were for potential contamination with *botulinum* toxin, and 1 was for unacceptable lead levels in beverage pitchers. The food products recalled included cantaloupe, frozen mussel meat, fish, cheese, and sesame seed.

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

We performed our fieldwork at FDA headquarters in College Park and Rockville, Maryland, and at six FDA district offices.

Methodology

To accomplish our objective, we:

- reviewed Federal laws, regulations, policies, and procedures related to food recalls;
- identified from FDA's recall database the 40 Class I recalls of imported food products and judgmentally selected 17 recalls involving the most hazardous substances for review;
- evaluated the timeliness and completeness of FDA's recall monitoring by reviewing information maintained at district offices and CFSAN and data in ORA's recall database;
- reviewed firm recall notices, strategies, and status reports for compliance with recall guidance;
- reviewed district office case file information to determine whether contaminated products were properly disposed of;
- reviewed firm inspection reports prepared by FDA investigators;
- reviewed the timeliness, accuracy, and completeness of FDA's audit checks of consignees; 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 objectives.

RESULTS OF AUDIT

FDA's guidance for developing and implementing food recalls was not adequate to ensure the safety of the Nation's food supply because it was not enforceable. In addition, FDA did not always follow its own procedures for ensuring that the recall process operated efficiently and effectively.

Our review of FDA's records relating to 17 recalls found the following problems:

- Firms did not promptly initiate recalls. Two of the seventeen recalls were not initiated until 28 and 102 days, respectively, after FDA became aware of the contamination.

- Firms did not submit recall strategies or strategies did not contain complete information. For 3 of the 17 recalls, firms did not submit any recall strategies. For the 14 other recalls, the strategies submitted did not contain complete information.

- Firms did not issue accurate and complete recall communications to their consignees. For 13 of the 17 recalls, firm communications did not contain essential information on the contaminated products or contained inaccurate information.

- Firms did not submit timely and complete recall status reports. Of the 17 recalling firms, 5 firms did not submit any reports, 10 firms submitted untimely and incomplete reports, and 2 firms submitted timely but incomplete reports.

Because FDA's food recall guidance is nonbinding on the industry, FDA cannot compel firms to follow it and therefore FDA cannot ensure the safety of the Nation's food supply.

FDA did not always follow its own procedures to ensure that the recall process operated efficiently and effectively. Specifically, FDA:

- did not conduct firm inspections or obtain complete information on the contaminated products in 14 of the 17 recalls,

- did not conduct any audit checks of consignees in 5 of the 17 recalls and conducted untimely and incomplete audit checks in the remaining 12 recalls,

- did not review recall strategies and promptly issue notification letters to firms conveying the review results and essential instructions in all 17 recalls, and

- did not witness the disposal of the products or obtain the required documentation showing that the products had been properly disposed of in 13 of the 17 recalls.

FIRMS' RECALL ACTIVITIES

Recall Initiation

Recall Guidance

Recall guidance (21 CFR § 7.46(c)) states: "A firm may decide to recall a product when informed by the Food and Drug Administration that the agency has determined that the product in question violates the law, but the agency has not specifically requested a recall."

Firms' Initiation of Recalls

Firms did not always take prompt action to initiate recalls. Although 15 recalls were initiated within 10 days after FDA became aware of the contaminated food products, the 2 remaining recalls were not initiated until 28 and 102 days, respectively, after FDA became aware of the contamination. The two recalls involved *Listeria monocytogenes*-contaminated mussel meat from a manufacturer/processor in New Zealand.

Recall Strategies

Recall Guidance

Recall guidance (21 CFR § 7.42(a)(1)) states that the recalling firm will develop a strategy for a firm-initiated recall and recommends that the 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 the product being recalled presents a serious health hazard. Furthermore, FDA's Industry Guidance, part B.1., states that when the product may pose a significant health hazard and is in the hands of consumers, a press release should be the highest priority and should be issued promptly.

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

Firms' Recall Strategies

Not all firms submitted recall strategies or strategies containing complete information on recall depth, public warnings, and the level of effectiveness checks.

Three firms did not submit any written recall strategies, and FDA did not maintain evidence of any verbal discussions with these firms on their recall strategies. The 14 other firms submitted incomplete recall strategies, as follows:

- For nine recalls, the strategies did not address the depth of the recalls. For example, the strategy for a recall of *Salmonella*-contaminated cantaloupes did not specify the level in the distribution chain to which the recall would extend. The firm's product distribution information indicated that its customers consisted of wholesalers, manufacturers/processors, and retailers. However, we found no evidence that the recall was extended to the retail level.

- For nine recalls, either the strategies did not address the need for public warnings or the firms did not issue prompt warnings. Eight of the nine strategies did not address the need for public warnings. These recalls involved contaminated products that were sold at the retail level, but we found no evidence that the public had been warned or an explanation for the lack of public warning. For example, in a recall of *Listeria monocytogenes*-contaminated mussel meat that a firm had distributed to 16 consignees, including retailers, neither the firm nor FDA issued a warning to inform the public of the recalled product and the names of the retailers that carried it. As a result, many consumers were unaware of the product's potential risk. For the other recall, the firms did not issue press releases for more than a week after initiating the recalls.

- For seven recalls, the strategies did not address the need to conduct effectiveness checks of consignees at the FDA-specified level. For example, one firm's recall strategy for *Salmonella*-contaminated cantaloupes did not contain any information on effectiveness checks. The firm's consignees consisted of distributors and retailers.

Recall Communications

Recall Guidance

Pursuant to 21 CFR § 7.49, the recalling firm is responsible for promptly notifying each consignee at the recall depth specified by the strategy that (1) the product in question is subject to recall, (2) further distribution or use of any remaining product should cease immediately, and (3) the consignee should notify its customers who received the product. The notice also should explain what to do with the product (e.g., remove the product from the market, cease distribution, or return the product to the recalling firm).

FDA's Industry Guidance, part B.2., states that the recalling firm should provide copies of all recall communications with consignees to the FDA district office. These communications should contain sufficient information to identify the recalled product.

Firms' Recall Communications

Firms' recall communications with consignees did not always contain accurate and complete information and instructions on how to proceed with recalls. Although 4 of the 17 recalling

firms issued accurate and complete recall communications, the 13 remaining firms' communications did not contain critical information or contained inaccurate information, such as product lot numbers, production dates, instructions for the return of recalled products, and instructions to consignees to notify subconsignees. For example, one firm's recall notice identified a 13-day production period associated with *Listeria monocytogenes*-contaminated mussel meat, but the product was actually produced for an additional 5 months. Thus, significant amounts of contaminated mussel meat remained available to the public until a corrected recall notice was issued 22 days after the initial recall notice.

Recall Status Reports

Recall Guidance

Pursuant to 21 CFR § 7.53, the recalling firm is requested to submit periodic recall status reports to the FDA district office so that FDA can assess the progress of the recall. Recall status reports should contain information on the number of consignees notified of the recall and the date and method of notification, the number of consignees that responded to the recall communication and the quantity of products on hand at the time it was received, the number of consignees that did not respond, the quantity of products accounted for, the quantity of products returned or corrected by each consignee contacted, the number and results of effectiveness checks conducted, and the estimated timeframe for completing the recall.

Firms' Recall Status Reports

Firms did not consistently submit timely and complete recall status reports so that FDA could assess ongoing recall activities, such as the results of the firm's effectiveness checks. Five of the seventeen recalling firms did not submit any status reports to FDA. The 12 remaining firms submitted untimely or incomplete status reports:

- Ten firms submitted their initial status reports 2 months to 1 year after the recall initiation dates. For example, in a recall of uneviscerated fish potentially contaminated with *Clostridium botulinum*, FDA did not receive a status report for nearly 7 months after the recall initiation date. Furthermore, none of the 10 firms' untimely status reports contained all required information, such as the dates, number, and results of the firms' effectiveness checks.

- Two firms submitted timely status reports that were missing requested information. For example, in a recall involving *Salmonella*-contaminated cheese, the firm's status reports did not indicate the number of consignees notified, the date and method of notification, the quantity of products accounted for and returned, or the number and results of effectiveness checks conducted.

FOOD AND DRUG ADMINISTRATION RECALL ACTIVITIES

Firm Inspections

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, FDA should inspect the recalling firm. The inspection should include a review of (1) the firm's batch records, processing logs, and other types of production records to identify contaminated lots and associated lots and (2) a list of all shipments of the product being recalled.

Food and Drug Administration's Firm Inspections

FDA did not always conduct firm inspections or obtain complete information on recalled products. For 3 of the 17 recalls, FDA inspected the firms and obtained all necessary information. However, for the 14 remaining recalls, FDA did not inspect the firms and/or obtain complete information on the products:

- For four recalls, FDA did not conduct firm inspections and therefore did not obtain certain information, such as the contaminated lots and a list of all shipments of the products. For example, in a recall of *Listeria monocytogenes*-contaminated mussel meat, FDA did not identify the contaminated lots. Without inspecting the recalling firms and reconciling their records, FDA could not be certain that all contaminated products had been identified.

- For 10 recalls, FDA conducted firm inspections but provided no evidence that it had identified contaminated lots and associated lots or reviewed a list of all shipments of the products. FDA's general practice was to accept the distribution information provided by the recalling firm.

Audit Checks

Food and Drug Administration's 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. Chapter 7-8-2 states that the district office often issues audit check assignments within 24 to 48 hours after learning of a Class I recall. In addition, chapter 7-8-2 states that the district office that receives audit check assignments should consider them high priority and, if possible, complete the assignments within 10 working days.

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 consignee (primarily distributors and retailers) to verify that the consignee has been notified of the recall and has taken appropriate action. Chapter 7.3.2.3 states that if a recall strategy includes subrecalls by a firm's direct

consignees, subrecall audit checks will be made at the level specified for the direct consignees. Chapter 7.3.2.4 states that the inspector should obtain 10 specific items of information, along with any additional information that the lead district or home district requests. For example, the inspector should obtain the amount of the 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 and its status.[2]

Food and Drug Administration's Audit Checks

FDA either did not perform audit checks or conducted untimely and incomplete audit checks, as follows:

- For 5 of the 17 recalls, FDA did not conduct any audit checks. FDA officials stated that two of these recalls were for perishable products, such as cantaloupes, that would most likely not be found on store shelves. FDA officials could not explain the lack of audit checks for the three other recalls. These three recalls were initiated by firms that did not conduct any effectiveness checks.

- For the 12 remaining recalls, FDA did not initiate audit checks until well after the recalls were completed, and/or the audit checks were missing one or more items of information, such as the amount of the product that the store had removed from its shelves and the amount still remaining. In the recall of lead-contaminated pitchers, FDA did not begin audit checks for more than 3 months after the recall initiation date. Even at this late stage, FDA found that more than 40 percent of the consignees selected for audit checks showed that proper action, such as posting product recall information, had not been taken. Had FDA performed timely audit checks, it could have better ensured that all retailers had removed contaminated products from store shelves.

Recall Strategies

Food and Drug Administration's Procedures

Recall guidance (21 CFR § 7.42(a)(2)) states that FDA will review the firm's recall strategy, advise the firm of the assigned recall classification, and recommend any necessary changes in the recall strategy. Furthermore, the Procedures Manual, chapter 7-7-1, instructs the FDA monitoring district office to promptly send the firm a notification letter that includes (1) the results of FDA's review of the recall strategy, including, among other things, the level of effectiveness checks that the firm should conduct, and (2) a request to notify FDA before product destruction so that FDA can witness such action.

[2] 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 locations were selected; and whether injury complaints had been received and, if so, details of the complaints.

Food and Drug Administration's Monitoring of Firms' Recall Strategies

FDA did not follow its own procedures for reviewing recall strategies and promptly issuing notification letters to firms conveying the review results and essential instructions. Specifically, for all 17 recalls, the FDA district offices did not issue notification letters until after the recalls had essentially been completed (51 to 183 days after the recall initiation dates).

Product Disposal

Food and Drug Administration's Procedures

Pursuant to 21 CFR § 7.55, FDA will terminate a recall only after it "determines that all reasonable efforts have been made to remove or correct the product in accordance with the recall strategy, and when it is reasonable to assume that the product subject to the recall has been removed and proper disposition or correction has been made commensurate with the degree of hazard of the recalled product."

The Operations Manual, chapter 7.3.3.2, states that FDA's final monitoring is a limited inspection to verify recall closeout by the firm. During this inspection, FDA should witness destruction of the recalled product when possible. Chapter 2.6.4.1 states that before supervising voluntary destruction of the product, FDA should prepare a statement on the firm's letterhead or on an FDA Form 463a Affidavit. The statement should specify the voluntary nature of the action, the condition of the lot, the name of the product, the amount of the product, and the method of destruction and should be signed by the responsible individual at the firm. If FDA is unable to witness the destruction, it should obtain written documentation from the firm and/or a State or local government agency certifying that the product has been properly disposed of.

Food and Drug Administration's Monitoring of Product Disposal

FDA documentation showed that FDA did not always follow its own procedures in monitoring recalling firms' disposal of contaminated products. For 4 of the 17 recalls, FDA provided evidence that it had monitored the disposal of the products. However, for the 13 remaining recalls, FDA was not able to provide evidence that it had witnessed the disposal or obtained written documentation from the firm or a State or local government agency certifying that all returned products had been properly disposed of. For example, in a recall of lead-contaminated pitchers, the recalling firm, an importer with approximately 300 retail stores in 35 States, did not provide FDA with adequate documentation that the product had been fully accounted for and disposed of. As a result, FDA had no assurance that the returned pitchers had not been redistributed.

RECOMMENDATIONS

We recommend that FDA:

- consider the results of this review in implementing the FDA Food Safety Modernization Act and

- follow its procedures for monitoring recalls.

FOOD AND DRUG ADMINISTRATION COMMENTS

In its written comments on our draft report, FDA agreed with our recommendations and described actions it has taken to improve how recalls are conducted and monitored. FDA's comments are included in their entirety as Appendix C.

APPENDIXES

APPENDIX A: PRIOR OFFICE OF INSPECTOR GENERAL REVIEWS

***FDA Inspections of Domestic Food Facilities* (OEI-02-08-00080), issued April 2010.** In this congressionally requested review, we found significant weaknesses in the Food and Drug Administration's (FDA) inspections of domestic food facilities, including declines in both the number of inspections and the number of violations identified by FDA inspectors. We also found that FDA did not routinely take swift and effective action to ensure that identified violations were remedied.

***FDA's Food Facility Registry* (OEI-02-08-00060), issued December 2009.** Our review of FDA's food facility registry found that some of the selected facilities had not registered with FDA as required. We also found that almost half of the selected registered facilities failed to provide accurate information either when they first registered or after the facility information changed.

***Review of the Food and Drug Administration's Monitoring of Pet Food Recalls* (A-01-07-01503), issued August 2009.** In this congressionally requested review, we examined FDA's oversight of pet food recalls. We found that FDA's lack of recall authority, its sometimes lax adherence to recall guidance and internal procedures, and the inadequacy of some of those procedures limited its ability to ensure that contaminated pet food was promptly removed from retailers' shelves.

***Traceability in the Food Supply Chain* (OEI-02-06-00210), issued March 2009.** Our review of food traceability found that most selected products could not be traced through each stage of the food supply chain. We also found that the majority of selected food facilities did not comply with FDA's recordkeeping requirements and that these requirements were not sufficient to ensure the traceability of the food supply.

APPENDIX B: REVIEW OF 17 SELECTED IMPORTED FOOD RECALLS

FDA Recall Event No.	Recall Initiation Date	Recalling Firm	Product Recalled	Reason for Recall
47439	3/26/08	Jard Marketing	Cantaloupes (Honduras)	*Salmonella*
46395	11/01/07	Mountain High Organics	Sesame seed (Uganda)	*Salmonella*
46213	11/19/07	Mark Foods	Frozen mussel meat (New Zealand)	*Listeria monocytogenes*
44932	9/20/07	Mexican Cheese	Cheese (Mexico)	*Salmonella*
46715	11/27/07	Central Seaway	Frozen mussel meat (New Zealand)	*Listeria monocytogenes*
38475	8/03/07	Cost Plus World Market	Beverage pitchers (China)	High lead levels
47485	3/23/08	Taylor Fresh	Cantaloupes (Honduras)	*Salmonella*
48469	5/29/08	Fresca Italia	Cheese (Italy)	*Listeria monocytogenes*
46755	2/07/08	Choyce Products	Frozen fish (Indonesia)	*Salmonella*
47206	3/04/08	Union Fish	Frozen mussel meat (New Zealand)	*Listeria monocytogenes*
47497	3/22/08	Legend Produce	Cantaloupes (Honduras)	*Salmonella*
46892	12/21/07	Pacific American Fish Co.	Frozen mussel meat (New Zealand)	*Listeria monocytogenes*
47544	3/22/08	Wuhl Shafman	Cantaloupes (Honduras)	*Salmonella*
46847	2/13/08	Summit Import	Dried fish (China)	*Clostridium botulinum*
39355	8/14/07	Everlasting Distributors	Dried fish (Philippines)	*Clostridium botulinum*
47483	3/24/08	Grand Super Center	Frozen fish (Korea)	*Clostridium botulinum*
46396	1/18/08	Seoul Shik Poom	Frozen fish (Korea)	*Clostridium botulinum*

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

DATE: April 28, 2011

TO: Inspector General

FROM: Acting Deputy Commissioner for Policy, Planning and Budget

SUBJECT: FDA's Comments to OIG Draft Report entitled, *FDA's Monitoring of Imported Food Recalls*

FDA is providing the attached comments to the Office of Inspection General Draft Report Entitled, *FDA's Monitoring of Imported Food Recalls.*

We appreciate the opportunity to review and comment on this draft report before it is published.

David Dorsey
Acting Deputy Commissioner for Policy, Planning and Budget

Attachment

The Food and Drug Administration's General Comments to the Office of Inspector General's Draft Report, *FDA's Monitoring of Imported Food Recalls*

The U.S. Food and Drug Administration (FDA or the Agency) appreciates the opportunity to respond to the Office of the Inspector General's (OIG) Draft Report. As OIG suggests, FDA will consider enhancements to the recall process in implementing the Food Safety Modernization Act of 2011 (FSMA). OIG's recommendations will be seriously considered as we work to implement this important new law.

FDA implemented nonbinding regulations in June 1978 and issued subsequent guidance on recall policy. These documents reflect that both FDA and regulated industries have obligations and roles in protecting consumers from using harmful products, and that these obligations are fulfilled by removing harmful products from the market or correcting improperly marketed products. Although food recalls were entirely voluntary at the time of the publication of the nonbinding regulations, recalls of violative products have been, on the whole, successful in removing these products from use and preventing harm to the public.

The enactment of FSMA will strengthen FDA in these efforts. The new law expands FDA's authority to regulate the safety of foods, and, among other things, gives FDA the authority to order the recall of foods under certain circumstances. This new law gives FDA authority to order that certain harmful and violative foods are promptly removed from commerce if firms do not conduct a voluntary recall.

Since the original recall policy was first implemented in 1978, the Agency has continued to improve how recalls are conducted and monitored. In addition, the Agency has seen an increase in the number of recalls of FDA-regulated products, some of which involve the largest and most complex recalls in FDA history. To address these issues and to make relevant improvements in the current recall business processes, FDA is conducting a study to examine the current process and ensure that it protects the public health and removes violative products from the marketplace as timely and efficiently as possible. The results of this study are under evaluation, but some of the proposals could include exploring the use of third parties to conduct some aspects of recall audit checks; triaging incoming recalls based on risk profiles in an effort to streamline the recall process; bolstering guidance to industry and enhancing opportunities to share best practices; improving consumer communications; and strengthening the management of the overall recall process. This process improvement study will help to inform FDA's decisions about future improvements to the recall process, and FDA will keep OIG and other stakeholders advised of our enhancements to the recall process.

FDA agrees with OIG's recommendations that FDA consider the results of the OIG study in implementing FSMA, and that FDA follow its procedures for monitoring voluntary recalls. The new tools provided by FSMA, coupled with FDA's current recall process improvement efforts, will benefit consumers by improving FDA's ability to remove violative products from the market and to protect the public health.