

*Contains Nonbinding Recommendations*

# **Guidance for Industry: Questions and Answers Regarding Food Facility Registration (Sixth Edition)**

**Contains Nonbinding Recommendations**

You may submit written comments regarding this guidance at any time. Submit comments on the guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.regulations.gov>. All comments should be identified with the docket number listed in the notification that publishes in the *Federal Register*.

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

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## Guidance for Industry Questions and Answers Regarding Food Facility Registration (Sixth Edition)

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the telephone number listed on the title page of this guidance.

### I. INTRODUCTION

On October 10, 2003, FDA issued an interim final rule to implement amendments to the Federal Food, Drug, and Cosmetic Act (FD&C Act) made by the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act) (Pub. L. 107-188). Section 415 of the FD&C Act (21 U.S.C. 350d) requires domestic and foreign facilities that manufacture, process, pack, or hold food for human or animal consumption in the U.S. to register

with FDA by December 12, 2003. This guidance was developed to answer frequently asked questions relating to the registration requirements of section 415.

The FDA Food Safety Modernization Act (FSMA) (Pub. L. 111-353), enacted on January 4, 2011, amended the food facility registration requirements in section 415 of the FD&C Act.

The first edition of this document was issued as Level 2 guidance pursuant to 21 CFR 10.115 and was made available on FDA's website on December 4, 2003. The second, third, fourth, and fifth editions of this document were issued as Level 1 guidance documents pursuant to 21 CFR 10.115 and were made available on FDA's website on January 12, 2004, February 17, 2004, August 2004, and December 2012, respectively. This revision (Sixth Edition) is being issued as Level 1 guidance and includes one additional question and answer relating to a proposed change to the farm definition in the supplemental notice of proposed rulemaking for preventive controls for human food (79 FR 58524 (Sept. 29, 2014)). The new question and answer is identified with the date that it was added to the guidance. This guidance is immediately effective because FDA has determined that prior public participation is not feasible or appropriate.

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.

## **QUESTIONS AND ANSWERS**

### **A. Amendments to Section 415 of the FD&C Act Made by Section 102 of FSMA**

#### **1. General Questions**

##### **1.1 Q: What Amendments are in Section 415 of the FD&C Act?**

##### **A: FSMA amended section 415 of the FD&C Act as follows:**

- Provides authority for FDA to require registration to be submitted in an electronic format. This authority does not take effect until 5 years from the date of enactment of FSMA (i.e., January 4, 2016).
- Requires biennial renewal of food facility registrations.
- Provides for an abbreviated biennial renewal process for facilities without information changes.
- Requires registrant to include in registration the e-mail address for the contact person of the facility. Or, for a foreign facility, the registration must include the e-mail address of the U.S. agent for the facility.
- Provides authority for FDA to determine and identify appropriate additional food categories to be included in the registration.
- Requires the registration to include an assurance that FDA will be permitted to inspect the facility.

- Amends the definition of “retail food establishment.”
- Defines “community supported agriculture program.”
- Clarifies that the term “consumer” does not include a business.
- Provides for FDA to suspend a food facility’s registration.
- Provides that food offered for import from a foreign facility with a suspended registration can be held at the port of arrival.
- Requires FDA to promulgate regulations to implement changes to section 415 regarding suspension of food facility registrations.

**1.2 Q: Has the scope of who is required to register under section 415 of the FD&C Act changed?**

**A:** No. At this time, the same type of food facilities that were required to register with FDA under section 415 of the FD&C Act before FSMA are required to register with FDA and renew such registrations every other year. Those facilities are domestic and foreign facilities that manufacture, process, pack, or hold food for human or animal consumption in the United States (21 CFR 1.225). For purposes of section 415, the term “facility” in relevant part does not include farms, restaurants, and retail food establishments (section 415(c)(1) of the FD&C Act; 21 CFR 1.226).

**1.3 Q: [Added November 2014] Under the supplemental notice of proposed rulemaking for preventive controls for human food, FDA has proposed changing the farm definition for registration and other purposes. Under the proposed change, a farm would no longer be required to register as a food facility solely because it packs or holds raw agricultural commodities grown on a farm under different ownership. While the rulemaking is still ongoing, what is FDA’s policy regarding farms that also pack or hold raw agricultural commodities grown on a farm under different ownership?**

**A:** FDA does not intend to prioritize enforcing the registration requirement in this circumstance.

**2.1 Q: How can registration be submitted?**

**A:** The owner, operator, or agent in charge of the facility, or a person authorized by one of them, can submit a facility's registration electronically at <http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/RegistrationofFoodFacilities/default.htm>. You may also use the electronic system to update your registration information or submit a cancellation (e.g., due to change in ownership or going out of business).

Alternatively, if you do not have reasonable access to the Internet, you may use a paper process. You may use paper Form FDA 3537 to register your facility, renew, and to update your registration information. You may send your registration or an update by fax or mail. For updates, you also may send the information by fax or mail on your company’s letterhead. You should include your registration number in the update communication.

Form FDA 3537 is available for download at

<http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/RegistrationofFoodFacilities/ucm073728.htm>.

You can request the paper forms and submit completed forms by fax to 301-436-2804 or by mail to:

U.S. Food and Drug Administration

Food Facility Registration (HFS-681)

5100 Paint Branch Pkwy

College Park, MD 20740.

You also may request the paper forms by phone at 1-800-216-7331 or 301-575-0156.

FDA currently also provides for submission of registration information on CD-ROM. Additional information relating to CD-ROM submissions is available at <http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/RegistrationofFoodFacilities/ucm073728.htm#cd>. You also may obtain information relating to CD-ROM submissions by fax, phone, or mail, as provided in the previous paragraph.

## **2.2 Q: Does FDA require registration to be submitted in an electronic format?**

**A:** No. Registration by a paper system is currently available. In the future, FDA may require registration, including the initial registration, biennial registration renewals, updates, and cancellations, to be submitted in an electronic format. The requirement for the electronic format can not take effect before January 4, 2016. Registrations can continue to be submitted using the paper process, as explained in Question 2.1 in this guidance, until the effective date of an electronic format requirement. However, FDA encourages use of the electronic format at this time because it is more efficient, provides for immediate submission of the registration information, and provides for immediate issuance of the registration number.

## **3. Biennial Registration Renewal**

### **3.1 Q: When does a facility that is required to register with FDA need to submit a registration renewal to FDA?**

**A:** Section 415(a)(3) of the FD&C Act requires facilities that are required to register with FDA to renew their registrations every other year, during the period beginning on October 1 and ending on December 31 of each even-numbered year.

As discussed in Question 28.1, the failure of a food facility to renew its registration with FDA, as required by section 415(a)(3) of the FD&C Act, means that a facility has failed to register in accordance with section 415. 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)). Because 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 intends to exercise enforcement discretion with respect to registration renewals submitted to FDA after December 31, 2012 for a period of 31 days, until January 31, 2013.

**3.2 Q: For the biennial registration renewal, must a facility resubmit all of the registration information?**

**A:** FDA will provide an abbreviated biennial renewal process for facilities without information changes. Facilities that need to make changes to the registration information must submit the changes, as explained in Question 2.1 in this guidance. For the first biennial registration renewal, all facilities that are required to register will need to resubmit their registration to include new registration information required by FSMA.

**4. FSMA Changes to Information Required to be Submitted**

**4.1 Q: Did FSMA change the information required to be submitted in the food facility registration?**

**A:** Yes. FSMA amended section 415(a)(2) of the FD&C Act to require the registrant to provide the following:

- The e-mail address for the contact person of the facility or, in the case of a foreign facility, the e-mail address of the U.S. agent for the facility;
- Appropriate additional food categories (as determined by FDA) of any food manufactured, processed, packed, or held at the 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.

See Question 23.1 in this guidance for additional information on the required information that must be submitted in a food facility registration.

**5. FSMA's Clarification of Retail Food Establishment**

**5.1 Q: How did FSMA clarify the definition of "retail food establishment?"**

**A:** FSMA requires FDA to amend the definition of the term "retail food establishment" in 21 CFR 1.227(b) to clarify that, in determining the primary function of an establishment or a retail food establishment, the sale of food products directly to consumers by such establishment and the sale of food directly to consumers by such retail food establishment include:

- The sale of such food products or food directly to consumers by such establishment at a roadside stand or farmers' market where such stand or market is located other than where the food was manufactured or processed;

- The sale and distribution of such food through a community supported agriculture program; and
- The sale and distribution of such food at any other such direct sales platform as determined by FDA.

**5.2 Q: What does “community supported agriculture program” mean for purposes of the “retail food establishment” definition?**

**A:** The term “community supported agriculture program,” which is used in the definition of “retail food establishment,” means a program under which a farmer or group of farmers grows food for a group of shareholders (or subscribers) who pledge to buy a portion of the farmer's crop(s) for that season. State agencies may purchase shares or subscribe to a community supported agriculture program on behalf of individual Senior Farmers’ Market Nutrition Program (SFMNP) participants (7 CFR 249.2).

**6. Suspension of Registration**

**6.1 Q: Can FDA suspend the registration of a food facility?**

**A:** Yes. Section 415(b) of the FD&C Act, as amended by FSMA, provides FDA the authority to suspend by order the registration of a facility registered under section 415.

**6.2 Q: When can FDA suspend the registration of a facility registered under section 415 of the FD&C Act?**

**A:** FDA can order suspension of a food facility’s registration when:

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

**6.3 Q: When are registered food facilities subject to the suspension of registration provisions of section 415 of the FD&C Act?**

**A:** Registered facilities became subject to the suspension of registration provisions in section 415(b) of the FD&C Act on July 3, 2011, which was 180 days after the January 4, 2011 enactment of FSMA (section 415(b)(6)(B) of the FD&C Act).

**6.4 Q: What is the effect of an order to suspend a food facility’s registration?**

**A:** If the registration of a food facility is suspended, no person can import or export food into the U.S., offer to import or export food into the U.S., or otherwise introduce food into interstate or intrastate commerce in the U.S. from such facility (section 415(b)(4) of the FD&C Act).

**6.5 Q: Who may issue an order to suspend a food facility's registration?**

**A:** The authority to issue an order to suspend a registration or to vacate an order of suspension may not be delegated by the Secretary of Health and Human Services to any officer or employee other than the FDA Commissioner (section 415(b)(7) of the FD&C Act).

**6.6 Q: Does the registrant have an opportunity for a hearing on a registration suspension?**

**A:** FDA will provide the registrant subject to a suspension order with an opportunity for an informal hearing. The hearing must be held as soon as possible but not later than two business days after the issuance of the suspension order or at such other time period as agreed upon by FDA and the registrant. The registrant will have an opportunity for an informal hearing on actions required for reinstatement of registration and why the registration that is subject to suspension should be reinstated. FDA shall reinstate a registration if it determines, based on evidence presented, that adequate grounds do not exist to continue the suspension of the registration (section 415(b)(4) of the FD&C Act).

**6.7 Q: What happens if FDA determines that the suspension of registration remains necessary after providing opportunity for an informal hearing?**

**A:** FDA will require the registrant to submit a corrective action plan to demonstrate how the registrant plans to correct the conditions found by FDA (section 415(b)(3)(A) of the FD&C Act).

**6.8 Q: When may a registration suspension order be vacated?**

**A:** FDA (the Commissioner) will vacate the suspension order and reinstate the registration of the facility subject to the order upon a determination that adequate grounds do not exist to continue the suspension actions required by the order (section 415(b)(3)(B) of the FD&C Act).

**6.9 Q: Will FDA promulgate regulations on suspension of registration?**

**A:** Section 415(b)(5)(A) of the FD&C Act requires FDA to promulgate regulations to implement the suspension of registration provisions. FSMA provides that FDA may promulgate the regulations on an interim final basis. However, FDA's authority to suspend a food facility's registration under section 415(b) became effective on July 3, 2011. Thus, registered facilities are currently subject to the suspension of registration provisions of section 415.

**7. Updating Food Categories (Reserved)**

**B. Who Must Register and When Must You Register?**

**8. General Questions**



**8.1 Q:** Who must register under the food facility registration requirements?

A: If you are the owner, operator, or agent in charge of either a domestic or foreign facility that is engaged in manufacturing/processing, packing, or holding of food for human or animal consumption in the U.S., you must register with FDA, unless you are exempt under 21 CFR 1.226 from the requirements to register. If you are an owner, operator, or agent in charge of a domestic facility, you must register your facility whether or not the food from the facility enters interstate commerce. If you are the owner, operator, or agent in charge of a facility, you may authorize an individual to register your facility on your behalf (21 CFR 1.225 and 1.227(b)(2)). A foreign facility's U.S. agent may, but is not required to, register the facility (21 CFR 1.230).

**8.2 Q:** When must you register initially under the food facility registration requirements?

A: If you are required to register with FDA, you must register before your facility begins manufacturing/processing, packing, or holding operations.

**C. Who is Exempt from Registration?**

**9. Farms:**

**9.1 Q: Is an establishment that manufactures/processes and sells seed to farmers a facility that is required to be registered if the seed is intended to be used as animal food? What if the seed is for cultivation?**

A: FDA requires registration of any facility that manufactures/processes, packs, or holds food for consumption in the U.S. "Food" is defined in section 201(f) of the FD&C Act (21 U.S.C. 321(f)) to include articles used for food or drink for man or other animals. The establishment that manufactures/processes and sells seed to farmers is a facility that must be registered if the owner, operator, or agent in charge of the establishment reasonably believes that the seed is reasonably expected to be directed to a food use, including animal food use or as an ingredient in animal food. However, if the seed is reasonably expected only to be cultivated, the establishment is not required to be registered. (See Comment 62 in the preamble to the Interim Final Rule).

**9.2 Q: Is a farm that grows tomatoes and sells them directly to consumers from a roadside stand located on the farm exempt from registration?**

A: Yes. Assuming that the farm on which the tomatoes are grown otherwise satisfies the definition of farm (21 CFR 1.227(b)(3)), it is exempt from registration. If the primary activity of the roadside stand is selling food (including the tomatoes) directly to consumers, it is exempt as a retail food establishment (21 CFR 1.227(b)(11)).

**9.3 Q: If a farm located in a foreign country ships food directly to the U.S., is it required to register?**

A: No. A "farm" located in a foreign country that ships food directly to the U.S. is exempt from the registration requirements of section 415 of the FD&C Act ((21 U.S.C. 350d; 21 CFR

1.227(b)(3)). However, if prior to shipping to the U.S., the “farm” ships the food to a foreign facility that manufactures/processes, packs, or holds the food, the second facility must register unless the food subsequently undergoes further manufacturing/processing of more than a *de minimis* nature at another foreign facility (21 CFR 1.226(a)). The *de minimis* provision (21 CFR 1.226) is discussed further in Questions 18.1 and 18.2 in this guidance and in the preamble to the Interim Final Rule (Comments 17, 21, 25, and 26).

**9.4 Q: Is a mixed-type facility, such as a farm that grows oranges and processes them into orange juice for sale to a distributor, required to register?**

**A:** Yes. FDA uses the term "mixed-type facility" in the preamble to the Interim Final Rule (response to Comment 46) to refer to an establishment that engages in both activities that are exempt from registration and activities that require the establishment to be registered. In this example, the farm is required to be registered because its processing activities are not covered by the farm definition (21 CFR 1.227(b)(3)).

**9.5 Q: Is applying pesticides on a farm considered a "traditional farming activity" within the scope of the farm definition and exemption? Does this include applying a pesticide, for example, on bananas in the field or in the packing station just prior to packing?**

**A:** Whether the application of a pesticide to a crop is an activity covered by the “farm” definition depends upon whether the application is prior to or post-harvest. A “farm” is "a facility in one general location devoted to the growing and harvesting of crops, the raising of animals (including seafood), or both" (21 CFR 1.227(b)). FDA considers application of pesticides to a crop prior to harvest as an integral part of growing crops. Such application generally does not involve close manipulation of the food being grown because the application is usually directed at the entire plant. Therefore, an establishment devoted to the growing and harvesting of crops that applies a pesticide to its crops in the field prior to harvest is a "farm" that is exempt from the registration requirements. However, post-harvest application is necessarily directed at the food, not the growing plant or crop in the field, and, thus, is considered to be manufacturing/processing under 21 CFR 1.227(b). Therefore, a farm that treats a crop against pests post-harvest, e.g., applies a pesticide to bananas in the packing station just prior to packing, must register with FDA unless all of the treated food is consumed on that farm or another farm under the same ownership (21 CFR 1.227(b)(3)(ii)).

**9.6 Q: Is use of chlorinated water to wash lettuce on a farm considered "processing," necessitating registration of the farm?**

**A:** If the farm is using water directly from a public or other water supply that is chlorinated for other purposes, FDA will consider this activity "washing" within the meaning of 21 CFR 1.227(b)(3). Accordingly, an establishment using chlorinated water in this manner is a "farm" and is not required to be registered. In addition, FDA's Good Agricultural Practices guidance document (section 2.2; <http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/ProduceandPlanProducts/ucm064574.htm>) notes that chlorine is commonly added to water at 50-200 parts per million

(ppm) total chlorine, at a pH of 6.0 -7.5, for post harvest treatment of fresh produce, with a contact time of 1-2 minutes. FDA recognizes that chlorination at these levels is the only way many growers and packers can raise the microbiological quality of the water they use to a level that is safe and suitable. Addition of chlorine to water at these levels, therefore, does not constitute "manufacturing/processing" within the meaning of 21 CFR 1.227(b)(3)(ii). In contrast, if water used as a wash on harvested foods on a farm contains added chlorine above levels of 200 ppm to create a specific wash, FDA considers this activity as "treating" food within the meaning of 21 CFR 1.227(b)(6), which is a manufacturing/processing activity that would require the farm to register, unless it falls under another exemption (e.g., foreign facility exemption in 21 CFR 1.226(a)).

**9.7 Q: Does placing stickers on fruit on a farm amount to "manufacturing/processing" and, therefore, require registration of the facility in which the application of the stickers occurs?**

**A:** A farm that places stickers on fruit is not required to register if all of the fruit on which the stickers are being placed is grown or consumed on that farm or another farm under the same ownership (21 CFR 1.227(b)(3)). Under 21 CFR 1.227(b)(3)(i), FDA considers on-farm facilities that pack or hold food as meeting the "farm" definition, if all food used in such packing or holding is grown, raised, or consumed on that farm or another farm under the same ownership. As stated in the response to Comment 41 in the preamble to the Interim Final Rule, FDA considers certain activities to be "packing," such as sorting, grading, wrapping, or boxing harvested food for the sole purpose of transporting this food off the farm. FDA also considers placing stickers on produce grown or consumed on a farm to be "packing."

**9.8 Q: Produce grown on a farm is picked and trimmed and then sent to be packed at a packing shed that is owned by the same person that owns the farm. The packing shed is not in the same general physical location as the farm. The packaged produce is then shipped by the farmer to a distributor. Does the packing shed have to be registered?**

**A:** Yes. The "farm" definition extends to facilities in the same general physical location as the farm (i.e., on the farm) that pack or hold food, provided all food used in such packing or holding is grown, raised, or consumed on that farm or another farm under the same ownership (21 CFR 1.227(b)(3)(i)). The "farm" definition also extends to facilities located on the farm that manufacture/process food if all food used in such manufacturing/processing is consumed on that farm or another farm under the same ownership (21 CFR 1.227(b)(3)(ii)). Because "farm" is defined in terms of location (i.e., one general physical location), and the packing shed is at a different physical location, the packing shed is not a "farm" and, thus, is not exempt from registration.

**9.9 Q: Does a farm need to be registered if it grows its own produce, harvests it, wraps it, and places it into cartons for the sole purpose of transporting the food off the farm?**

**A:** No. The "farm" definition extends to facilities that pack food, provided that all food used in such activities is grown, raised, or consumed on that farm or another farm under the same ownership (21 CFR 1.227(b)(3)(i)). In the situation described in this question, the farm is packing produce grown on the farm and, thus, meets the definition of "farm."

**9.10 Q: Is a farm required to be registered if the farmer transports workers out to the field on a truck, where the workers pick strawberries from the field and place them into plastic clamshells? The filled clamshells are then transported off the farm.**

**A:** No. The farm in this example is exempt from registration. FDA recognizes that the activity in this example -- placing strawberries directly into consumer-ready packages -- is likely to provide better protection for such fragile produce than placing the produce into a larger bin or box for transport off the farm, with consumer packaging of the produce further down the distribution chain. Two definitions in 21 CFR 1.227 are relevant to the status of the farm in this example: "manufacturing/processing" and "packaging." "Packaging" is an example of "manufacturing/processing" (21 CFR 1.227(b)(6)) and is defined as "placing food into a container that directly contacts the food and that the consumer receives" (21 CFR 1.227(b)(8)). The definition of "packaging" suggests that packing the strawberries into plastic clamshells is manufacturing/processing because the strawberries directly contact the clamshell and consumers receive the berries in the clamshell. FDA believes, however, that the definition of "packaging" must be read in the context of the definition of "manufacturing/processing." "Manufacturing/processing" is defined as "making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food, including food crops or ingredients." Thus, a manufacturing/processing activity, including packaging, must involve some sort of change to or manipulation of the food. Thus, simply placing produce into containers (such as clamshells, baskets, mesh bags, or plastic bags) without altering or manipulating the food is more akin to packing, even if the containers are ultimately received by the consumer. Under 21 CFR 1.227(b)(3)(i), the term "farm" includes facilities that pack food, provided that all of the packed food is grown on that farm or another farm under the same ownership. Accordingly, a farm that simply places a raw agricultural commodity into containers such as clamshells is not "manufacturing/processing" and thus, "packing," rather than "packaging" the food. The truck that transports the workers and the filled containers off the farm is not a facility that is required to be registered because it is holding the food only in its usual course of business as a carrier 21 CFR 1.227(b)(2)).

**9.11 Q: As vegetables are harvested on some farms, after field trimming and washing, the harvested product is transferred to a truck mounted operation in the field where it is placed in a consumer package and cooled. The mobile unit is not permanently located at the farm, but moves from farm to farm for the same operation. The packaged product is then transferred to a truck for movement off-farm. Does the farm or truck mounted packaging/processing unit, or both, need to be registered with FDA?**

**A:** Neither the truck nor the farm is required to be registered. A mobile facility located on a farm conducting an operation that results in the packaging of the food must be registered. As noted in the answer to Question 9.10, "packaging" is an example of "manufacturing/processing," which is defined in 21 CFR 1.227(b)(8) as involving some modification or manipulation of the food, and simply placing produce into containers (such as clamshells, baskets, mesh bags, or plastic bags) without altering or manipulating food is more akin to packing, even if the containers are ultimately received by the consumer. A truck mounted operation that does not include modifying or manipulating the food is not manufacturing/processing within the meaning of 21 CFR 1.227(b)(6) and, thus, the truck is not required to be registered.

**9.12 Q: Is a truck-mounted operation under separate ownership from the farm required to register if it cuts produce grown on the farm (e.g., chops carrots) and places them into consumer-ready bags before transporting them off the farm? If the truck-mounted operation is required to register, what address should it use?**

**A:** The truck-mounted operation in this scenario is a mobile facility (21 CFR 1.227(b)(2)). The mobile facility is required to register since it is performing a manufacturing/processing activity and does not meet the definition of “farm.” The mobile facility and the farm are separately owned and, thus, are not the same establishment. When registering, the owner, operator, or agent in charge of the mobile facility must provide FDA with sufficient information to enable FDA to contact the facility, when warranted. A fixed address for the owner, operator, or agent in charge of the mobile facility may be used. Addresses of mobile facilities are discussed in the preamble to the Interim Final Rule (Comment 38).

**9.13 Q: Is a truck-mounted operation required to register if it travels from one vineyard to another and bottles wine made from grapes grown and processed into wine at the vineyard?**

**A:** Yes, a truck-mounted operation that travels from one vineyard to another and bottles wine is a mobile facility that must be registered. Bottling wine is “packaging,” which is an activity included in the definition of “manufacturing/processing” (21 CFR 1.227(b)(6) and (b)(8)). “Manufacturing/processing” is defined as “making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food, including food crops or ingredients.” To constitute “manufacturing/processing,” an activity, including “packaging,” must involve some sort of change to or manipulation of the food. Placing wine into bottles involves manipulation of the wine because it is preserving the manufactured condition of the wine by vacuum-sealing it and corking it. Thus, the truck-mounted operation that bottles wine is a facility that is required to be registered.

**9.14 Q: Are maple syrup producers “farms” and, thus, exempt from registering?**

**A:** The response to this question depends upon the activities of the maple syrup producer. The activities of maple syrup producers customarily consist of two types: gathering sap from sugar maple trees and concentrating the sap through the application of heat to make syrup. Gathering sap is “harvesting,” which is included in the definition of farm (21 CFR 1.227(b)). The “farm” is exempt from registration. However, concentrating sugar maple sap by heating is a form of manufacturing/processing (21 CFR 1.227(b)). Accordingly, a facility that concentrates sugar maple sap is performing a manufacturing/processing activity and is required to be registered, unless all of the concentrated sap is consumed on the farm or another farm under the same ownership.

**9.15 Q: Does a farm need to be registered if it grows a crop, harvests it, and holds it for a period of time before shipping it to a distributor or manufacturer/processor?**

**A:** No. The “farm” definition extends to facilities that hold food, provided that all food used in such activities is grown, raised, or consumed on that farm or another farm under the same

ownership (21 CFR 1.227(b)(3)(i)). In the situation described in this question, the farm meets this definition.

**9.16 Q: If a farm grows hay and sells the hay as feed to a dairy farm that is not under the same ownership, does the hay farm need to be registered? Does the dairy farm need to be registered?**

**A:** As described in the question, both facilities are "farms," as defined in 21 CFR 1.227(b)(3). Thus, they are not required to be registered.

**9.17 Q: A farmer sells his potato crop to a processor and the processor takes ownership but does not harvest the potatoes immediately. The processor in effect stores the potatoes in the ground and removes them when ready to process. Must the processor register the farm as a storage warehouse facility?**

**A:** Assuming that the potato processor takes ownership of only the potato crop, and not the land on which the potatoes are located, the farm does not lose its farm exemption merely because the potato processor takes ownership of the potatoes before harvesting them. The farm definition extends to facilities located on a farm that hold food if all the food that is held is grown, raised, or consumed on that farm or another farm under the same ownership (21 CFR 1.227(b)(3)(i)).

**9.18 Q: A peppermint farmer harvests his crops by cutting, trimming, and washing the leaves, and then places the harvested crop in a barn to allow it to dehydrate. The entire crop is sold to a manufacturer. Does the process of dehydrating constitute manufacturing/processing, thus necessitating registration for this farm?**

**A:** The examples in the definition of "manufacturing/processing" in 21 CFR 1.227(b) do not include dehydrating. Moreover, the dehydration occurs while the peppermint grown on the farm is being held in the barn on the farm under conditions that allow for dehydration. Thus, FDA considers that this satisfies the definition of "farm" in 21 CFR 1.227(b). The farm is not required to be registered.

## **10. Retail Food Establishments:**

**10.1 Q: Does a warehouse club that sells to both consumers and businesses need to be registered?**

**A:** A warehouse club is exempt from registration as a retail food establishment if it sells food products directly to consumers as its primary function. A retail food establishment's primary function is to sell food directly to consumers if the annual monetary value of sales of food products directly to consumers exceeds the annual monetary value of sales of food products to all other buyers. Businesses are not considered consumers. Thus, if the annual monetary value of sales of food products directly to businesses exceeds the annual monetary value of sales of food products to consumers, the warehouse club must register (21 CFR 1.227(b)).

**10.2 Q: If a supermarket has a bakery on the premises that bakes bread and sells it to other stores in the same chain, is the supermarket required to be registered?**

**A:** The supermarket is exempt from registration as a retail food establishment (21 CFR 1.227(b)(11)) if its primary function is to sell food products directly to consumers from the supermarket. As explained in Question C.19 in this guidance, a retail food establishment's primary function is to sell food directly to consumers if the annual monetary value of sale of all food products directly to consumers exceeds the annual monetary value of sales of food products to all other buyers.

**10.3 Q: Are retail food establishment storerooms, distribution centers, or warehouses considered "holding facilities" that are required to be registered?**

**A:** If a facility is a "retail food establishment" under 21 CFR 1.226(c) and 1.227(b)(11), storerooms for the retail food establishment that are co-located with, and thus, part of, the retail food establishment, are not required to be registered. However, a distribution center or warehouse that is not at the same general physical location as the retail food establishment does not meet the definition of "retail food establishment" (21 CFR 1.227(b)(11)) because it does not sell food from the facility directly to consumers. Thus, the distribution centers and warehouses are required to be registered.

**10.4 Q: If a retail food reaches its shelf life and is stored at the retail facility pending return to the manufacturing facility, does the retail store become a holding facility that must be registered?**

**A:** No. The retail food establishment does not become a holding facility. This is considered a normal business practice of a retail food establishment.

**10.5 Q: If a bakery primarily sells its food directly to consumers, but 40% of its annual sales are to wholesale facilities, does the bakery have to be registered?**

**A:** No. The bakery is a retail food establishment and does not need to be registered. A "retail food establishment" is exempt from registration if the annual monetary value of sales of food products directly to consumers exceeds the annual monetary value of sales of food products to all other buyers (21 CFR 1.226(c) and 1.227(b)(11)).

**11. Restaurants:**

**11.1 Q: Are central kitchens that prepare food for a chain of restaurants considered to be restaurants and, therefore, exempt from registration?**

**A:** Central kitchens that do not sell the food they prepare directly to consumers for immediate consumption are not "restaurants," as defined in 21 CFR 1.227(b)(10). Thus, they are not exempt, as restaurants, from registration.

**11.2 Q: Are pet shelters, kennels, and veterinary facilities that provide food to animals exempt from registration?**

**A: The definition of “restaurant” includes pet shelters, kennels, and veterinary facilities that provide food to animals (21 CFR 1.227(b)(10)(ii)).**

## **12. Nonprofit Food Facilities:**

**12.1 Q: Are exporters of food for charity exempt from the registration requirements?**

**A: Yes.** A facility, including a non-profit facility, is not required to be registered if all food manufactured/processed, packed, or held at the facility is not for consumption in the U.S. (21 CFR 1.225 and 1.227(b)(7)).

**12.2 Q: Are exporters for food for charity considered to be non-profit establishments that are exempt from the registration requirements?**

**A: Such an exporter is not a "nonprofit food establishment" because it does not prepare or serve food directly to the consumer or otherwise provide food or meals for consumption by humans or animals in the U.S. (21 CFR 1.227(b)(7)). However, if all food held at this facility is exported, the facility is not required to be registered because the food held in the facility is not "food for consumption in the U.S." (21 CFR 1.225(a)).**

**12.3 Q: Does an agricultural feed cooperative that manufactures food for its members and owners and is recognized as a cooperative under U.S. laws have to be registered?**

**A: In general, a cooperative where food is manufactured/processed, packed, or held is required to be registered unless the cooperative is otherwise exempt from registration, e.g., a "nonprofit food establishment" as defined in 21 CFR 1.227(b)(7).**

**12.4 Q: Is an establishment operated by a public or other not-for-profit organization in which food is prepared, such as food for a school lunch program, including the National School Lunch Program (NSLP), or for a food service program, including the Summer Food Service Program (SFSP) and the Child and Adult Care Food Program (CACFP), required to register?**

**A: Establishments such as those identified in the question are exempt from the food facility registration requirements if they are “nonprofit food establishments” (21 CFR 1.226(e)). "Nonprofit food establishment" is defined in 21 CFR 1.227(b)(7) as "a charitable entity that prepares or serves food directly to the consumer or otherwise provides food or meals for consumption by humans or animals in the U.S. The term includes central food banks, soup kitchens, and nonprofit food delivery services. To be considered a nonprofit food establishment, the establishment must meet the terms of section 501(c)(3) of the U.S. Internal Revenue Code (26 U.S.C. 501(c)(3))."**



*Contains Nonbinding Recommendations*

To qualify under 26 U.S.C. 501(c)(3), an entity (such as a corporation, community chest, fund, or foundation) must satisfy the following four criteria: (1) it must be organized and operated exclusively for religious, charitable, or educational purposes (among others); (2) no part of the net earnings of the entity may inure to the benefit of any private individual; (3) no substantial part of the entity's activities may be for the purpose of influencing legislation; and (4) the entity cannot participate in any political campaign of any candidate for public office (26 U.S.C. 501(c)(3)). The requirement in the definition of "nonprofit food establishment" in 21 CFR 1.226(e) to "meet the terms of section 501(c)(3)" means that the institution or organization that runs a food service program under which the establishment operates must satisfy the criteria of 26 U.S.C. 501(c)(3). However, the public institution or organization need not be formally designated as a 26 U.S.C. 501(c)(3) institution or organization.

FDA is aware that certain lunch and food service programs are sponsored by private nonprofit institutions or organizations that have been granted tax-exempt status under 26 U.S.C. 501(c)(3) of the Internal Revenue Code. An establishment operating under a food service program that is conducted by such an institution or organization is exempt from registration under 21 CFR 1.226(e) if, in addition to the institution or organization having 26 U.S.C. 501(c)(3) status, the establishment satisfies the remaining elements of the "nonprofit food establishment" definition in 21 CFR 1.227(b)(7).

FDA is also aware that many food service programs are conducted by public institutions or organizations, such as public school systems, that do not have formal 26 U.S.C. 501(c)(3) status. If a public institution or other organization that runs a food service program satisfies the four 26 U.S.C. 501(c)(3) criteria listed in a previous paragraph in this answer, an establishment operating under a food service program of such an institution or organization is exempt from registration under 21 CFR 1.226(e) if, in addition to the institution or organization satisfying the 26 U.S.C. 501(c)(3) criteria, the establishment satisfies the remaining elements of the "nonprofit food establishment" definition in 21 CFR 1.227(b)(7).

In addition, a "restaurant" (21 CFR 1.227(b)(10)) that is part of a school lunch or other food service program is exempt from registration, regardless of whether it is a "nonprofit food establishment."

Also, a "retail food establishment" (21 CFR 1.227(b)(11)) that is part of a school lunch or other food service program is exempt from registration, regardless of whether it is a "nonprofit food establishment."

### **13. Fishing Vessels**

#### **13.1 Q: Are fishing vessels that catch, head and eviscerate, and then hold fish in cold storage until it can be off-loaded for delivery to a processor required to be registered?**

**A:** Fishing vessels are exempt from registration unless processing is done on board the ship. "Processing," relating to fish and fishery products, means, "Handling, storing, preparing, heading, eviscerating, shucking, freezing, changing into different market forms, manufacturing, preserving, packing, labeling, dockside unloading, or holding." However, a fishing vessel that

engages in harvesting or transporting fish or fishery products, without otherwise engaging in processing, or that engages in practices such as heading, eviscerating, or freezing, intended solely to prepare a fish for holding on board a harvest vessel,” are exempt from registration (21 CFR 1.126(f) and 123.3(k)(2)).

#### **14. Facilities Regulated Exclusively by the United States Department of Agriculture (USDA)**

##### **14.1 Q: Are facilities that process deer, elk, and bison required to register with FDA?**

**A:** Yes. Facilities that process deer, elk, and bison are required to be registered because these foods are under FDA’s jurisdiction and, thus, are not regulated exclusively, throughout the entire facility, by USDA (21 CFR 1.226(g)).

#### **D. Definitions**

##### **15. Facility:**

##### **15.1 Q: If a person has a business in his or her home that involves manufacturing, processing, packing, or holding food, does that person need to register that private residence as a food facility?**

**A:** No. A private residence is not a facility as defined in the Interim Final Rule (21 CFR 1.227(b)(2)). Thus, a private residence that meets customary expectations for a private residence that is also used to manufacture, process, pack, or hold food need not be registered. For examples, if a person uses their home to store food that is to be sold as a school activity or youth organization such as Girl Scouts or prepares food for a bake sale, FDA considers that these activities meet customary expectations for a private residence.

##### **15.2 Q: If a person is selling food from his or her private residence through the Internet, does that person need to register his residence as a food facility?**

**A:** No. A private residence from which a person also sells food through the Internet is not a facility as defined in 21 CFR 1.227(b)(2) and, thus, need not be registered.

##### **15.3 Q: Most sugar makers in Massachusetts operate from their own property, on which their private residence is also located. Are these sugar makers required to register the facility that is on their property and used for sugar production?**

**A:** Under 21 CFR 1.227(b)(2), a private residence is not a "facility" and thus, is not required to be registered. A private residence must meet customary expectations for a private home and does not otherwise include commercial facilities in which a person also happens to reside. A private residence includes the parcel of real property on which the residence is located. Accordingly, if the sugar production occurs in the private home or in a detached building that meets customary expectations for use as part of the private home, such as a detached garage that has not been modified for manufacturing and processing so that it can no longer practically be used as

customary for a garage, the home or building would not have to be registered. If, however, a separate building located on the real property of the private residence site is used as a sugar manufacturing or processing facility and does not have a use as customarily expected for a private residence, that facility must be registered, unless that facility qualifies for another exemption (e.g., as a retail facility; 21 CFR 1.227(b)(11)).

**15.4 Q: Are facilities that import food into the U.S. solely for export from a bonded warehouse required to register? Does the bonded warehouse that holds the food have to be registered?**

**A:** No. Facilities that manufacture/process, pack, or hold food entering the U.S. solely for the purpose of exportation or trans-shipment to another country (i.e., none of the food is for consumption in the U.S.) are not required to be registered. The intent of the regulation is to identify facilities that manufacture/process, pack, or hold food for consumption in the U.S. However, food entering the U.S. solely for future export is subject to the Prior Notice of Imported Food regulation (21 CFR 1.277).

**15.5 Q: A university research facility may sell some of its animals into commercial channels for food use. Does the facility have to be registered?**

**A:** A university research facility that sells live animals for human or animal consumption is required to be registered unless the facility meets one or more of the exemptions from registration in 21 CFR 1.226 (e.g., farm, exclusive regulation by USDA).

**15.6 Q: A company has a physically separate central storage building for holding food prior to use in a restaurant operated by the company. The central storage building is located within the same general area as the restaurant that it supplies (i.e., on the same property as the restaurant). Is the storage building exempt from registration?**

**A:** Facility is defined to include structures under one ownership at one general physical location (21 CFR 1.227(b)(2)). Since the storage building and restaurant are owned by the same company and are located on the same property, the storage building is exempt from registration. However, if the storage building was at a separate location or owned by a different person, it would be a distinct facility that is required to be registered.

## **16. Food:**

**16.1 Q: Are facilities that manufacture/process, pack, or hold fertilizers required to register?**

**A:** Fertilizers are not food for consumption. Thus, facilities that hold fertilizers are not required to be registered.

**16.2 Q: Are pharmaceuticals considered "food" for purposes of the food facility registration requirement?**

**A:** Pharmaceuticals are not "food," as defined in section 201(f) of the FD&C Act (21 U.S.C. 321(f)), because they are not consumed for their taste, aroma, or nutritive value (*Nutrilab v. Schweiker*, 713 F.2d 335, 338 (7th Circ. 1983)). Therefore, facilities that manufacture, process, pack, or hold pharmaceuticals are not required to be registered as food facilities under section 415 of the FD&C Act. However, such facilities may be subject to registration under other statutory provisions. Pharmaceutical manufacturers may wish to consult with the Office of Compliance in FDA's Center for Drug Evaluation and Research regarding facility registration (301-796-3130).

**16.3 Q: Are dietary supplements considered "food" for purposes of the food facility registration requirement?**

**A:** Under section 201(ff) of the FD&C Act (21 U.S.C. 321(ff)), a dietary supplement and a component of a dietary supplement is a "food." Accordingly, a facility that manufactures/processes, packs, or holds a dietary supplement or a component of a dietary supplement is required to be registered as a food facility unless it qualifies for an exemption from registration.

**16.4 Q: Do pet rawhide chew manufacturing facilities need to be registered?**

**A:** Yes. These facilities are required to be registered because rawhide chews are consumed by animals and thus are "food," as defined in section 201(f) of the FD&C Act (21 CFR 1.227(b)(4)).

**16.5 Q: In terms of food facility registration, what is the responsibility of a manufacturer of a chemical, substance X, if the manufacturer sells the substance to a customer who uses substance X to produce an indirect food additive?**

**A:** The term "indirect food additive" is not defined in the FD&C Act or FDA regulations, but is generally used to refer to a food contact substance. For the purposes of food facility registration, the definition of "food" in 21 CFR 1.227(b)(4) excludes food contact substances, as defined in section 409(h)(6) of the FD&C Act (21 U.S.C. 348(h)(6)). Consequently, facilities that manufacture chemicals used in the production of food contact substances are not required to be registered with FDA. However, if substance X is intended to have a technical effect in or on the food, it is "food" as defined in 21 CFR 1.227(b)(4) and the facility that manufactures substance X must be registered. In addition, if an owner, operator, or agent in charge of a manufacturing facility for substance X reasonably believes that the substance is reasonably expected to be directed to food use, the owner, operator, or agent in charge must register its facility with FDA.

(See Comment 62 in the preamble to the Interim Final Rule for additional information).

**16.6 Q: We produce enzymes that can be used to manufacture food additives. Are the facilities in which these enzymes are manufactured/processed, packed or held subject to these regulations?**

**A:** The answer to this question depends upon the use of the enzymes in question. As explained in Question D.12 in this guidance, for the purposes of food facility registration, the definition of

“food” excludes food contact substances (21 CFR 1.227(b)(4)). If an enzyme produced by the facility is added to food and is intended to have a technical effect in the food, the facility is required to be registered. If the manufactured enzymes are used to manufacture a substance that will be a food contact article (or component of a food contact article), the facility is not required to be registered.

**16.7 Q: Are facilities that manufacture gum base substances, such as polyvinyl acetate used to produce chewing gum base, required to be registered?**

**A:** Yes. Chewing gum is “food” (section 201(f)(2) of the FD&C Act; 21 CFR 1.227(b)(4)). Because polyvinyl acetate chewing gum base is an ingredient (component) of chewing gum, a facility that manufactures/processes, packs, or holds it is required to be registered, unless the facility is exempt from registration under 21 CFR 1.226.

**16.8 Q: Are facilities that manufacture products that are not considered to be for consumption, but are partially consumed because of the way they are used (e.g., lip balms and toothpaste, required to be registered?**

**A:** No. Products such as lip balms and toothpaste are cosmetics and are not “food,” as defined in section 201(f) of the FD&C Act (21 U.S.C. 321(f)), because they are not consumed for their taste, aroma, or nutritive value (*Nutrilab v. Schweiker*, 713 F.2d 335, 338 (7th Circ. 1983)). Accordingly, a facility that manufactures/processes, packs, or holds these cosmetics is not required to be registered as a food facility.

**16.9 Q: Does a facility need to be registered if it manufactures raw materials for dietary supplements?**

**A:** Yes. Dietary supplements are “food” (sections 201(f) and 201(ff) of the FD&C Act and 21 CFR 1.227(b)(4)(ii)). Accordingly, a facility that manufactures/processes, packs, or holds a dietary supplement or a component of dietary supplement (i.e., a raw material) is required to be registered as a food facility.

**16.10 Q: Are facilities that manufacture food packaging required to be registered as food facilities?**

**A:** No. The definition of “food” in 21 CFR 1.227(b)(4)(i)(A), for the purposes of food facility registration, excludes food contact substances as defined in section 409(h)(6) of the FD&C Act (21 U.S.C. 348(h)(6)). Consequently, a facility that manufactures/processes, packs, or holds food contact substances, i.e., food packaging, is not required to be registered.

**16.11 Q: Are facilities that manufacture/process, pack, or hold food used in research and development or as food samples required to be registered with FDA?**

**A:** Yes. Food used in research and development or as product samples is “food” for purposes of the food facility registration requirements of section 415 of the FD&C Act. Accordingly, a facility that manufactures/processes, packs, or holds food used in research and development or as

product samples is required to be registered with FDA. However, if the food is not for consumption in the U.S. by humans or animals, the facility is not required to be registered.

**16.12 Q: Are the "secondary direct additives" listed in 21 CFR part 173 considered "food contact substances" as defined in section 409(h)(6) of the FD&C Act? Are facilities that manufacture/process, pack, or hold secondary direct additives required to be registered?**

**A:** The answer to these questions depends upon the specific use of the secondary direct additive. The regulations in 21 CFR part 173 stipulate the conditions of safe use for certain additives that are added directly to food (such as enzyme preparations) as well as additives that are food contact substances (such as ion exchange resins). A facility used to manufacture/process, pack, or hold a substance approved in 21 CFR part 173 is exempt from registration only if the substance satisfies the definition of "food contact substance" in section 409(h)(6) of the FD&C Act (21 U.S.C. 348(h)(6)). Otherwise, a facility that manufactures/processes, packs, or holds a substance approved in 21 CFR part 173 is required to be registered.

## **17. Holding:**

**17.1 Q: Is a local collecting facility for grains exempt from the registration requirement?**

**A:** All establishments at which food is manufactured/processed, packed, or held are required to be registered, unless otherwise exempt. If the local "collecting facility" is storing or holding the grain, e.g., collecting grain in a silo or grain elevator from multiple farms that are not under the same ownership, the facility must be registered with FDA. However, if the collecting facility is storing grain grown on the farm where it is located and from other farms under the same ownership, it is not required to be registered (21 CFR 1.225 and 1.227(b)).

**17.2 Q: If a facility receives packaged produce for shipping and holds it in cold storage, is it required to register?**

**A:** Yes. A facility that holds food, such as packaged produce, that it receives for shipping must be registered (21 CFR 1.225 and 1.227(b)).

**17.3 Q: If finished food products for consumption in the U.S. are held at a third party facility before consolidation for import into the U.S., must this facility be registered?**

**A:** Yes, if finished products are held at a third party facility for import into the U.S., the facility is required to be registered (21 CFR 1.225 and 1.227(b)).

**17.4 Q: In a lessor-lessee relationship, such as a food-producing business that rents space from a landlord, who is legally obligated to register the facility?**

**A:** Either the lessor or the lessee may register the facility as follows. The Bioterrorism Act and the Registration Interim Final Rule place the duty to register a facility on the owner, operator, or agent-in-charge of the facility. Each of these persons has an independent obligation to comply with the registration requirement, and any one of them may satisfy the obligation for the other

two. On the other hand, if a facility is not registered, FDA could proceed with an enforcement action against one or all of the three. A facility is defined as "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 U.S." Thus, for a public warehouse, either the owner of the entire warehouse may register the warehouse and satisfy the obligation for all lessees, or an individual lessee, functioning as the operator or agent-in-charge of the portion of the warehouse he/she leases, may register that portion of the facility.

**17.5 Q: Post offices and similar facilities owned or operated by express couriers may have packages containing food on their premises as part of the shipment process. Are these types of establishments required to be registered with FDA as food facilities?**

**A:** No. Post offices and express courier facilities are not required to be registered as food facilities. The activities of postal services and express courier services are focused on the transport of goods. Their facilities generally serve only as a point of transfer of packages and other freight, including packages containing food. Thus, it is appropriate to view both types of facilities as part of the transportation process. The definition of "facility" in 21 CFR 1.226(b)(2) provides that transport vehicles are not facilities "if they hold food only in the usual course of business as carriers." Although FDA did not define "transport vehicle" for the purpose of food facility registration, the agency's definition of "transporter" in 21 CFR 1.328, relating to the establishment and maintenance of records, is relevant. "Transporter" is defined as "a person who has possession, custody, or control of an article of food in the U.S. for the sole purpose of transporting the food..." FDA believes that it is appropriate to apply this same rationale to exclude from registration facilities that hold food only because they are part of the process of transporting it from one location to another. This analysis is also consistent with the definition of "facility" in 21 CFR 1.227(b)(2). Thus, because post offices and express courier facilities operating in a manner comparable to post offices are part of the transportation network and have possession, custody, or control of food for the sole purpose of transporting, they are not required to be registered as food facilities.

**17.6 Q: Truck terminals and freight forwarders may have food on their premises as part of the shipment process. Are these types of establishments required to be registered with FDA as food facilities?**

**A:** No. Truck terminals and other stationary facilities that serve merely to assist transportation vehicles in the process of transporting food are not required to be registered with FDA. As with post offices and similar facilities discussed in Question 17.4 in this guidance, truck terminals and freight forwarders that are part of the transportation network and have possession, custody, or control of food for the sole purpose of facilitating its transport are not required to be registered as food facilities. FDA acknowledges that this response is not completely consistent with certain prior guidance (See Comment 36 in the preamble to the Interim Final Rule). However, FDA further considered this issue, as well as related ones, and determined that the earlier guidance should be revised.

**17.7 Q: Is a vessel carrier that only transports food from one facility to another considered to be a facility that must be registered?**

**A:** No. A vessel carrier that holds food only in its usual course of business as a carrier is a transport vehicle. A transport vehicle is not a “facility,” as defined in 21 CFR 1.227(b). Therefore, a vessel carrier is not a facility that must be registered.

**17.8 Q: Are foreign storage facilities that hold finished food products prior to export to the U.S. required to be registered?**

**A:** Yes. Generally, a foreign storage facility that holds food prior to export to the U.S. is required to be registered with FDA. However, if the food subsequently undergoes manufacturing/processing of more than a *de minimis* nature in another foreign facility, the former foreign storage facility is not required to be registered.

**17.9 Q: Do the facilities of both the exporter and the importer of food for consumption in the U.S. need to be registered if they each hold food?**

**A:** Yes. The facilities of both the exporter and the importer are required to be registered if they hold food for consumption in the U.S. However, as indicated in the response to Question 17.8 in this guidance, the foreign facility need not be registered if all of the food held by that facility undergoes further manufacturing/processing of more than a *de minimis* nature in another facility outside the U.S.

**17.10 Q: Does a cruise ship have to be registered if it is holding food for consumption for passengers and returns to the U.S. with food not consumed on the cruise?**

**A:** Under section 415(b)(1) of the FD&C Act, a restaurant is not a "facility" for purposes of registration. “Restaurant” is defined in 21 CFR 1.227(b) as an establishment that "prepares and sells food directly to consumers for immediate consumption." A food service establishment on a cruise ship is exempt as a restaurant. The remainder of the ship is not required to be registered because it is not manufacturing/processing, packing, or holding food for consumption in the U.S. In addition, even if a cruise ship carries food as cargo, it is not required to be registered because, in such circumstances, it would be considered a transport vehicle (21 CFR 1.227(b)).

**18. Manufacturing/Processing:**

**18.1 Q: Is fumigation (such as of bagged cocoa beans or coffee beans) considered *de minimis* processing?**

**A:** No. FDA considers that treating a food with a fumigant is not a *de minimis* activity. "Treating," such as fumigating, a food is a manufacturing/processing activity (21 CFR 1.227(b)(6)). Therefore, a foreign facility that fumigates a food that is for consumption in the U.S. is required to be registered unless another facility outside the U.S. conducts further manufacturing/processing of more than a *de minimis* nature. (Comments 17 and 41 in the



preamble of the Interim Final Rule also discuss fumigation of cocoa beans and treating food against pests).

**18.2 Q: Is it necessary for a facility housing cotton gins to register if the cotton gins separate cotton from its seeds and hulls and the facility then sells these seeds or hulls to a manufacturer who then further processes the seeds and hulls into food for sale to livestock operations?**

**A:** Because the seeds and hulls are to be used for animal food, the facility is required to be registered. FDA believes that the owner, operator, or agent in charge of a cotton gin facility generally knows or should know that the cotton by-products are reasonably likely to be used as components of animal feed. If the cotton gin establishment is located in the U.S., the establishment is required to be registered because it is manufacturing/processing food (components of animal food), and the facility does not appear to otherwise be exempt from registration. A facility that subsequently processes the cotton seed and hulls into animal food is also required to be registered.

However, if the cotton gin establishment and the establishment that processes the cotton seed and hulls into animal food are both located in a foreign country, the cotton gin establishment would not be required to be registered because a subsequent foreign facility (the animal food manufacturer) conducts further manufacturing/processing of the cotton by-products prior to export to the U.S. The foreign food manufacturing/processing facility must be registered unless, before the food is exported to the U.S., the food undergoes further manufacturing/processing of more than a *de minimis* nature at a third foreign facility (21 CFR 1.226(a)). The third foreign facility would then be required to be registered.

**18.3 Q: Do all manufacturing/processing sites under one ownership have to be registered, even if only one is involved with foods for consumption in the U.S.?**

**A:** No. Only facilities that manufacture/process, pack, or hold food for consumption in the U.S. are required to be registered. Thus, facilities that manufacture/process, pack, or hold food that will be consumed outside of the U.S. do not need to be registered.

**19. Packing:**

See Questions and Answers 9.7 – 9.10 under section C in this guidance.

**20. Trade Names:**

**20.1 Q: Does a distributor of food products need to register the trade names of all products it distributes, or repacks and then distributes, or only the trade names of those products manufactured at its facility?**

**A:** Under 21 CFR 1.227(b), a "trade name" is a name under which a facility conducts business, as opposed to a "brand name," which is a name associated with a product. A distributor is required to include in a facility's registration all trade names under which the facility conducts

business. A facility's registration is not required to include all brand names for products manufactured/processed, packed, or held at the facility.

## **21. U.S. Agent:**

**21.1 Q: For foreign facilities, may the U.S. agent for the facility also serve as the facility's emergency contact?**

**A:** Yes. The U.S. agent will be considered the emergency contact for a registered foreign facility unless another name is provided in the facility's registration as the emergency contact (21 CFR 1.227(b) and 1.233(e)).

**21.2 Q: Some U.S. law firms are charging fees to serve as a foreign facility's U.S. agent. Some of these firms have the word "FDA" in their name. Must a foreign facility use one of these firms as its U.S. agent?**

**A:** No. A foreign facility's U.S. agent may be an individual, partnership, corporation, or association. The only requirements for such an agent are that the agent must have a place of business or residence in the U.S. and be physically present in the U.S. For example, a foreign facility may use its U.S. importer as its U.S. agent. FDA does not recommend or endorse any particular firm, organization, person, or company to serve as a foreign facility's U.S. agent. FDA is not affiliated with any firm offering its services as a U.S. agent.

**21.3 Q: May a foreign government official residing in the U.S., such as a representative from the foreign country's embassy, act as a foreign facility's U.S. agent for purposes of food facility registration?**

**A:** FDA is concerned that acting as a U.S. agent may conflict with the duties of foreign government representatives (Comment 90 in the preamble to the Interim Final Rule). Whether it is proper for a foreign government representative to act as a U.S. agent is a fact-specific inquiry, depending on the title and status of the foreign government representative and the functions that the representative assumes as a U.S. agent. FDA will consider such situations on a case-by-case basis in consultation with the U.S. State Department.

**21.4 Q: I am a foreign facility that does business with several different brokers. May I use more than one of these as my U.S. agent?**

**A:** No. Under 21 CFR 1.227(b), each foreign facility is required to have only one U.S. agent for food facility registration purposes. However, having a single U.S. agent for FDA registration purposes does not preclude a facility from having multiple brokers for other business purposes. A foreign facility is not required to conduct all of its business in the U.S. through the U.S. agent designated for purposes of registration (21 CFR 1.227(b)(13)(iii) and Comment 86 in the preamble to the Interim Final Rule).

**21.5 Q: Is a power of attorney required for a U.S. agent to work on behalf of the facility?**

**A:** A facility's U.S. agent, as defined in 21 CFR 1.227(b), is not required to have a power of attorney from the facility, nor is such arrangement precluded.

**21.6 Q: May a foreign food processor change U.S. agents after registration?**

**A:** Yes. A foreign facility may change its U.S. agent at any time. Under 21 CFR 1.234(a), updates to required information, including the U.S. agent designation by foreign facilities, must be made within 60 calendar days of the change. Updates may be submitted electronically at <http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/RegistrationofFoodFacilities/default.htm>. If you do not have access to the Internet, you also may update the U.S. agent information through the paper system, as explained in Question 2.1 in this guidance document.

**21.7 Q: May the emergency contact for a foreign facility have a phone number outside the U.S.?**

**A:** Yes. A foreign facility's emergency contact may have a phone number outside the U.S. However, the facility is also required to identify a U.S. agent who resides or maintains a place of business in the U.S. and is physically located in the U.S. The U.S. Agent must have a U.S. phone number. In addition, the FSMA amendments to section 415 of the FD&C Act require that an e-mail address for the U.S. agent be provided in the foreign facility's registration.

**21.8 Q: What information must the U.S. agent have on the foreign facility? For example, does the U.S. agent need to know and understand the company and product? Or is it sufficient for the U.S. agent to be able to contact the manufacturer quickly in case of emergency, as well as serve as a conduit for the general information flow to and from FDA?**

**A:** Under 21 CFR 1.227(b)(13), there are two qualifications for a U.S. agent. The agent (1) must reside or maintain a place of business in the U.S. and (2) must be physically present in the U.S. Although the U.S. agent is not required to know and understand the facility's company and product, the U.S. agent must be able to serve as the communication link between FDA and the foreign facility because FDA will contact the foreign facility's U.S. agent when an emergency occurs (unless the registration specifies another emergency contact). Thus, at a minimum, the U.S. agent needs to know whom to contact at the facility if any emergency arises.

**21.9 Q: How does a foreign facility "authorize" someone in the U.S. to be their agent (e.g., letter to FDA, notarized document)?**

**A:** From FDA's perspective, for registration purposes, listing the name and contact information for the U.S. agent in the registration is sufficient to "authorize" the agent. For its own business reasons, however, a facility may want to formalize its relationship with the agent with some sort of written agreement. Regardless of whether there is a formalized relationship between the facility and its U.S. agent, FDA does expect that the personnel from the facility will have verified that the person designated in the facility's registration as its U.S. agent is willing to serve as the agent.

**21.10 Q: May a foreign facility appoint one U.S. agent for part of the year and another U.S. agent for the rest of the year?**

**A:** Yes. However, any change in a facility's U.S. agent must be communicated to FDA through an update of the registration information within 60 days of the change (21 CFR 1.234).

**21.11 Q: May foreign facilities belonging to the same parent company use different U.S. agents for registration purposes?**

**A:** Yes. Each foreign facility must identify, as part of the registration process, its U.S. agent, and there is no requirement that facilities belonging to the same parent company utilize the same U.S. agent. Also, any or all facilities belonging to the same parent company may designate the same U.S. agent for registration purposes.

**21.12 Q: Traditionally, a U.S. broker has been utilized for routine and emergency communications with respect to the disposition of a particular shipment. Will that continue or will only the designated U.S. agent be the facilitator for communications between a shipping facility, carrier, broker, and importer?**

**A:** Routine registration and emergency communications under the registration regulation relate to facilities, not to specific shipments. FDA expects that the registration Interim Final Rule, including the U.S. agent requirement, will have no impact on customary communications regarding the disposition of a particular food shipment. A firm's commercial business in the U.S. need not be conducted exclusively through the U.S. agent designated for registration purposes (21 CFR 1.227(b)). Ordinarily, for example, for questions relating to an import food shipment subject to the prior notice requirements (21 CFR part 1, subpart I), FDA will contact the transmitter or submitter of the prior notice, rather than the U.S. agent for the facility associated with the shipment.

**21.13 Q: If someone agrees to be the U.S. agent for a foreign facility and later wishes to be removed as the U.S. agent, how would this be accomplished?**

**A:** The owner, operator, or agent in charge of the foreign facility, or an individual authorized by one of them, must update the information identifying the facility's U.S. agent in the facility's registration (21 CFR 1.234). To ensure that FDA is aware of the U.S. agent's intention of being removed from the facility's registration, the U.S. agent may notify FDA of its intention by sending an e-mail to [FURLS@FDA.gov](mailto:FURLS@FDA.gov). This e-mail should include the information previously provided on the registration form regarding the U.S. agent (i.e., name, address, phone number) and the name(s) and either address(es) or registration number(s) of the facility or facilities from which the U.S. agent wishes to be removed.

**21.14 Q: How can the U.S. agent be accessible 24 hours a day, 7 days a week? How can a small company make such an assurance?**

**A:** The foreign facility is responsible for making arrangements with the person designated as its U.S. agent or its designated emergency contact. Because the role of the U.S. agent is to act as a

communications link between the facility and FDA, FDA intends to communicate through the U.S. agent in both routine registration matters and emergency situations. This means that the U.S. agent must be accessible to FDA 24 hours a day, 7 days a week, unless the foreign facility opts to designate a different person other than the facility's U.S. agent as the facility's emergency contact by providing the information specified in 21 CFR 1.233(e) in the facility's registration. In terms of ensuring such accessibility, FDA suggests that the foreign facility may wish to specify the terms of availability in any written agreement it has with its U.S. agent or emergency contact.

**21.15 Q: Can a person in the U.S., who has not been designated as the U.S. agent for a foreign facility, perform the registration function for that facility?**

**A:** Registration must be performed by the owner, operator, or agent in charge of a facility, or an individual authorized to register the facility by one of them. (21 CFR 1.230) The authorized individual may be, but is not required to be, the U.S. agent for the facility.

**21.16 Q: Under 21 CFR 1.232(d), the registration for a foreign facility is required to include the "name, address, phone number, and emergency contact phone number for its U.S. agent..." "U.S. agent" is defined in 21 CFR 1.227(b) as a "person... residing or maintaining a place of business in the U.S. whom a foreign facility designates as its agent" for purposes of registration of food facilities. As used in this definition, what does a facility need to do to "designate" a person as a U.S. agent?**

**A:** A foreign facility's U.S. agent must reside or maintain a place of business in the U.S. and must be physically present in the U.S. (21 CFR 1.227(b)). FDA expects the facility management to contact the person and confirm that the person is willing and able to serve as the facility's U.S. agent. The facility should "designate" a person as the facility's U.S. agent only if the person has affirmatively agreed to serve in that capacity. The person's name and other identifying information must be given in section 7 of the Form FDA 3537 (DHHS/FDA -- Food Facility Registration Form) or in response to the appropriate prompt when a facility is registered electronically.

**21.17 Q: What is the status of a foreign facility's registration when the person listed as the U.S. agent for the facility do not agree to serve as the facility's U.S. agent?**

**A:** FDA contacts the person listed as a U.S. agent in a foreign food facility registration to notify the person that he or she has been identified by a foreign facility to serve in such capacity using the contact information provided by the foreign facility in the registration. If a person listed as U.S. agent informs FDA that he has not agreed to serve as the facility's U.S. agent, FDA will inform the facility (through its owner, operator, or agent-in-charge) of that fact and request that the facility amend the registration to designate as its U.S. agent a person who has affirmatively agreed to serve as the facility's U.S. agent. For foreign facilities registered electronically, FDA intends to contact the owner, operator, or agent in charge electronically and request that the facility amend its registration within 15 calendar days. For foreign facilities registered by paper or by CD-ROM, FDA intends to contact the owner/operator/agent in charge using regular mail and request that the facility amend its registration within 30 calendar days. If the registration for

a foreign facility is not amended within the 30 calendar days, FDA will regard the facility's registration to be invalid and will flag the registration as invalid in FDA's electronic system.

**21.18 Q: What will happen to an article of food that is offered for import into the U.S. from a facility with an invalid registration that FDA determined to be invalid because it does not include a U.S. agent who affirmatively agreed to serve in that capacity?**

**A:** When FDA determines that the registration for a foreign food facility is invalid because it does not provide a U.S. agent, FDA will hold shipments offered for import from that facility at the U.S. border until the facility amends their registration to list a U.S. agent who has affirmatively agreed to serve as such.

## **22. Other Definitions:**

**22.1 Q: How does FDA define "owner," "operator," and "agent in charge?"**

**A:** The owner, operator, or agent in charge is a person (as defined in section 201(e) of the FD&C Act; 21 U.S.C. 321(e)) who has an ownership interest in, or management authority of, a facility or a portion of a facility (e.g., a lessee of a part of a public warehouse).

**22.2 Q: How does FDA define "parent company?"**

**A:** The term "parent company" is used in 21 CFR 1.232(b) and is intended to have the meaning it has in the corporate context. If a facility is part of a company that is owned by another corporation, then the corporation would be the parent company. For example, if a facility is owned by Company X, and Company X is a subsidiary of Corporation Y, then the owner of the facility is Company X and the parent company is Corporation Y.

## **E. What Information is Required in the Registration?**

### **23. General Questions:**

**23.1 Q: What information is required in the registration of a food facility, including new requirements from FSMA?**

**A:** The following information is required for domestic and foreign food facility registrations:

- Facility name, address, phone number, and emergency contact phone number;
- Parent company name, address, and phone number (if applicable);
- Name, address, and phone number of the owner, operator, or agent in charge;
- Email address for the contact person of the facility or, in case of a foreign facility, the U.S. Agent for the facility;
- All trade names the facility uses;
- Applicable food product categories, as listed on the registration form;
- Name, address, and phone number of a foreign facility's U.S. agent, and phone number of the facility's emergency contact if it is someone other than the U.S. agent;

- Certification that the information submitted is true and accurate and that the person submitting the registration is authorized to do so; and
- Assurance that FDA will be permitted to inspect the facility at the times and in the manner permitted by the FD&C Act.

## **F. What Optional Items are Included in the Registration?**

### **24. General Questions:**

#### **24.1 Q: What optional information may be provided in the registration?**

**A:** The following information is optional, but may be provided when submitting a food facility registration:

- Facility fax number and email address;
- Preferred mailing address, if different from that of the facility;
- Fax number and e-mail address of the owner, operator, or agent in charge of the facility;
- Fax number and e-mail address of the parent company (if applicable);
- For a foreign facility: the fax number of its U.S. agent;
- Type of activity conducted at the facility (i.e., manufacturing, processing, packing, or holding food);
- Type of storage (if it's a holding facility); and
- Approximate dates of operation (if the facility's business is seasonal).

## **G. How and When Do You Update Your Facility's Registration Information?**

### **25. General Questions:**

#### **25.1 Q: When must you update the information submitted in a food facility's registration?**

**A:** The owner, operator, or agent in charge of the facility must submit an update to the facility's registration within 60 calendar days of any change to any of the required information. If the reason for an update is a change in ownership, the former owner must cancel the facility's registration within 60 calendar days. The new owner must submit a new registration for the facility before the facility begins to manufacture/process, pack, or hold food for consumption in the U.S. (21 CFR 1.230 and 1.234).

## **H. How and When Do You Cancel Your Facility's Registration Information?**

### **26. General Questions:**

#### **26.1 Q: How and when must a facility cancel its registration?**

**A:** The owner, operator, or agent in charge of the facility, or a person authorized by one of them, must cancel the registration within 60 calendar days of the reason for the cancellation (e.g., if a facility goes out of business or comes under new ownership, the owner, operator, or agent in

charge must cancel the registration within 60 days (21 CFR 1.235)). The owner, operator, or agent in charge of the facility, or a person authorized by one of them, can submit a food facility's registration electronically at <http://www.access.fda.gov>. Alternatively, you can obtain paper Form FDA 3537a and use the paper process for faxing or mailing the cancellation to the fax number or address indicated in Question A.2 in this guidance.

## **I. What Other Registration Requirements Apply?**

### **27. General Questions:**

#### **27.1 Q: What other registration requirements apply to foods?**

**A:** In addition to the food facility registration requirements under section 415 of the FD&C Act and 21 CFR part 1 subpart H, commercial processors of low-acid canned foods and acidified foods must register as required in 21 CFR part 108. Food facilities that are required to register must also comply with any other applicable Federal, State, or local registration requirements.

## **J. What Are the Consequences of Failing to Register, Renew, Update, or Cancel Your Registration?**

### **28. General Questions:**

#### **28.1 Q: What are the consequences if an owner, operator, or agent in charge of a facility does not register, renew, update, or, cancel the facility's registration, as required in section 415 of the FD&C Act and 21 CFR part 1, subpart H?**

**A:** The failure of an owner, operator, or agent in charge of a facility to register their facility, renew their registration (as required by section 415(a)(3) of the FD&C Act), update required registration elements, or to cancel their registration is a prohibited act under the FD&C Act (section 301(dd); 21 U.S.C. 331(dd)). The U.S. can bring a civil action in Federal court to enjoin a person who commits a prohibited act. The U.S. also can bring a criminal action in Federal court to prosecute a person who is responsible for the commission of a prohibited act (21 CFR 1.241(a)).

If food being imported or offered for import into the U.S. is from a foreign facility for which registration has not been submitted, the food must be held at the port of entry for and may not be delivered to the importer, owner, or consignee of the food until the foreign facility is registered. However, the food may be directed to a secure facility by FDA or the Customs and Border Protection Service (section 801(l) of the FD&C Act).

## **K. What Does Assignment of a Registration Number Mean?**

### **29. General Questions:**

#### **29.1 Q: When is a food facility registration number assigned?**



**A:** FDA assigns a registration number to confirm that a food facility is registered. For an electronic registration, the number is assigned electronically and immediately after the registration is submitted. For registration by fax, FDA sends the registration number by fax. For registration by surface mail or CD-ROM, FDA sends the registration number by surface mail.

**29.2 Q: What does assignment of a registration number mean?**

**A:** Assignment of a registration number to a facility means that the facility is registered with FDA. Assignment of a registration number does not in any way convey FDA's approval or endorsement of a facility or its products.

**L. Is Food Registration Information Available to the Public?**

**30. General Questions:**

**30.1 Q: Is the information included in a food facility's registration or relating to such registrations (e.g., list of registered facilities) available to the public?**

**A:** Section 415(a)(5) of the FD&C Act provides that the list of registered facilities and registration documents, including information provided in those documents, that is submitted under 21 CFR part 1, subpart H, are not subject to public disclosure under the Freedom of Information Act (5 U.S.C. 552). In addition, any information derived from such list or registration documents that would disclose the identity or location of a specific registered person is not subject to disclosure under 5 U.S.C. 552.

**30.2 Q: Is a registered facility responsible for ensuring that the companies with which they deal are registered?**

**A:** There are no direct penalties for doing business with a company that is not registered. However, if a company offers food for import into the U.S. and the food is from a foreign manufacturing facility that is not registered, the company may be unable to complete the prior notice for the shipment (21 CFR 1.281(a)(6)), which is required to import the shipment.

**30.3 Q: Is a facility required to provide its food facility registration number, assigned by FDA when the registration is submitted, to customers or other businesses who request the number. Is a facility prohibited from revealing its registration number?**

**A:** Section 415(a)(5) of the FD&C Act prohibits FDA from publicly disclosing certain registration-related information, including the registration number. However, this prohibition does not prevent a facility itself from disclosing such information. In fact, for imports, a facility will likely need to provide its registration number to any downstream commercial entity who will be submitting prior notice for a food manufactured by the facility. The FD&C Act does not prevent a foreign facility from entering into an agreement with its customers to limit the circumstances in which the facility's registration number may be disclosed to third parties.

**30.4 Q: FDA's list of facilities and registration documents are not subject to public disclosure. How do we know that a supplier, for instance, is registered?**

**A:** Section 415(a)(5) of the FD&C Act prohibits FDA from disclosing food facility registration information. However, disclosure of such information by the facility itself is not prohibited. FDA expects that generally, foreign suppliers and their customers will resolve this question as part of their agreement to buy and sell food for consumption in the U.S.

**30.5 Q: Will FDA require the food facility registration number to be displayed as part of a food label?**

**A:** No. There is no requirement to list on the food label the registration number (or numbers) for the facility (or facilities) associated with manufacturing/processing, packing, or holding the food. FDA actually discourages food facilities from including their registration numbers on the food label to prevent others from using the registration number for improper purposes.

**M. General Registration Questions**

**31.1 Q: Will the food facility regulations be published in other languages?**

**A:** No. FDA has no plans to publish the Interim Final Rule in any language other than English. However, the transcript for FDA's broadcast public meeting concerning the registration requirement is available in English, French, and Spanish. In addition, outreach materials regarding the Interim Final Rule are available on FDA's website in the following languages: Arabic, Chinese, French, Hindi, Japanese, Malay, Portuguese, and Spanish.