Guidance for FDA Staff

Compliance Policy Guide
Sec. 100.250 Food Facility Registration – Human and Animal Food

Draft Guidance

This guidance is being distributed for comment purposes only.

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For questions regarding this draft document contact the Center for Food Safety and Applied Nutrition at 240-402-1887.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition
Center for Veterinary Medicine
Office of Regulatory Affairs
April 2013

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I. Introduction:

*The purpose of this document is to provide guidance for FDA staff on food facility registration under section 415 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 350d), including the requirement that certain food facilities register with FDA, the requirement that registered facilities biennially renew their registrations with FDA, and FDA's authority to suspend a food facility's registration.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

II. Background:

Food Facility Registration

Section 305 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) (Pub. L. 107-188) amended the FD&C Act by adding section 415, which established requirements for food facilities to register with FDA. Under section 415 of the FD&C Act (21 U.S.C. 350d), owners, operators, or agents in charge of domestic and foreign

facilities that manufacture, process, pack, or hold food for human or animal consumption in the United States are required to register their facilities with FDA, unless an exception applies (see 21 CFR 1.226 and 1.227). The term "facility" is described in section 415(c)(1) of the FD&C Act and defined by regulation in 21 CFR 1.227(b)(2). Facilities that do not have to register are listed in 21 CFR 1.226. Certain other establishments are not required to register because they do not manufacture, process, pack, or hold "food," as defined in 21 CFR 1.227(b)(4). This definition for "food" excludes food contact substances (including packaging materials), as defined in section 409(h)(6) of the FD&C Act (21 U.S.C. 348(h)(6)), and pesticides as defined in 7 U.S.C. 136(u). Thus, facilities that manufacture, process, pack, or hold only food contact substances or only pesticides are not required to register with FDA under section 415 of the FD&C Act.

A domestic facility means any facility located in any State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico that manufactures, processes, packs, or holds food for consumption in the United States (21 CFR 1.227(b)(2)(i)). A domestic food facility that is required to register must register whether or not food from that facility enters interstate commerce (21 CFR 1.225(b)). A foreign facility means a facility other than a domestic facility that manufactures, processes, packs, or holds food for consumption in the United States (21 CFR 1.227(b)(2)(ii)). Only facilities - domestic and foreign - that manufacture, process, pack or hold food for consumption in the United States are required to register with FDA under section 415 of the FD&C Act.

Under section 415(a)(2) of the FD&C Act, the registrant for a facility must notify FDA in a timely manner of changes to the facility's registration information. The failure to register a food facility in accordance with section 415 is a prohibited act under section 301(dd) of the FD&C Act (21 U.S.C. 331(dd)).

The FDA Food Safety Modernization Act (FSMA) (Pub. L. 111-353), enacted on January 4, 2011, amended section 415 of the FD&C Act in relevant part to require registrants for food facilities to submit additional registration information to FDA, including the email address of the contact person for a domestic facility, the email address of the U.S. agent for a foreign facility, and an assurance that FDA will be permitted to inspect the facility at the times and in the manner permitted by the FD&C Act. FSMA also amended section 415 of the FD&C Act to require food facilities to renew registrations with FDA biennially, and to provide FDA with the authority to suspend the registration of a food facility in certain circumstances, as discussed further below. Further, FSMA amended section 801(l)(1) of the FD&C Act (21 U.S.C. 381(l)) to provide that if an article of food being imported or offered for import into the United States is from a foreign facility for which a registration has not been submitted to FDA, as required by section 415 of the FD&C Act, or is from a foreign facility for which a registration has been suspended under section 415, the article must be held at the port of entry for the article, and may not be delivered to the importer, owner, or consignee of the article, until the foreign facility is registered. Unlike the requirements related to a drug or device establishment, which provide that the failure of such an establishment to register with FDA, as required under section 510 of the FD&C Act (21

U.S.C. 360), causes the drugs or devices manufactured, prepared, propagated, compounded, or processed in such an establishment to be misbranded under section 502(o) of the FD&C Act (21 U.S.C. 352 (o)), and therefore subject such misbranded drugs and devices to refusal of admission under section 801(a) of the FD&C Act, the failure of a food facility to register with FDA, or the suspension of a food facility's registration, alone does not cause food manufactured, processed, packed, or held in such facility to be misbranded under the FD&C Act.

FDA's guidance "What You Need to Know About Registration of Food Facilities" provides information on how to submit registration for a food facility, including electronic registration, at www.access.fda.gov.

Biennial Registration Renewal

Section 415(a)(3) of the FD&C act, as amended by FSMA, requires food facilities required to register with FDA to renew such registrations biennially. Specifically, section 415(a)(3) requires that, during the period beginning on October 1 and ending on December 31 of each even-numbered year, a food facility that has submitted a registration to FDA must submit to FDA a renewal registration that contains the required information specified in section 415(a)(2). A registrant that has not had any changes to the previously submitted registration information may use an abbreviated registration renewal process provided by FDA. A food facility that fails to renew its registration with FDA, as required by section 415(a)(3), has failed to register in accordance with section 415 and thereby has committed a prohibited act under section 301(dd) of the FD&C Act. However, there was a delay in FDA's implementation of biennial registration renewal for the 2012 cycle, and registration renewal did not become available until October 22, 2012. FDA has provided guidance on its plans regarding the delay in the implementation of biennial registration renewal for the 2012 cycle in another food facility registration guidance entitled Guidance for Industry: Questions and Answers Regarding Food Facility Registration (Fifth Edition), available at www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/FoodDefense/ucm331959.htm.

Suspension of Registration

Section 415(b) of the FD&C Act, as amended by FSMA, provides that FDA may suspend the registration of a food facility in certain circumstances. Specifically, if FDA determines that food manufactured, processed, packed, received, or held by a registered facility has a reasonable probability of causing serious adverse health consequences or death to humans or animals, FDA may by order suspend the registration of a facility that:

1. Created, caused, or was otherwise responsible for such reasonable probability; or
2. Knew of, or had reason to know of, such reasonable probability; and packed, received, or held such food.

Under section 415(b)(4) of the FD&C Act, as amended by FSMA, if the registration of a human or animal food facility is suspended, no person can import or export, or offer to import or export, food from the facility into the United States, or otherwise introduce food from the facility into interstate or intrastate commerce in the United States while the suspension order for the facility is in effect. Under section 301(d) of the FD&C Act (21 U.S.C. 331(d)), the introduction or delivery for introduction into interstate commerce of an article of food in violation of section 415 is a prohibited act. Section 801(l) of the FD&C Act, as amended by FSMA, provides, in relevant part, that an article of food being imported or offered for import into the United States that is from a foreign facility for which a registration has been suspended under section 415 must be held at the port of entry for the article of food, and may not be delivered to the importer, owner, or consignee of the article.

III. Policy:

Food Facility Registration

FDA will enforce the registration requirements of section 415 of the FD&C Act and implementing regulations in 21 CFR Part 1, Subpart H as appropriate in each situation. The failure to register a food facility in accordance with section 415 is a prohibited act under section 301(dd) of the FD&C Act. FDA may consider a facility to not be registered in accordance with section 415 if: (1) the facility has not submitted a registration to FDA; (2) the facility's registration is incomplete; or (3) the facility's registration has expired because the facility failed to renew is registration.

FDA's prior notice for imported foods system is the agency's primary tool for ensuring that foreign facilities that offer food for import into the United States are registered under section 415 of the FD&C Act. (See 21 CFR 1.285 and CPG Sec. 110.310 Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness Response Act of 2002). If FDA determines that a foreign food facility is not registered in accordance with section 415 and 21 CFR Part 1, Subpart H, FDA will hold the food being imported or offered for import into the United States from the foreign facility at the port of entry (as defined in 19 CFR 101.1), in accordance with section 801(l) of the FD&C Act, unless U.S. Customs Border Protection (CBP) concurrence is obtained for the export of the food and the food is immediately exported from the port of arrival (as defined in 21 CFR 1.276(b)(11) (see 21 CFR 1.285(b)). FDA will not permit the food to be delivered to the importer, owner, or consignee until the foreign facility is registered in accordance with section 415 and 21 CFR Part 1, Subpart H, and the appropriate registration number is provided in prior notice as specified in 21 CFR 1.285(i). FDA may allow the food held at the port of entry to be moved to a secure facility, as appropriate (21 CFR 1.285(c)(2)). However, FDA ordinarily will not allow the food to be transferred by any person from the port of entry into the U.S. or from the secure facility.

Biennial Registration Renewal

FDA will consider a registration for a food facility to be expired if the registration is not renewed, as required by section 415(a)(3) of the FD&C Act. Thus, if a food facility that previously submitted a registration to FDA does not submit a registration renewal to FDA during the period beginning on October 1 and ending on December 31 of each even-numbered year, FDA will consider the registration for the facility to be expired, and will notify the registrant for the facility that the facility's registration has expired. FDA will consider a food facility with an expired registration to have failed to register in accordance with section 415. As previously stated in this document, the failure of a food facility to renew its registration with FDA, as required by section 415(a)(3), means that the facility has failed to register in accordance with section 415 of the FD&C Act. The failure to register a food facility in accordance with section 415 is a prohibited act under section 301(dd) of the FD&C Act.

Suspension of Registration

Under section 415(b)(4) of the FD&C Act, if the registration of a food facility is suspended, no person can import or export, or offer to import or export, food from the facility into the United States, or otherwise introduce food from the facility into interstate or intrastate commerce in the United States while the suspension order for the facility is in effect. The introduction or delivery for introduction into interstate commerce of an article of food in violation of section 415 is a prohibited act under section 301(d) of the FD&C Act.

If a domestic facility that is subject to a registration suspension order introduces food from such facility into intrastate or interstate commerce, FDA may pursue enforcement action, such as administrative detention, seizure, injunction, mandatory recall, prosecution, or a combination of such actions, as appropriate, provided that the applicable legal requirements are satisfied.

If FDA determines that a food being imported or offered for import into the United States is from a foreign food facility with a suspended registration, FDA will hold the food at the port of entry according to section 801(l) of the FD&C Act.

IV. Regulatory Action Guidance:

Food Facility Registration

The owner, operator, or agent in charge of a domestic facility, as defined in 21 CFR 1.227(b)(2)(i), must register the facility with FDA, unless exempted, as provided in 21 CFR 1.226, whether or not food from the facility enters interstate commerce. FDA anticipates that it, or a State agency acting on behalf of FDA, may discover a domestic facility's failure to be

registered during a routine inspection of the facility. During an inspection, the investigator should determine whether a facility is registered and whether information in the registration is accurate and current. If the investigator identifies a registration violation, the investigator should advise the facility's management of the requirement to register or the requirement to update mandatory elements of the registration. The investigator should also provide the management with FDA's guidance, "What You Need to Know About Registration of Food Facilities." The investigator should document in the establishment inspection report the information obtained regarding the facility's registration. The investigator also should document information provided to the management of the unregistered facility regarding the registration requirements of section 415 of the FD&C Act.

The Districts have direct reference authority to issue an Untitled Letter to a domestic food facility and the Centers (CFSAN or CVM, as appropriate) may issue an Untitled Letter to a foreign food facility when the facility is required to register under section 415 of the FD&C Act, the facility has not registered, and the following conditions apply:

- The facility manufactures, processes, packs, or holds food for human or animal consumption in the U.S. and it is clear that the facility is not exempt from the registration requirement;
- The establishment file documents that management at the facility have been advised orally or in writing of the duty of the owner, operator, or agent in charge to register the facility; and
- The authoring office has verified that the facility is not registered.

CFSAN or CVM, as appropriate, should advise the Division of Food Defense Targeting (DFDT), formerly known as the Prior Notice Center, when a foreign facility has not registered with FDA in accordance with section 415. The DFDT should add applicable prior notice targeting criteria into OASIS/MARCS to identify food articles offered for import into the U.S. from a foreign facility that is not registered with FDA in accordance with section 415. Articles of food from the foreign facility for which a registration has not been submitted to FDA in accordance with section 415 should be held at the port of entry pursuant to section 801(l) of the FD&C Act.

Biennial Registration Renewal

CFSAN, Office of Compliance, or CVM, Office Of Surveillance and Compliance, as appropriate, may notify a facility that has not submitted a registration renewal to FDA, as required by section 415(a)(3) of the FD&C Act, of the requirement for biennial registration renewal.

Suspension of Registration

The District or appropriate Center may recommend suspension of registration for a human or

animal food facility based on evidence that food manufactured, processed, packed, received, or held by the facility has a reasonable probability of causing serious adverse health consequences or death to humans or animals and the facility:

1. Created, caused, or was otherwise responsible for such reasonable probability; or
2. Knew of, or had reason to know of, such reasonable probability; and packed, received, or held such food. (See section 415(b) of the FD&C Act).

Suspension of a food facility's registration may be considered whenever the criteria for suspension in section 415(b) of the FD&C Act are met. Examples of circumstances in which the District or Center should give priority consideration to recommending suspension of a food facility's registration include, but are not limited to, the following:

1. Inspectional or other evidence (e.g., evidence of Class 1 recall situation or evidence of food associated with foodborne illnesses) indicates that the firm has significant violations of the FD&C Act and has not permanently corrected the source of the problem.
2. The firm is subject to a prehearing order to cease distribution and give notice under FDA's mandatory recall authority, section 423(b) of the FD&C Act (21 U.S.C. 350l(b)).
3. The firm is subject to an emergency permit order under 21 CFR Part 108 or an emergency permit recommendation is being considered.
4. The firm is a foreign facility and food from the firm is subject to an Import Alert that provides for detention without physical examination because the food may cause serious adverse health consequences or death to humans or animals.

Under section 415(b)(4) of the FD&C Act, if the registration of a food facility is suspended, no person can import or export, or offer to import or export, food from the facility into the United States, or otherwise introduce food from the facility into interstate or intrastate commerce in the United States while the suspension order for the facility is in effect. The introduction or delivery for introduction into interstate commerce of any article of food in violation of section 415 is a prohibited act under section 301(d) of the FD&C Act. While a registration suspension order is in effect for a domestic facility, the District in which the facility is located should take appropriate actions to ensure that food from the facility is not introduced into interstate or intrastate commerce in the United States.

CFSAN or CVM, as appropriate, should advise the DFDT when a registration suspension order is issued to a foreign facility. The DFDT should add applicable prior notice targeting criteria into OASIS/MARCS to identify food articles offered for import into the U.S. from the foreign facility. While the registration suspension order is in effect, FDA can hold articles of food from the foreign facility at the port of entry pursuant to section 801(l) of the FD&C Act.*

Material between asterisks is new or revised

Issued: 12/2003
Revised: 11/2004, 8/2006, [insert date]