

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**FDA'S FOOD FACILITY
REGISTRY**



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Inspector General

December 2009
OEI-02-08-00060

Office of Inspector General

<http://oig.hhs.gov>

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OBJECTIVES

To determine the extent to which selected domestic food facilities:

- (1) registered with the Food and Drug Administration (FDA) and
- (2) provided complete and accurate information for FDA's food facility registry.

BACKGROUND

Each year, more than 300,000 Americans are hospitalized and 5,000 die after consuming contaminated foods and beverages. In the event of an outbreak of a foodborne illness, FDA is responsible for finding the source of the contamination and helping to remove the contaminated food products from the food supply chain. Recent outbreaks of foodborne illness involving peanut butter, peppers, and spinach have raised serious questions about FDA's ability to protect the Nation's food supply.

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 requires certain food facilities to register with FDA. The purpose of registration is to provide FDA with sufficient and reliable information about food facilities. This information enables FDA to quickly locate facilities during an outbreak of foodborne illness and to locate these facilities for inspection.

FDA requires each domestic food facility to provide information for the registry, including (1) contact information (i.e., name, full address, telephone number, and all trade names under which the facility conducts business); (2) contact information for the parent company; (3) contact information for the owner or operator of the facility; and (4) an emergency contact telephone number. If there is a change in a facility's information, such as a new name or address, the facility must provide FDA with the updated information within 60 days. The information provided by facilities is stored in a database called the FDA Unified Registration and Listing System (hereinafter referred to as the registry).

We based this study on a purposive sample of 130 selected domestic food facilities. To complete our analysis, we compared information about the selected facilities in the registry with information obtained during structured interviews with the facility managers.

FINDINGS

Seven percent of selected facilities either failed to register or failed to cancel their registration with FDA, as required. Specifically, 5 percent of selected facilities (7 of 130) did not register with FDA. For each of these facilities, FDA was missing critical information that could be used to locate the facility in an emergency. In addition, 2 percent of selected facilities (2 of 130) failed to cancel their registration. As a result, the registry contained information about inactive food facilities, which could hinder FDA's ability to accurately identify food facilities that may be linked to an outbreak of foodborne illness.

Almost half of the selected facilities failed to provide accurate information for the registry. Forty-eight percent (62 of 130) of selected facilities either failed to provide accurate information when they first registered or failed to provide accurate information after changes in the facility's information, as required. Specifically, 30 facilities did not provide accurate contact information for the facilities, 26 facilities did not provide an accurate emergency contact phone number, 20 facilities did not provide accurate contact information for the owner or operator, and 14 facilities did not provide accurate contact information for their parent company. In addition, seven facilities created multiple registrations for the same facility. Facility managers most commonly reported that they failed to provide FDA with accurate information either because they did not update the information for the registry as required; they incorrectly entered the information during the initial registration; or the responsibility for maintaining the registration was transferred to another person who mistakenly reregistered the facility.

FDA regulations do not ensure that the registry contains certain information that may be needed to locate a facility in an emergency. In many cases, facilities failed to provide information that may be useful to FDA in an emergency because certain information in the registry is optional. Specifically, 23 percent of the facilities (30 of 130) did not provide a valid emergency contact name or a physical address for contacting the parent company or the owner or operator. This lack of information may hamper FDA's ability to contact food facilities in an emergency.

Over half of the managers at the selected facilities were unaware of FDA's registry requirements. Fifty-two percent of the managers (67 of 130) reported that they were unaware of FDA's registry requirements. This included 5 managers who reported that they were unaware of any

requirements to register, as well as 62 managers who were unaware of the requirement to update the information in the registry within 60 days of a change in the facility's information.

RECOMMENDATIONS

To address the findings in this report, we recommend that FDA:

Improve the accuracy of the information in the registry.

FDA should develop strategies to systematically verify and ensure that the information in the registry is accurate. FDA should seek statutory authority to require food facilities to reregister on a routine basis. It should also consider seeking statutory authority to impose a registration fee to deter facilities from submitting multiple registrations. FDA should also revise the registration process to allow for more checks as the data are entered in the registry and conduct additional checks of information that has already been entered.

Consider seeking statutory authority to impose civil penalties through administrative proceedings against facilities that do not comply with the registry requirements. FDA should consider seeking the authority to impose civil penalties through administrative proceedings against facilities that either fail to register or fail to provide accurate information.

Consider making some of the optional fields within the registry mandatory. To improve the usefulness of the registry, FDA should carefully consider what information is needed in an emergency and should take action—including seeking statutory authority, if necessary, and making regulatory changes—to ensure that this information is mandatory. Specifically, FDA should consider requiring facilities to identify at least one individual who can be contacted during an emergency. Similarly, for the parent company's address and the address of the owner or operator, FDA should consider requiring facilities to provide physical addresses rather than mailing addresses.

Work with the food industry to increase facilities' awareness of the registry requirements. FDA should work with the food industry to conduct additional education and outreach activities to inform food facilities about the registry requirements and the importance of providing complete and accurate information.

AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

FDA generally agreed with our recommendations. FDA noted that the study confirms problems that the agency has encountered as well as the need for additional statutory authority. FDA further noted that it already has in progress several efforts that respond to our recommendations and that provisions in proposed legislation are intended to address many of the problems we identified.

FDA agreed in principal to our second recommendation to consider seeking statutory authority to impose civil penalties through administrative proceedings against facilities that do not comply with registry requirements. It indicated that proposed legislation would create a strong incentive to ensure timely and proper registration. We agree that this is a strong incentive to maintain accurate registrations. However, we still recommend that FDA consider seeking statutory authority to impose civil penalties, such as a daily fine, as an intermediate step before taking more severe actions.

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OBJECTIVES

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- (2) provided complete and accurate information for FDA's food facility registry.

BACKGROUND

Each year, more than 300,000 Americans are hospitalized and 5,000 die after consuming contaminated foods and beverages.¹ In the event of an outbreak of a foodborne illness, FDA is responsible for finding the source of the contamination and helping to remove the contaminated food products from the food supply chain. Recent outbreaks of foodborne illness involving peanut butter, peppers, and spinach have raised serious questions about FDA's ability to protect the Nation's food supply.

Section 305(a) of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 requires certain food facilities to register with FDA.² The purpose of registration is to provide FDA with sufficient and reliable information about food facilities.³ This information enables FDA to quickly locate facilities during an outbreak of foodborne illness and to locate these facilities for inspection.⁴

This report is part of an ongoing body of work by the Office of Inspector General (OIG) on food safety. In a 2009 report on food traceability, we found that only 5 of the 40 products we purchased could be traced through each stage of the food supply chain.⁵ That report also found that 59 percent of selected food facilities did not comply with FDA's

¹ Paul S. Mead et al., "Food-Related Illness and Death in the United States," *Emerging Infectious Diseases*, Vol. 5, 1999, pp. 607–625. Available online at <http://www.cdc.gov/ncidod/eid/Vol5no5/mead.htm>. Accessed on April 1, 2009.

² P.L. No. 107-188 § 305(a) (codified at 21 U.S.C. § 350d).

³ Federal Register Interim Final Rule, 68 Fed. Reg. 58894 (Oct. 10, 2003): Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Volume 68, Number 197). Available online at <http://www.fda.gov/Food/FoodDefense/Bioterrorism/FoodFacilityRegistration/ucm081637.htm>. Accessed on June 22, 2009.

⁴ *Ibid.*

⁵ OIG, "Traceability in the Food Supply Chain," OEI-02-06-00210, March 2009.

recordkeeping requirements. A forthcoming study will assess the extent which FDA inspects domestic food facilities and identifies and addresses food facility violations.⁶

FDA's Food Facility Registry

As of December 2003, FDA began requiring food facilities—both foreign and domestic—that manufacture, process, pack, or hold food for consumption in the United States to register with FDA.⁷ FDA requires each domestic facility to provide:

- a facility name, full address, telephone number, and all trade names the facility uses;⁸
- a name, address, and phone number of the parent company (if applicable);
- a name, address, and phone number for the owner, operator, or agent in charge of the facility;⁹ and
- an emergency contact phone number.¹⁰

FDA also requires each facility to provide information about the categories of foods handled and a statement that the information provided

⁶ “Food and Drug Administration Inspections of Domestic Food Facilities,” OEI-02-08-00080 (forthcoming).

⁷ 21 CFR §§ 1.225(a) and 1.230. Note that pursuant to 21 CFR § 1.226, certain facilities (such as farms, restaurants, and retail food establishments) are exempt from the registration requirements. Facilities that are required to register include processors, manufacturers, distributors, and warehouses.

⁸ Notice that the regulations require the “full address” for the facility, but require only an “address” for the parent company and the owner or operator. FDA provides further guidance on the address requirements in its Registration of Food Facilities Step-by-Step Instructions. These instructions specify that the address of the facility is the “physical location of the facility being registered. This is normally a street address, but may be some other physical/geographical designation used in rural locations.” Registration of Food Facilities Step-by-Step Instructions. Available online at <http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/RegistrationofFoodFacilities/OnlineRegistration/ucm073706.htm>. Accessed on June 23, 2009.

⁹ For the purposes of this report, we refer to this as the requirement to identify the owner or operator.

¹⁰ Pursuant to 21 CFR § 1.232, foreign facilities are required to submit the same information as domestic facilities, except for the emergency contact phone number. In addition, 21 CFR § 1.232(d) requires each foreign facility to provide the name; address; phone number; and, if no emergency contact is designated under 21 CFR § 1.233(e), the emergency contact phone number of the foreign facility's U.S. agent. Section 21 CFR § 1.227(b)(13) defines a U.S. agent to mean a person residing or maintaining a place of business in the United States whom a foreign facility designates as its agent for purposes of the registration.

I N T R O D U C T I O N

is true and that the submitter was authorized to submit the registration.¹¹ FDA asks each facility to provide, in addition to the required information, optional information, such as the name of an individual to contact in an emergency and a preferred mailing address, fax number, and email address for the facility.¹² Appendix A provides additional information about the registry requirements.

FDA requires facilities to provide complete and accurate information for each of the mandatory requirements outlined above. If there is a change in a facility's information, such as a new name or address, a facility must update this information within 60 days.¹³ Facilities are also required to cancel their registration within 60 days if they go out of business, cease providing food for consumption in the United States, or change ownership.¹⁴ If a facility changes ownership, the former owner must cancel the facility's registration within 60 days of the change and the new owner must reregister the facility.¹⁵

Failure to register a facility, failure to update required elements of a facility's registration, or failure to cancel a facility's registration as required is a prohibited act.¹⁶ The United States can bring a civil action in Federal court to enjoin a person who commits a prohibited act. The United States can also bring a criminal action in Federal court to prosecute a person who is responsible for the commission of a prohibited act.¹⁷

Information provided by facilities is stored in a database called the FDA Unified Registration and Listing System (hereinafter referred to as the registry). Facilities may submit their information through FDA's Web site. If a facility does not have reasonable access to the Internet, it may mail or fax the registration form. Facilities may also mail multiple submissions on a CD-ROM.¹⁸ As of January 2009, the registry contained approximately 150,000 domestic food facility registrations and 216,000 foreign food facility registrations.¹⁹

¹¹ Ibid.

¹² 21 CFR § 1.233.

¹³ 21 CFR § 1.234(a).

¹⁴ 21 CFR §§ 1.235 and 1.234(b).

¹⁵ 21 CFR § 1.234(b).

¹⁶ 21 CFR § 1.241(a).

¹⁷ Ibid.

¹⁸ 21 CFR § 1.231.

¹⁹ FDA, "Compliance Information: Registration." January 2009.

Related Work

In October 2006, FDA conducted a study to assess the accuracy of certain information in the registry. Specifically, FDA evaluated the accuracy of: (1) the required emergency contact phone numbers, (2) the optional fax numbers, and (3) the optional email addresses. The study sampled 400 domestic food facilities in the registry and found that this information was inaccurate for 18.5 percent of the facilities. To improve the accuracy of the information in the registry, FDA proposed, among other things, to increase education of food facilities and to implement additional electronic checks to improve data quality.

METHODOLOGY**Scope**

This study assesses the extent to which selected facilities registered with FDA and the extent to which selected facilities provided complete and accurate information. This study includes only domestic food facilities. In addition, the findings are limited to selected facilities and are not projectable to all food facilities subject to FDA's registration requirements. We also limited our review to the key fields in the registry that would likely be needed by FDA in a food emergency.

Sample Selection

We based our sample on information from a previous OIG study entitled "Traceability in the Food Supply Chain."²⁰ In that study, we purchased 40 food products from different retail stores around the country and attempted to trace these products through each stage of the food supply chain back to the farm or the border.²¹ For each of these 40 products, we asked facilities to identify the sources of these food products. In addition, for each facility that was not a retailer, we requested information about the recipients of the food products. We contacted a total of 118 facilities that were required by FDA to maintain records about their sources or recipients. To select the sample for the current study, we identified 83 of the 118 facilities in our previous study that were also subject to FDA's registry requirements. For each of these facilities, we randomly selected

²⁰ OIG, "Traceability in the Food Supply Chain," OEI-02-06-00210, March 2009.

²¹ The products—selected in consultation with FDA officials—included bottled water, ice, milk, eggs, yogurt, flour, oatmeal, tomatoes, leafy vegetables, and juice.

up to three facilities that were identified as recipients of the food products. Based on this information, we identified 58 additional facilities that were subject to FDA's registry requirements for a total of 141 facilities.²²

Structured Interviews

We conducted structured telephone interviews with managers or other representatives (hereinafter referred to as managers) of the facilities in our sample.²³ In total, we were able to contact the managers for 130 of the 141 facilities, resulting in a 92-percent response rate.

For each facility, we asked the manager to verify key information contained in the registry as of February 14, 2008. Specifically, we asked each manager to provide: (1) the facility name, full address, telephone number, and all trade names under which the facility conducted business; (2) the name, address, and telephone number of the parent company (if applicable); (3) the name, address, and telephone number of the owner or operator of the facility; and (4) the emergency contact telephone number.

If the information provided by the manager differed from the information in the registry, we asked the manager to explain the discrepancies. For example, we asked whether the manager had failed to update the information for the registry or whether it was inaccurate for other reasons, such as a mistyped phone number or address.

Finally, we asked managers about their familiarity with the registry requirements as well as their experiences updating and maintaining their registration. We also asked them where they typically obtained information about FDA rules and regulations. We completed these interviews between June and August 2008.

Data Analysis

We compared the data from the structured interviews to the information in the registry to determine:

- (1) the number of facilities that failed to register with FDA,
- (2) the number of facilities that failed to cancel their registration when they ceased operations, and

²² Note that we were able to identify only 58 facilities primarily because not all of the 83 facilities had recipients that were subject to the registry requirements.

²³ In several instances, the same individual or parent company registered multiple facilities. In these cases, we asked the managers to provide relevant information for each of the facilities that they were responsible for, and we counted their responses separately for each facility.

- (3) the number of facilities that failed to provide accurate and complete information.

Specifically, we assessed the accuracy of (1) the required facility name, full address, telephone number, and all trade names the facility uses; (2) the required name, address, and telephone number of the parent company (if applicable); (3) the required name, address, and telephone number of the owner or operator of the facility; and (4) the required emergency contact telephone number.²⁴ In addition, we determined the number of facilities that did not provide an optional emergency contact name or a physical address for contacting the owner or operator or the parent company.²⁵ We also analyzed the responses from the structured interviews to determine managers' awareness of the registry requirements.

Standards

This study was conducted in accordance with the "Quality Standards for Inspections" approved by the Council of the Inspectors General on Integrity and Efficiency.

²⁴ This study does not assess compliance with the two remaining requirements, which are: (1) to provide a statement that the information submitted in the registry is true and accurate and, if the individual submitting the form is not the owner, operator, or agent, a statement that the submitter was authorized to submit the registration, together with information about the individual who authorized the submission, and (2) to provide information about certain categories of foods handled by the facility.

²⁵ The regulations require an address for the owner or operator and the parent company; however, the regulations do not specify that it must be the full address or physical address. In addition, FDA's Registration of Food Facilities Step-by-Step Instructions provide that for the parent company and for the owner or operator, the address "can be a physical/geographical location or other mailing address."

► FINDINGS

Seven percent of selected facilities either failed to register or failed to cancel their registration with FDA, as required

FDA requires all food facilities to register if they manufacture, process, pack, or hold food for consumption in the United States. FDA also requires facilities to cancel their registration if they go out of business, cease providing food for consumption in the United States, or change ownership.

Five percent of selected facilities failed to register with FDA

In total, 7 of 130 facilities that we contacted did not register with FDA. Five of these facilities had never registered with FDA, whereas two facilities failed to register after a change in ownership. As noted earlier, when a facility changes ownership, the new owner must register the new facility within 60 days of the change. The managers at these two facilities confirmed that the change in ownership occurred more than 60 days prior to this review. For all seven facilities, FDA was missing critical information that could be used to locate them in an emergency.

Two percent of selected facilities failed to cancel their registration with FDA

Of the 130 facilities that we contacted, 2 facilities failed to cancel their registration with FDA. FDA requires facilities to cancel their registration if they go out of business, cease providing food for consumption in the United States, or change ownership. The managers at these two facilities reported that changes in ownership occurred more than 60 days prior to this review and they had failed to cancel their registration. As a result, the registry contained information about inactive food facilities, which could hinder FDA's ability to accurately identify food facilities that may be linked to an outbreak of foodborne illness.

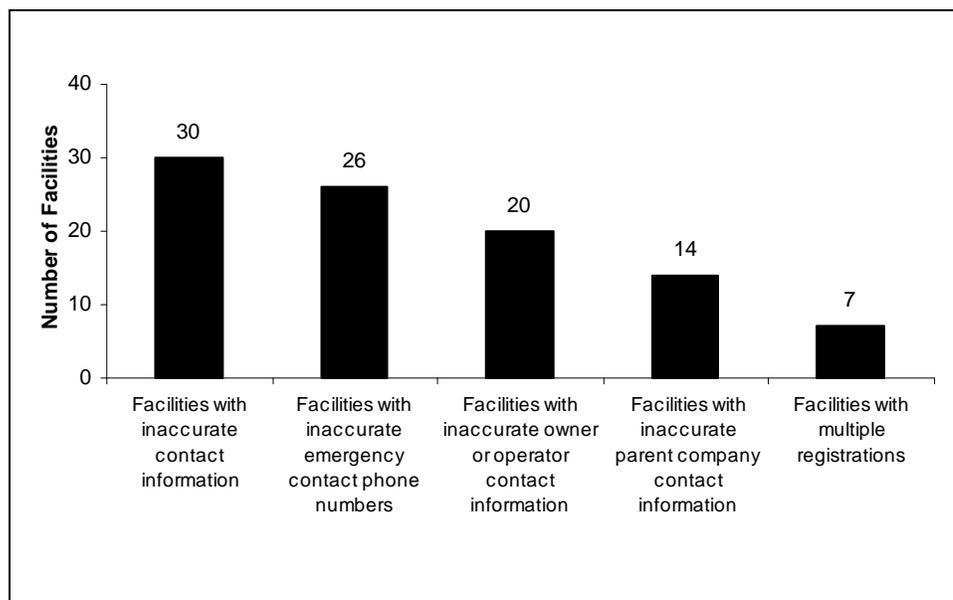
Almost half of the selected facilities failed to provide accurate information for the registry

Forty-eight percent of selected facilities (62 of 130) either failed to provide accurate information when they first registered or failed to provide accurate information after a change in the facilities' information, as required. As noted earlier, FDA requires each facility to provide accurate information for the registry. If there is a change in a facility's information, such as a new name or address, the facility must provide FDA with the updated information within 60 days.

As shown in Figure 1, 30 facilities did not provide accurate contact information for the facilities, 26 facilities did not provide an accurate emergency contact phone number, 20 facilities did not provide accurate contact information for the owner or operator, and 14 facilities did not provide accurate contact information for their parent company. In addition, seven facilities created multiple registrations for the same

facility. Pursuant to FDA regulations, each facility should register only once. However, these seven facilities created duplicate registrations rather than updating their existing registration, which resulted in the inclusion of inaccurate information in the registry.

Figure 1:
Number of Selected
Facilities With
Inaccurate
Information in the
Registry



Source: OIG analysis of food facilities' responses, 2009.

Note: These categories are not mutually exclusive.

Facility managers most commonly reported that they failed to provide FDA with accurate information either because they did not update the information in the registry, as required; they incorrectly entered the information during the initial registration; or the responsibility for maintaining the registration was transferred to another person who mistakenly reregistered the facility.

In addition, 26 percent of the managers at the facilities with inaccurate registrations (16 of 62) reported that they experienced technical difficulties when they tried to register or update information for their facilities. The most common problems reported were difficulties updating information, navigating the Web site, and obtaining passwords for the Web site.

FDA’s regulations do not ensure that the registry contains certain information that may be needed to locate a facility in an emergency

In many cases, facilities failed to provide information that may be useful to FDA in an emergency because certain information in the registry is optional. Specifically, 23

percent of the facilities (30 of 130) did not provide a valid emergency contact name or a physical address for contacting the parent company or the owner or operator.

Eighteen percent of selected facilities did not provide a valid emergency contact name

The emergency contact name is an optional field in the registry, and 18 percent of facilities (23 of 130) did not provide a valid emergency contact name. Eight of the facilities did not provide any emergency contact name for the registry, whereas 15 provided the name of a person who was either no longer employed at the facility, changed positions in the facility, or was unknown to the manager. These inaccuracies may hamper FDA’s ability to contact these food facilities in an emergency.

In addition, of the facilities that did not provide a valid emergency contact name, eight did not identify a person responsible for the facility elsewhere in the registration. These facilities did not provide the name of an individual as the owner or operator of the facility, but instead had provided the name of the facility or parent company. Although FDA’s guidance does not require that facilities provide the name of a specific individual for the registry, it may be difficult for FDA to quickly locate an individual responsible for a facility in an emergency if the name of an owner, operator, or emergency contact is not included in the registry.

Eight percent of selected facilities did not provide a physical address for the owner, operator, or parent company

Of the 130 facilities we contacted, 10 facilities provided a mailing address rather than physical address for the owner, operator, or parent company. These facilities provided a post office box where it could receive mail from FDA. Although FDA does not require a physical address for the owner, operator, or parent company, the lack of a physical address could hinder FDA’s ability to respond rapidly to an emergency.

FINDINGS

Over half of the managers at the selected facilities were unaware of FDA's registry requirements

Fifty-two percent of the managers (67 of 130) reported that they were not aware of FDA's registry

requirements. This included 5 managers who reported that they were unaware of any requirements to register, as well as 62 managers who were unaware of the requirement to update the information in the registry within 60 days of a change in the facility's information.

Of the managers who were aware of the registry requirements, they most commonly reported that they received information about the requirements from FDA. Specifically, 33 managers reported they receive information from FDA's emails, listserv, or Web site. They also reported receiving information from other sources, such as trade publications; industry groups; or internal sources, such as their parent companies or legal departments.

The purpose of food facility registration is to provide FDA with accurate and useful information about food facilities. This information enables FDA to quickly locate facilities during an outbreak of foodborne illness and to locate these facilities for inspection.

Our review raises questions about the accuracy and utility of the registry. Specifically, we found that 7 percent of selected facilities either failed to register or failed to cancel their registration and almost half of the selected facilities failed to provide accurate information for the registry, as required. In addition, we found that FDA's regulations do not ensure that the registry contains certain information that may be needed to locate a facility in an emergency. Finally, we found that over half of the managers at the selected facilities were unaware of the registry requirements.

To address the findings in this report, we recommend that FDA:

Improve the accuracy of the information in the registry

FDA should develop strategies to systematically verify and ensure that the information in the registry is accurate. To accomplish this, FDA should:

- Seek statutory authority to require facilities to reregister on a routine basis. If FDA determines that this is not feasible, FDA should develop other methods to verify the information in the registry, such as routinely mailing the information in the registry to the person authorized to maintain it, so that he or she can ensure that the information provided is accurate.
- Consider seeking statutory authority to impose a registration fee. FDA should collect a fee for each facility registration to deter facilities from submitting multiple registrations.
- Revise the registration process to allow for more checks as the data are entered in the registry, and conduct additional checks of the information that has already been entered. For example, FDA could implement electronic checks that would alert facilities if information in the registry was incomplete. FDA could also analyze registry data to identify blank fields or incongruous information and request that the facility correct the registration. In addition, FDA should consider using other data sources—such as FDA's database

R E C O M M E N D A T I O N S

of food facilities within its jurisdiction, called the Official Establishment Inventory—to verify that the information in the registry is complete and accurate.

Consider seeking statutory authority to impose civil penalties through administrative proceedings against facilities that do not comply with the registry requirements

FDA should consider seeking the authority to impose civil penalties through administrative proceedings against facilities that either fail to register or fail to provide accurate information. Civil penalties could be an effective method of encouraging facilities to comply with the registry requirements.

Consider making some of the optional fields within the registry mandatory

To improve the usefulness of the registry, FDA should carefully consider what information is needed in an emergency and should take action—including seeking statutory authority, if necessary, and making regulatory changes—to ensure that this information is mandatory. Specifically, FDA should consider requiring facilities to identify at least one individual that can be contacted during an emergency, such as an emergency contact name or the name of the individual who may be the owner or operator of the facility. Similarly, for the parent company's address and the address of the owner or operator, FDA should consider requiring facilities to provide physical addresses rather than mailing addresses.

Work with the food industry to increase facilities' awareness of the registry requirements

FDA should work with the food industry to conduct additional education and outreach activities to inform food facilities about the registry requirements and the importance of providing complete and accurate information. FDA should focus its education and outreach activities on informing facilities about the requirement to update their information within 60 days of a change in the facility's information. FDA should consider using industry Web sites and trade publications, in addition to its Web site and listserv, to highlight this requirement.

AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

FDA generally agreed with our recommendations. FDA noted that the study confirms problems that the agency has encountered as well as the need for additional statutory authority. FDA further noted that it already has in progress several efforts that respond to our recommendations and that provisions in proposed legislation are intended to address many of the problems we identified.

FDA agreed with our first recommendation to improve the accuracy of the information in the registry. Specifically, FDA noted that proposed legislation includes provisions for either annual or biennial registration, and a provision for an annual registration fee. FDA also stated that it had already revised the registration process to allow for more checks as the data are entered into the registry. FDA further stated that it is using other data sources to verify the accuracy of the registration information.

FDA agreed in principle with our second recommendation to consider seeking statutory authority to impose civil penalties through administrative proceedings. FDA noted that proposed legislation would allow FDA to deem a facility's food misbranded if that facility is not properly registered, and allow FDA to cancel a registration. We agree that this is a strong incentive to maintain accurate registrations. However, we still recommend that FDA consider seeking statutory authority to impose civil penalties, such as a daily fine, as an intermediate step before taking more severe actions, such as seizures.

FDA agreed with our third recommendation to consider making some of the optional fields within the registry mandatory. FDA noted that proposed legislation includes a provision for mandating additional information as the Secretary may require. We note that there may be additional revisions FDA can make that do not require statutory changes.

FDA did not specifically state whether it agreed with our fourth recommendation to work with the food industry to increase awareness of the registry requirements. However, FDA noted that it has conducted extensive outreach, and that it continues to work with trade associations. We ask that, in its final management decision, FDA more clearly indicate whether it agrees with this recommendation.

For the full text of FDA's comments, see Appendix B.

Registration of Food Facilities Regulations

Title 21 of the Code of Federal Regulations, Chapter I, Subchapter A, Part 1, Subpart H, describes the specific information that each facility must submit under the Registration of Food Facilities provision of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. Pursuant to 21 CFR § 1.227(b)(2), a facility is:

any establishment, structure, or structures under one ownership at one general physical location, or, in the case of a mobile facility, traveling to multiple locations, that manufactures/ processes, packs, or holds food for consumption in the United States. Transport vehicles are not facilities if they hold food only in the usual course of business as carriers. A facility may consist of one or more contiguous structures, and a single building may house more than one distinct facility if the facilities are under separate ownership. The private residence of an individual is not a facility. Nonbottled water drinking water collection and distribution establishments and their structures are not facilities.

Pursuant to 21 CFR §1.232, each registrant must submit the following information:

- (a) the name, full address, and phone number of the facility;
- (b) the name, address, and phone number of the parent company, if the facility is a subsidiary of the parent company;
- (c) for domestic and foreign facilities, the names, addresses, and phone numbers of the owner, operator, and agent in charge;
- (d) for a foreign facility, the name, address, phone number, and, if no emergency contact is designated under § 1.233(e), the emergency contact phone number of the foreign facility's U.S. agent;
- (e) for a domestic facility, an emergency contact phone number;
- (f) all trade names the facility uses;
- (g) applicable food product categories as identified in § 170.3 of this chapter, unless you check either "most/all human food product categories," pursuant to § 1.233(j), or "none of the above mandatory categories" because your facility

manufactures/processes, packs, or holds a food that is not identified in § 170.3 of this chapter;

- (h) the name, address, and phone number for the owner, operator, or agent in charge;
- (i) a statement in which the owner, operator, or agent in charge certifies that the information submitted is true and accurate. If the individual submitting the form is not the owner, operator, or agent in charge of the facility, the registration must also include a statement in which the individual certifies that the information submitted is true and accurate; certifies that he/she is authorized to submit the registration; and identifies by name, address, and telephone number, the individual who authorized submission of the registration. Each registration must include the name of the individual registering the facility submitting the registration, and the individual's signature (for the paper and CD-ROM options).

In addition, pursuant to 21 CFR § 1.233, FDA encourages, but does not require, facilities to submit the following optional information:

- (a) fax number and email address of the facility;
- (b) preferred mailing address, if different from that of the facility;
- (c) fax number and email address of the parent company, if the facility is a subsidiary of the parent company;
- (d) for a domestic facility, emergency contact name, title, and email address;
- (e) for a foreign facility, an emergency contact name, title, phone number and email address. FDA will consider the facility's U.S. agent the facility's emergency contact unless the facility chooses to designate another person to serve as an emergency contact under this section;
- (f) for a foreign facility, title, fax number, and email address of the U.S. agent;
- (g) type of activity conducted at the facility (e.g., manufacturing/processing or holding);
- (h) food categories not identified in § 170.3 of this chapter, which are provided in Form 3537, sections 11a (e.g., infant formula, animal byproducts and extracts) and 11b (e.g., grain products, amino acids);

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- (i) type of storage, if the facility is primarily a holding facility;
- (j) a food product category of “most/all human food product categories,” if the facility manufactures/processes, packs, or holds foods in most or all of the categories identified in § 170.3 of this chapter;
- (k) approximate dates of operation, if the facility's business is seasonal;
- (l) the fax number and email address of the owner, operator, or agent in charge; and
- (m) the fax number and email address of the individual who authorized submission of the registration.

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Agency Comments



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

DATE: September 25, 2009
TO: Inspector General
FROM: Principal Deputy Commissioner of Food and Drugs
SUBJECT: FDA's General Comments to OIG's draft report titled, *FDA's Food Facility Registry (OEI-02-08-00060)*

FDA is providing the attached general comments to the Office of Inspector General's draft report titled: *FDA's Food Facility Registry (OEI-02-08-00060)*.

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

/S/

Joshua M. Sharfstein, M.D.
Principal Deputy Commissioner of Food and Drugs

Attachment

**FDA's General Comments to the Office of Inspector General's (OIG) Draft Report,
FDA Food Facility Registry (OEI-02-08-00060)**

The OIG Food Facility Registry study was prompted in part by a study FDA conducted in October 2006 in which FDA found that a significant percentage of owners, operators, or agents-in-charge of facilities subject to the Food Facility Registration Final Rule, 21 CFR Part 1, Subpart H, were not updating mandatory contact information, as required by the final rule. The results of FDA's study are available at

<http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/RegistrationofFoodFacilities/ucm170589.htm>. The purpose of the current OIG Food Facility Registry study was to determine whether facilities' compliance with existing registration requirements had improved or whether FDA needed additional statutory authority to improve the quality of food facility registration data. Generally, FDA finds the study helpful. It confirms problems the agency has encountered with facilities that either fail to update information as required by the agency's regulations or are unaware of their ongoing registration obligations (e.g., updating information when such information changes). The study also confirms the need for additional statutory authority. Limits on FDA's current statutory authority may prevent FDA from adopting or fully implementing recommendations 1, 2, and 3.

FDA notes that it already has in progress several efforts that respond to the OIG recommendations. First, FDA has contracted with Dunn & Bradstreet to compare the registrations in the current database with the information on facilities that Dunn & Bradstreet maintains. When discrepancies are discovered, FDA contacts the facilities to request that updated information be submitted to the database. Second, FDA has done a significant amount of outreach about the food facility registration requirements, including establishing a website (www.access.fda.gov) that provides information, such as tutorials on 20 different topics to educate facilities about particular registration elements; holding live satellite broadcasts transmitted to more than 1,000 sites around the world and which remain on the website to explain the requirements; and setting up a help desk to respond to facilities' questions about the registration requirements and process.

FDA further notes that provisions in HR 2749, the Food Safety Enhancement Act of 2009 that the House passed in July, are intended to address many of the problems identified by the OIG Food Facility Registry report. In particular, the bill would require annual facility registration, an annual fee, and would enhance FDA's authority to require updated registration information. If enacted, these additional authorities would improve the quality of the data in the food facilities registration database, which in turn would enhance FDA's efforts to target its inspection efforts.

OIG Recommendations

OIG recommends that FDA take the following actions:

Improve the accuracy of the information contained in the registry. FDA should develop strategies to systematically verify and ensure that the information in the registry is accurate. FDA should seek statutory authority to require food facilities to reregister on a routine basis. If FDA determines that this is not feasible, FDA should develop other methods to verify the

information in the registry, such as routinely mailing the information in the registry to the person authorized to maintain it, so that he or she can ensure that the information provided is accurate.

FDA Response

FDA agrees with this recommendation and notes that HR 2749, which has passed the House, includes a provision for annual registration. Similarly, S 510, the FDA Food Safety Modernization Act, which is pending in the Senate, includes a provision for biennial registration. FDA believes that annual registration would be more effective in ensuring that the registry contains updated and accurate information.

Consider seeking statutory authority to impose a fee associated with the registration process. FDA should collect a fee for each facility registration to deter facilities from submitting multiple registrations and to increase the accuracy of the information provided.

FDA Response

FDA agrees with this recommendation and notes that HR 2749 would require an annual fee to accompany each facility registration. Similarly, the President's 2010 budget includes a registration fee.

Revise the registration process to allow for more checks as the data are entered in the registry, and also conduct additional checks of the information that has already been entered in the registry.

FDA Response

FDA has already implemented this recommendation. FDA notes that a number of the registrations that contain incomplete data were submitted before such checks were in place. The requirement for facilities to register was established with the enactment of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. The Act required FDA to propose and issue final regulations that would implement the registration requirements within 18 months, or by December 12, 2003, which was a very ambitious timeframe. FDA exceeded this timeframe by publishing the final rule and building and launching the registry on October 10 and October 12, 2003, respectively, which gave owners, operators, and agents-in-charge of affected facilities two months to understand the requirements and register their facilities. Given the challenge of establishing a system from startup within 18 months with limited resources, FDA was not able to program in the types of checks recommended by OIG into the registry in 2003. By 2004, however, FDA had instituted a number of edit checks into the registry, including the following:

- Address validation check – if the domestic or foreign street address entered cannot be verified, the user is prompted to check and validate the address;
- Postal validation check – if the user enters a postal code that does not match with a U.S. city or state, the user is prompted to verify and reenter the address;

- To reduce creating duplicate registrations when registering a facility for the first time, the system informs the user to not click the submit button more than once or he or she will inadvertently create a duplicate registration; and
- If a user checks the box that marks the registration as a domestic facility and then enters a foreign address, the system will not process the registration.

Given that two or more facilities can be owned or operated by different persons, yet have the same address (e.g., if two or more persons own or rent different parts of a warehouse to hold food), edit checks that would not accept a registration on the basis of having the same address as an existing registration are not possible. FDA may not inform persons who are not affiliated with a facility about the existence or lack thereof of another person's registration; thus, FDA may not query the person submitting a registration with the same address and different facility name about whether the registrations are affiliated. In addition, differences in a facility's name, even with the same address (e.g., Jones Packing Company, Jones Bros. Packing Company, and Jones Brothers Packers) are considered different facilities by the system, and thus, edit checks alone will not recognize such entries as potential duplications -- they must be manually reviewed in order to make such a determination. This latter type of situation can occur when different persons at a facility are or become responsible for the facility's registration over time, but use different names or abbreviations to refer to the facility.

FDA believes that in addition to these types of edit checks, requiring facilities to register annually and pay a registration fee, as is provided in HR 2749, will drastically reduce the errors, duplications, and other data problems in the registry.

FDA also is using other data sources to verify the accuracy of the registration data. As noted above in the General Comments, FDA has contracted with Dunn & Bradstreet to compare the registrations in the current database with the information on facilities that Dunn & Bradstreet maintains. When discrepancies are discovered, FDA contacts the facilities to request that updated information be submitted to the database. FDA also has been using the information in its Official Establishment Inventory to verify the accuracy of the registration information, as recommended above.

Consider seeking statutory authority that would allow FDA to impose civil penalties through administrative proceedings against facilities that do not comply with the registry requirements. FDA should consider seeking the authority to impose civil penalties through administrative proceedings against facilities that either fail to register or fail to provide accurate information for the registry.

FDA Response

FDA agrees in principle with this recommendation and notes that § 101 of HR 2749 would deem to be misbranded food that is manufactured, processed, packed, or held in a facility that is not properly registered, which includes registrations that are not properly updated. A misbranded food may be seized, condemned, and/or forfeited, which would create a strong incentive to ensure the timely and proper registration and updating of registration information from all facilities. HR 2749 also would authorize FDA to cancel registrations that contain inaccurate,

incomplete, or outdated information, which would help ensure the Agency has accurate, updated information in its registration database.

Consider making some of the optional fields within the registry mandatory. To improve the usefulness of the registry, FDA should carefully consider what information is needed in an emergency and should take action—including seeking statutory authority, if necessary, and making regulatory changes—to ensure that this information is mandatory. Specifically, FDA should consider requiring facilities to identify at least one individual that can be contacted during an emergency, such as an emergency contact name or the name of the individual who may be the owner or operator of the facility. Similarly, for the parent company's address and the address of the owner or operator, FDA should consider requiring facilities to provide physical addresses rather than mailing addresses in the registry.

FDA Response

FDA agrees with this recommendation and notes that § 101 of HR 2749 would mandate additional information not currently required by statute or regulation, such as “[t]he name, address, and 24-hour emergency contact information of the U.S. distribution agent for the facility, which agent shall have access to the information required to be maintained under section 414(d) for food that is manufactured, processed, packed, or held at the facility[,]” and “[s]uch additional information pertaining to the facility as the Secretary may require by regulation.”

Work with the food industry to increase facilities' awareness of the registry requirements. FDA should work with the food industry to conduct additional education and outreach activities to inform food facilities about the registry requirements and the importance of providing complete and accurate information to FDA.

FDA Response

FDA has conducted extensive outreach on this rule beginning in October 2003, two months before the requirements took effect. More recently, as noted in the general comments above, this outreach has included establishing a website (www.access.fda.gov) that provides information about registration, including a September 2009 guidance document that provides answers to frequently asked questions (<http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodDefenseandEmergencyResponse/ucm082703.htm>); holding satellite broadcasts that were transmitted live to more than 1,000 sites around the world and remain available on FDA's website to explain the requirements; providing tutorials on 20 different topics related to registration on FDA's website to educate the industry about particular registration elements; and setting up a help desk to respond to facilities' questions about the registration requirements and process. FDA also continues to work with trade associations to ensure their members are aware of all applicable requirements related to registration. In order to contact facilities without e-mail addresses, FDA has mailed postcards to registered facilities, reminding them of the duty to update their registrations. However, given the significant numbers of facilities with outdated information, many of these postcards were returned as undeliverable. Given the costs of mail, FDA has limited this particular outreach effort.

FDA will continue to assist affected entities in understanding all requirements that apply to them, in order to assist such entities to fulfill their responsibilities to be aware of, and comply with, all applicable regulations at the federal, state, and local level.



A C K N O W L E D G M E N T S

This report was prepared under the direction of Jodi Nudelman, Regional Inspector General for Evaluation and Inspections in the New York regional office, and Meridith Seife, Deputy Regional Inspector General.

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