

Guidance for Industry

**Questions and Answers Regarding
Registration of Food Facilities
(Edition 4)***

Final Guidance

Comments and suggestions regarding this document may be submitted at any time. Submit comments to Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the Docket Number 2003D-0545.

For questions regarding this document, contact Melissa S. Scales at the Center for Food Safety and Applied Nutrition (CFSAN) at (Tel) 301-436-1720, (Fax) 301-436-2637, or e-mail melissa.scales@fda.hhs.gov.

*Additional copies are available from:
Office of Regulations and Policy, HFS-24
Center for Food Safety and Applied Nutrition
Food and Drug Administration, 5100 Paint Branch Parkway
College Park, MD 20740
<http://www.cfsan.fda.gov/guidance.html>*

**U.S. Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition (CFSAN)
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Guidance for Industry⁽¹⁾

Questions and Answers Regarding the Interim Final Rule on Registration of Food Facilities (Edition 4)

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 may 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 appropriate number listed on the title page of this guidance.

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I. INTRODUCTION

On October 10, 2003, FDA issued an interim final regulation to implement the Bioterrorism Act's requirement that domestic and foreign facilities that manufacture, process, pack, or hold food for human or animal consumption in the United States must register with FDA by December 12, 2003. (See 68 FR 58894; October 10, 2003.) The interim final rule implements section 305 of the Bioterrorism Act. Section 305 requires domestic and foreign facilities to register with FDA by December 12, 2003, even in the absence of final regulations.

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 and third 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 and February 17, 2004, respectively. This revision (Edition 4) is being issued as Level 1 guidance and includes answers to new inquiries regarding the implementation of the Registration of Food Facilities Interim Final Rule (21 CFR Part 1, Subpart H). This guidance is immediately effective because FDA has determined that prior public participation is not feasible or appropriate. The revisions made by this edition (Edition 4) are identified below by date.

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

II. Questions and Answers

A. Who Must Register?

1. Private Residences:

- 1.1 **Q:** If a person has a business in his/her home that involves manufacturing/processing, packing, or holding food, does that person need to register his 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)) and thus, need not be registered.

- 1.2 **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 is not a facility as defined in the Interim Final Rule (21 CFR 1.227(b)(2)) and thus, need not be registered.

1.3 Q: Is a private residence in which low acid canned food is produced exempt from the regulations for low acid canned food (21 CFR Part 113)?

A: No. Although such a residence is not required to be registered as a food facility under 21 CFR Part 1, Subpart I, it is not exempt from any other requirements established by any other laws or regulations (21 CFR 1.240).

1.4 Q: [Added February, 2004] Most sugar makers in Massachusetts operate from their own property. Private residences are exempt, but what about sugar makers who operate on land outside of their property?

A: Under 21 CFR §1.227(b)(2), a private residence is not a "facility" and thus, is not required to be registered. Importantly, such an establishment 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 in question is produced in a private residence or a detached building that would be considered part of the residence, such as a detached garage, the facility would not have to be registered. If, however, there is a separate sugar manufacturing/processing facility that is located on the private residence site, the establishment would be considered a mixed-type establishment and the manufacturing/processing facility would have to be registered, unless that facility qualified for another exemption (e.g., as a retail facility, 21 CFR 1.227(b)(11)).

B. Who is Exempt from Registration?

2. Farms:

2.1 Q: Is a facility that manufactures/processes and sells seed to farmers required to be registered if the seed is intended for cultivation? What if the seed is an ingredient that will be included in animal feed?

A: FDA requires registration of any facility that manufactures/processes, packs, or holds food for consumption in the U.S. As noted in a response to a comment in the Interim Final Rule (Comment 62), FDA will consider a product as one that will be used for food if the owner, operator, or agent in charge of the facility reasonably believes that the substance is reasonably expected to be directed to a food use. Therefore, if the owner, operator, or agent in charge of the facility in this question reasonably believes that the seed is reasonably expected to be used as an ingredient for animal feed, the seed is considered "food" and thus, the facility is required to be registered. However, if the seed is reasonably expected only to be cultivated, the facility is not required to be registered.

2.2 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)).

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

A: No. Assuming that the farm otherwise satisfies the definition of farm (21 CFR 1.227(b)(3)), the farm is exempt from registration if it ships food directly to the U.S. However, if prior to export to the U.S., food grown on the farm is shipped 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 is discussed further in question 21 of this guidance and in the preamble to the Interim Final Rule (responses to comment 17, 21, 25, and 26).

2.4 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)).

2.5 Q: [Added December 30, 2003] 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. Section 1.227(b)(3) defines a farm as "a facility in one general location devoted to the growing and harvesting of crops, the raising of animals (including seafood), or both." 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 prior to harvest is a "farm"

within the meaning of the Interim Final Rule. However, post-harvest application is necessarily directed at the food, not the entire plant, and thus, is considered to be manufacturing/processing under §1.227(b)(6). Therefore, a farm that treats a crop against pests post-harvest must register with FDA unless it satisfies the conditions of § 1.227(b)(3)(ii).

2.6 Q: [Added December 30, 2003] Is use of chlorinated water to wash lettuce on a farm considered "processing," necessitating registration of a 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.foodsafety.gov/~dms/prodguid.html>) 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(c)(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).

2.7 Q: [Added December 30, 2003] 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 produce grown or consumed on the farm is not required to register as long as the farm otherwise satisfies the definition of farm (21 CFR 1.227(b)(3).) Under §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 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 part of "packing."

2.8 Q: [Added February, 2004] The produce on our farm is picked, trimmed, and packed at a packing shed owned by the farm (but not on the farm) or in the fields.

The produce is then shipped off the farm. Do the farm or packing shed have to be registered?

A: Under the scenario described in the question, the packing shed is required to be registered. The farm is not required to be registered. 21 CFR §1.226(b). The farm definition extends to facilities located on the farm that pack or hold food if 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 the Interim Final Rule defines "farm" in terms of its location ("one general physical location"), the manufacturing/processing, packing, or holding activities must be co-located in order to be exempt.

2.9 Q: [Added February, 2004] 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: 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 satisfies this definition.

2.10 Q: [Added February, 2004] 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, place them into plastic clamshells, and the filled clamshells are transported off the farm?

A: The farm in this example is exempt from registration. FDA recognizes that the activity in this example -- placing a raw agricultural commodity directly into consumer-ready packages -- is likely to provide better protection to fragile produce, such as berries, 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 the interim final rule are relevant to the status of the farm in this example: "manufacturing/processing" and "packaging." "Packaging" is given as one example of "manufacturing/processing" (21 CFR 1.227(b)(6)), and is later 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" would appear to suggest that the activity in this example is manufacturing/processing (because the strawberries directly contact the clamshell and consumers receive the berries in the clamshell.) FDA believes, however, that the definition in § 1.227(b)(8) must be read in light of the definition of "manufacturing/processing" in § 1.227(b)(6). "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. Thus, 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. Under § 1.227(b)(3)(i) of the interim final rule, a farm may engage in this packing activity so long as all of the involved produce is grown on the farm or a 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, is not "packaging" because the activity does not involve altering the form of 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 under § 1.227(b)(2).

2.11 Q: [Added February, 2004] Is a packing shed located off the farm required to be registered if workers transport strawberries from the farm to the packing shed, place the strawberries into clamshells, and transport them to a distributor?

A: The packing shed in this example must be registered with FDA. All facilities that manufacture/process, pack, or hold food for consumption in the U.S. are subject to the registration requirement. As explained in the answer to question 2.10, placing fresh strawberries into clamshells is an example of "packing." Because the packing shed does not meet any exemptions provided in the Interim Final Rule, it must be registered with FDA.

2.12 Q: [Added February, 2004] 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 2.10, "packaging" is an example of "manufacturing/processing," which is defined in § 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 § 1.227(b)(6) and thus, the truck is not required to be registered.

2.13 Q: [Added February, 2004] 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) before placing them into consumer-ready bags and transporting them off the farm? If the truck is required to register, what address should it use?

A: The truck is required to register in this example, as it is performing a manufacturing/processing activity and does not meet the definition of a farm. In this example, the farm does not need to be registered, even if the truck is engaged in manufacturing/processing, because the truck and the farm are separately owned and thus, are not the same establishment. The truck in this scenario is a mobile facility. Generally, the owner, operator, or agent in charge of a mobile facility has a fixed address. FDA recommends that that fixed address be provided in the truck's food facility registration. Addresses of mobile facilities are addressed further in the preamble to the Interim Final Rule (Response to Comment 38).

2.14 Q: [Added February, 2004] 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: In this example, the truck-mounted operation is required to register because it is packaging wine. The Interim Final Rule provides "packaging" as one example of "manufacturing/processing" (21 CFR 1.227(b)(6)), and later defines "packaging" as "placing food into a container that directly contacts the food and that the consumer receives" (21 CFR 1.227(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 facility that bottles wine is required to be registered.

2.15 Q: [Added February, 2004] Would maple syrup producers be exempt from registering as farms?

A: The response to this question depends upon the activities of the maple syrup producers. FDA believes that 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" as defined in the Interim Final Rule (21 CFR §1.227(b)(3)). However, concentrating sugar maple sap by heating is a form of manufacturing/processing. (21 CFR §1.227(b)(6)).

Accordingly, a farm that both gathers and concentrates sugar maple sap is a "mixed-type" facility that is required to be registered, unless all of the

concentrated sap is consumed on the farm or another farm under the same ownership.

2.16 Q: [Added February, 2004] 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 (21 CFR §1.227(b)(3)(i)) 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. In the situation described in this question, the farm meets this definition.

2.17 Q: [Added February, 2004] If a farm grows hay and sells the hay as feed to a dairy farm operation, does the hay farm need to be registered? Does the dairy farm?

A: Under the facts described in the question, both farms satisfy the definition of "farm" (21 CFR § 1.227(b)(3)) and thus, are not required to be registered.

2.18 Q: [Added February, 2004] 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).)

2.19 Q: [Added February, 2004] A peppermint farmer harvests his crops by cutting, washing and trimming outer 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 the Interim Final Rule do not include dehydrating. Moreover, dehydration is a natural process that occurs while the peppermint is being held in the barn. Thus, the location where the peppermint is grown satisfies the definition of "farm" in § 1.227(b)(3)(i) and is not required to be registered.

3. Retail Food Establishments:

3.1 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 (21 CFR 1.227(b)(11)) 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.

3.2 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 noted, an 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.

3.3 Q: [Added February, 2004] Are food retail storerooms, distribution centers, or warehouses considered "holding facilities" that are required to be registered?

A: If a facility qualifies as a "retail food establishment" under 21 CFR § 1.226(c) and 1.227(b)(11), storerooms that are co-located do not need to be registered because they are considered to be part of the retail food establishment. In contrast, a separate distribution center or warehouse is required to be registered because these facilities are not part of a "retail food establishment," and further, these facilities themselves do not satisfy the definition of "retail food establishment" because they do not provide the food directly to consumers from their facility.

3.4 Q: [Added February, 2004] If a retail product 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 establishment does not become a holding facility; this is considered a normal business practice of a retail food establishment.

3.5 Q: [Added February, 2004] If a bakery is primarily a retail establishment but 40% of its annual sales are to wholesale facilities, does the bakery have to be registered?

A: No. This bakery does not need to be registered. Under 21 CFR § 1.226(c) and 1.227(b)(11), a retail food establishment is exempt 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.

4. Restaurants:

FDA has addressed questions we received on this issue in the Interim Final Rule.

5. Nonprofit Food Facilities:

5.1 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)).

5.2 Q: [Added February, 2004] Are exporters of 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 United States. (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 United States" (21 CFR 1.225(a)).

5.3 Q: [Added February, 2004] Does an agricultural feed cooperative that manufactures for its members/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 satisfies any of the exemptions in the Interim Final Rule, such as the definition of "nonprofit food establishment" (21 CFR § 1.227(b)(7)). However, only a charitable entity that satisfies the terms of § 501(c)(3) of the Internal Revenue Code is a "nonprofit food establishment" as defined in the Interim Final Rule. A feed cooperative, even if established as a "not-for-profit" organization, may not satisfy this aspect of the definition of "nonprofit food establishment."

5.4 Q: [Added August, 2004] 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), a "nonprofit food establishment" that is not required to be registered under 21 CFR 1.226(e) and 1.227(b)(7)?

A: The interim final rule defines a “nonprofit food establishment” 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 United States. 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)).” 21 CFR 1.227(b)(7).

To qualify under § 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 interim final rule’s statement that, to be considered a “nonprofit food establishment,” an establishment must “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 §501(c)(3) but need not be formally designated as a §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 §501(c)(3) of the IRS 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 § 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 §501(c)(3) status. If a public institution or other organization that runs a food service program satisfies the four §501(c)(3) criteria listed above, 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 § 501(c)(3) criteria, the establishment satisfies the remaining elements of the "nonprofit food establishment" definition in 21 CFR 1.227(b)(7).

FDA notes that a “restaurant” (which is defined in the interim final rule at 21 CFR 1.227(b)(10)) is exempt from registration. Thus, if an establishment that is part of a school lunch or other food service program satisfies the definition of “restaurant,” it is exempt from registration regardless of its status as a “nonprofit food establishment.”

FDA further notes that a “retail food establishment” (which is defined in the interim final rule at 21 CFR 1.227(b)(11)) is also exempt from registration. Thus, if an establishment that is part of a school lunch or other food service program satisfies the definition of “retail food establishment,” it is exempt from registration regardless of its status as a “nonprofit food establishment.”

6. Fishing Vessels

FDA has addressed questions we received on this issue in the Interim Final Rule.

7. Facilities Regulated Exclusively, Throughout the Entire Facility, by USDA

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

A: Yes. These facilities are required to be registered with FDA because they are not regulated exclusively by the United States Department of Agriculture (USDA) (21 CFR 1.226(g).)

C. Definitions:

8. Facility:

8.1 Q: [Added February, 2004] Do importers of FDA food products need to be registered if the food is not entered for consumption in the U.S. but entered solely for export from a bonded warehouse?

A: No. Facilities that manufacture/process, pack, or hold food products entering the U.S. that will not be consumed in the U.S. (e.g., for the sole purpose of transshipment to another country) 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 United States. However, food entering the U.S. solely for reexport is subject to the Prior Notice of Imported Food regulation (21 CFR Part 1, Subpart I; 68 FR 58974; Oct. 10, 2003).

8.2 Q: [Added February, 2004] 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 selling 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).

8.3 Q: [Added February, 2004] What address should a mobile facility give on its registration? If the mobile facility consists of tables and scales, would that be a facility or would it be the physical site where the tables and scales are located?

A: As stated in the response to comment 38 of the Interim Final Rule, the address of a mobile facility is the fixed address of the owner or operator of the facility. The tables and scales would be considered part of the equipment of a mobile facility. The vehicle or conveyance that houses and transports the equipment would be the mobile facility.

8.4 Q: [Added February, 2004] 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. The storage building would appear to be exempt from facility registration as an operation incidental to the restaurant. Is this accurate?

A: The restaurant exemption applies to the storage facility described in this question, because it is the same facility (i.e., in the same general area and under the same ownership.) If the warehouse was at a separate location or separately owned, it would be considered a distinct facility that would be required to be registered.

9. Food:

9.1 Q: [Added February, 2004] 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 with FDA under the Bioterrorism Act.

9.2 Q: [Added February, 2004] Are pharmaceuticals considered "food" for purposes of the registration requirement?

A: Pharmaceuticals are not "food," 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 with FDA under the registration Interim Final Rule. 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- 594-0054). FDA further notes that under §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," not a drug. Accordingly, facilities that manufacture/process, pack, or hold dietary supplements or components of dietary supplements are required to be registered unless they qualify for an exemption from registration.

9.3 Q: [Added February, 2004] 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 considered "food" under 21 CFR §1.227(b)(4).

9.4 Q: [Added February, 2004] 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 statute or FDA regulations but is generally used to refer to a food contact substance. The registration Interim Final Rule excludes from the definition of "food" food contact substances as defined in § 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 because such chemicals are not food or components of food within the meaning of the Interim Final Rule. If the substance in question is intended to have a technical effect in/on the food, however, it is "food" within the meaning of 21 CFR 1.227(b)(4). If an owner, operator, or agent in charge of a manufacturing facility for a substance 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.

In this question, the manufacturer knows how the "indirect additive" substance will be used. Accordingly, if the "indirect additive" substance is intended to have a technical effect in the food of which it is a component, the facility in which the substance is manufactured/processed, packed, or held must be registered with FDA. See comment 62 and FDA's response at 68 FR 58894 at 58910 (Oct. 10, 2003) for additional information.

9.5 Q: [Added February, 2004] 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. The Interim Final Rule recognizes a distinction between food contact substances and all other food additives, and defines "food" for purposes of the rule to exclude food contact substances. If the enzymes in question are added to food and are intended to have a technical effect in the food, the facility is required to be registered. If 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 with FDA.

9.6 Q: [Added February, 2004] Are gum base substances such as polyvinyl acetate used to produce chewing gum base subject to these regulations?

A: For the purposes of the registration Interim Final Rule, chewing gum is a "food." (In fact, the registration Interim Final Rule lists chewing gum as an example of "food" covered by the rule.) Because polyvinyl acetate chewing gum base is an ingredient of chewing gum, a facility that manufactures/processes, packs, or holds it is required to be registered with FDA, unless such facility satisfies an exclusion under the rule.

9.7 Q: [Added February, 2004] What about items that are not considered products for consumption but are partially consumed such as "chap stick" or toothpaste?

A: Cosmetics such as lip balm and toothpaste are not "food," 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, facilities in which these items are manufactured/ processed, packed, or held are not required to be registered with FDA.

9.8 Q: [Added February, 2004] Does a facility need to be registered if it manufactures raw materials for dietary supplements?

A: Dietary supplements are "food" for purposes of the registration Interim Final Rule. See 1 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 with FDA.

9.9 Q: [Added February, 2004] My company manufactures food packaging. Are food-packaging facilities exempt from the food facility registration provisions?

A: Yes. The definition of "food" in the registration Interim Final Rule excludes food contact substances as defined in § 409(h)(6) of the FD&C Act (21 U.S.C. 348(h)(6)). Consequently, facilities that manufacture/process, pack, or hold food contact substances are not required to be registered with FDA.

9.10 Q: [Added February, 2004] Are facilities in which food used in research and development or as product samples is manufactured/processed, packed, or held required to be registered with FDA?

A: Yes. Food used in research and development or as product samples is "food" for purposes of the registration Interim Final Rule. Accordingly, facilities that manufacture/process, pack, or hold food used in research and development or as product samples are required to be registered with FDA. However, if the food is not for consumption in the U.S. by humans or animals, facilities that manufacture/process, pack, or hold such food are not required to be registered.

9.11 Q: [Added February, 2004] Are what are called "secondary direct additives" and listed in 21 CFR Part 173 considered "food contact substances" as defined in

§ 409(h)(6) of the FD&C Act, and therefore, exempt from registration requirements?

A: The answer to this question depends upon the specific use of the substance in question. The regulations in 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 Part 173 is exempt from registration only if the substance satisfies the definition of "food contact substance" in § 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 Part 173 is required to be registered with FDA.

10. Holding:

10.1 Q: Are local collecting facilities 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. FDA understands the term "collecting facilities" to refer to facilities that store or hold food, such as silos or grain elevators. Such a facility must be registered with FDA because food (grain) is held by the facility (21 CFR 1.225; 1.227(b)(5)).

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

A: Yes. The facility in this example is holding food and therefore, must be registered (21 CFR 1.225; 21 CFR 1.227(b)(5)).

10.3 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 the finished products are held at a third party facility prior to export to the U.S., the facility is required to be registered (21 CFR 1.225; 1.227(b)(5)).

10.4 Q: [Added December 30, 2003] 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 United States." 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.

10.5 Q: [Added December 30, 2003] 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. For purposes of the registration Interim Final Rule, post offices and express courier facilities are not required to be registered with FDA as food facilities. The activities of both 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 the Interim Final Rule (21 CFR 1.226(b)(2)) does not include transportation vehicles "if they hold food only in the usual course of business as carriers." Although the registration Interim Final Rule does not define "transportation vehicles," the proposed rule on the establishment and maintenance of records (68 FR 25188 at 25238; May 9, 2003) defines "transporter" as "a person who has possession, custody, or control of an article of food -- 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 house 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, for the purpose of the registration Interim Final Rule, post offices and express courier facilities operating in a manner comparable to post offices that are part of the transportation network and have possession, custody, or control of food for the sole purpose of transporting it are not required to be registered with FDA.

10.6 Q: [Added December 30, 2003] 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. The analysis for post offices and similar facilities is also applicable here. Thus, for the purpose of the registration Interim Final Rule, 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 with FDA.

FDA acknowledges that this response is not completely consistent with certain prior guidance (Response to Comment 36; 68 Fed. Reg. 58894 at 58904; October 10, 2003). The agency has further considered this issue, as well as related ones, resulting in a revision of the earlier guidance.

10.7 Q: [Added February, 2004] Is a vessel carrier considered a facility for purposes of this regulation if the vessel is only engaged in transporting food from one facility to another facility?

A: No. A vessel carrier that holds food only in its usual course of business as a carrier is exempt from registration as a transport vehicle.

10.8 Q: [Added February, 2004] Must foreign storage facilities that hold finished food products prior to export to the U.S. be registered?

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

10.9 Q: [Added February, 2004] 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 noted in the response to Question 10.8, 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 foreign facility.

10.10 Q: [Added February, 2004] 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 § 415(b)(1) of the FD&C Act, a restaurant is not a "facility" for purposes of registration. The Interim Final Rule, 21 CFR 1.227(10), defines a restaurant 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)(2).

11. Manufacturing/Processing:

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

A: No. The Interim Final Rule states that "treating" food is a manufacturing/processing activity (21 CFR 1.227(b)(6); also see the response to Comment 41 in the rule). Therefore, a foreign facility that performs fumigation of food that is for consumption in the U.S., is required to be registered unless another foreign facility conducts further manufacturing/processing of more than a *de minimis* nature before the food is shipped to the U.S. FDA notes that even if fumigation were considered to be a *de minimis* activity, the facility at which the fumigation occurs would be required to be registered. The Bioterrorism Act *de minimis* provision is relevant to whether a particular foreign facility that manufactures/processes, packs, or holds food prior to the "*de minimis* facility" is required to be registered. The response to comment 17 in the preamble of the Interim Final Rule also discusses fumigation of cocoa beans.

11.2 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 feed for sale to livestock operations?

A: FDA notes that the answer to this question depends in part on whether the cotton by-products are "food" as defined in the interim final rule (21 CFR 1.227(b)(4)) and whether the establishment housing the cotton gins is domestic or foreign.

In the preamble to the Interim Final Rule, FDA responded to a comment (Comment 62) regarding facilities that manufacture/process, pack, or hold multi-use substances. (68 Fed. Reg. 58894 at 58910; October 10, 2003.) The agency believes that discussion is relevant to this question. In the Interim Final Rule, the agency stated that "a product is one that will be used for food if the owner, operator, or agent in charge of the facility reasonably believes that the substance in question is reasonably expected to be directed to a food use." In this example, the facility containing the cotton gins is a food facility because the owner, operator, or agent in charge of the facility 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 feed), and the facility does not appear to satisfy any exemption from registration. FDA notes that any subsequent facility that processes the cotton seed and hulls into animal feed is also required to be registered.

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

11.3 Q: [Added February, 2004] Do we have to register all of our manufacturing/processing sites even if there is only one involved with food products sent to 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.

12. Packing:

FDA has addressed questions we received on this issue in the Interim Final Rule.

13. Trade Names:

13.1 Q: [Added February, 2004] 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)(12), 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 a facility.

14. US Agent:

14.1 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)(13); 1.233(e)).

14.2 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 requirement for such an agent is 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, persons, 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.

14.3 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: In the preamble to the Interim Final Rule (Comment 90), FDA noted that the agency has concerns that acting as a U.S. agent may conflict with the duties of foreign government representatives. 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.

14.4 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. The Interim Final Rule requires that each foreign facility 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. FDA notes that 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 the response to comment 86 in the preamble to the Interim Final Rule further discuss this issue.

14.5 Q: Is the U.S. agent legally liable in the event something goes wrong with food manufactured/processed, packed, or held at the foreign facility for which he serves as U.S. agent?

A: FDA generally does not intend to hold a foreign facility's U.S. agent responsible for violations of the Bioterrorism Act that are committed by the foreign facility. FDA, however, would consider legal action against a U.S. agent where the agent knowingly submits false information to FDA or the U.S. agent and the foreign facility are effectively the same entity. Liability issues between the facility and its U.S. agent must be resolved between the private parties (i.e.,

the facility and its U.S. agent), most likely through the terms of their contractual relationship.

14.6 Q: [Added February, 2004] What, if any, involvement will FDA have in the business relationship between a U.S. agent and its foreign principal? Will FDA take any action to enforce or otherwise intervene in that business relationship?

A: FDA does not intend to have any involvement in the business relationship between a foreign principal and its U.S. agent because the principal/agent relationship is a private matter between the two parties. FDA generally will not take any action to enforce or otherwise intervene in that business relationship, nor does FDA intend to hold the U.S. agent responsible for violations of the Bioterrorism Act that are committed by the foreign facility. FDA will, however, consider legal action against a U.S. agent if the agent knowingly submits false information to FDA or the agent and the foreign facility were effectively the same entity.

14.7 Q: [Added February, 2004] What type of routine communications will occur between FDA and a facility's U.S. agent?

A: Routine communications may include notification of new guidance or regulations that may have an impact on the facility, or public meetings that may be of interest to the facility's owner, operator, or agent in charge.

14.8 Q: [Added February, 2004] Is a power of attorney required for a U.S. agent to work on behalf of the facility?

A: The Interim Final Rule does not require that a facility's U.S. agent have a power of attorney from the facility, nor is such arrangement precluded by the Interim Final Rule.

14.9 Q: [Added February, 2004] 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, by submitting a registration update either electronically or through the paper system. 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.

14.10 Q: [Added February, 2004] 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 United States and is physically located in the U.S. The U.S. Agent must have a U.S. phone number.

- 14.11 Q:** [Added February, 2004] 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: The Interim Final Rule (21 CFR 1.227(13)) establishes only two qualifications for a U.S. agent: the agent is required (1) to reside or maintain a place of business in the United States and (2) to be physically present in the United States. Although the registration Interim Final Rule does not require that the U.S. agent 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.

- 14.12 Q:** [Added February, 2004] How does a foreign facility "authorize" someone in the U.S. to be their agent (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.

- 14.13 Q:** [Added February, 2004] 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. See 21 CFR §1.234.

- 14.14 Q:** [Added February, 2004] Must foreign facilities belonging to the same parent company be registered by the same agent or may each of them use a different agent for registration and emergency contact purposes?

A: The Interim Final Rule permits, but does not require, a foreign facility to be registered by its U.S. agent. 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/all facilities belonging to the same parent company may designate the same U.S. agent for registration purposes.

14.15 Q: [Added February, 2004] 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 and emergency communications contemplated 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. As noted in 21 CFR 1.227(13)(iii), a firm's commercial business in the United States need not be conducted exclusively through the U.S. agent designated for registration purposes. Generally speaking, for questions related to imported food shipments subject to the prior notice requirement (21 CFR Part 1, Subpart I; 68 FR 58974, Oct. 10, 2003), FDA intends to contact the transmitter or submitter of the prior notice, not the U.S. agent for the facility associated with the shipment.

14.16 Q: [Added February, 2004] 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, would need to update the information identifying the facility's U.S. agent in the facility's registration. See 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. 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.

14.17 Q: [Added February, 2004] 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 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 required under the Interim Final Rule in any written agreement it has with its U.S. agent or emergency contact.

14.18 Q: [Added February, 2004] 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. The authorized individual may be, but is not required to be, the U.S. agent for the facility. However, an individual other than the U.S. agent may not register the facility unless authorized to do so by the facility's owner, operator, or agent in charge.

14.19 Q: [Added August, 2004]: 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" The interim final rule (21 CFR 1.227(b)(13)) defines "U.S. agent" as a "person ... residing or maintaining a place of business in the United States 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: The interim final rule for registration of food facilities states that a foreign facility's U.S. agent must satisfy two qualifications: the agent is required to reside or maintain a place of business in the United States and to be physically present in the United States. 68 Fed. Reg. 58894 at 58915 (October 10, 2003). Once the management of a foreign food facility identifies a person who satisfies these two criteria, FDA expects the management to contact the person and confirm that the person is willing and able to serve as the facility's U.S. agent. FDA intends that a person will be "designated" as a 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 3537 (DHHS/FDA -- Food Facility Registration Form) or in response to the appropriate prompt when a facility is registered electronically.

14.20 Q: [Added August, 2004]: What is the status of a foreign facility's registration where the person listed as the U.S. agent for the facility has not affirmatively agreed to serve as the facility's U.S. agent?

A: FDA contacts each person listed as a U.S. agent in a foreign food facility registration to determine whether such person has agreed to serve in such capacity. Where a person listed as U.S. agent notifies FDA that he has not agreed

to serve as the facility's U.S. agent, FDA intends to inform the facility (through its owner/operator/agent-in-charge) of that fact and request that the facility's registration be amended 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/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 specified time period, FDA intends to regard the facility's registration to be invalid, and the agency plans to consider flagging the registration as invalid in FDA's electronic system.

14.21 Q: [Added August, 2004] What will happen to an article of food that is imported or offered for import into the United States from a facility with a registration that FDA considers to be invalid because it does not include a U.S. agent who has affirmatively agreed to serve in that capacity?

A: Where FDA considers invalid a registration for the facility of the manufacturer or shipper of an article of food imported or offered for import into the United States, the shipment will be held at the U.S. border until the facility's registration is amended to list a U.S. agent who has affirmatively agreed to serve as such.

15. Other Definitions:

15.1 Q: [Added December 30, 2003] How does FDA define "owner," "operator," and "agent in charge?"

A: The owner, operator, or agent in charge is a person (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).

15.2 Q: [Added December 30, 2003] 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.

D. When Must You Register?

16.1 Q: [Added February, 2004] If a shipment from Japan leaves before December 12, 2003, and arrives at the West coast on or after December 12, when are the manufacturers supposed to be registered? Or, does this act take effect on shipments leaving Japan on December 12, 2003 and after?

A: All facilities subject to the registration requirements were required to be registered by December 12, 2003. Therefore, a facility in Japan producing the food for consumption in the U.S. is required to be registered by December 12, 2003. Facilities that have not registered as required still may do so either electronically or by paper, as specified in the Interim Final Rule. A facility that begins after December 12, 2003, to manufacture/process, pack, pack, or hold food for consumption in the U.S. is required to be registered before it begins operations.

E. How and Where Do You Register?

Please see the guidance posted at <http://www.cfsan.fda.gov/~furls/ffrmqa.html> for questions and answers regarding this issue.

F. What Information is Required in the Registration?

FDA has addressed questions we received on this issue in the [Interim Final Rule](#).

G. What Optional Items are Included in the Registration Form?

FDA has addressed questions we received on this issue in the [Interim Final Rule](#).

H. How and When Do You Update Your Facility's Registration Information?

FDA has addressed questions we received on this issue in the [Interim Final Rule](#).

I. How and When Do You Cancel Your Facility's Registration Information?

FDA has addressed questions we received on this issue in the [Interim Final Rule](#).

J. What Other Registration Requirements Apply?

FDA has addressed questions we received on this issue in the [Interim Final Rule](#).

K. What Are the Consequences of Failing to Register, Update, or Cancel Your Registration?

FDA has addressed questions we received on this issue in the [Interim Final Rule](#).

L. What Does Assignment of a Registration Number Mean?

FDA has addressed questions we received on this issue in the Interim Final Rule.

M. Is Food Registration Information Available to the Public?

- 17.1 **Q:** [Added February, 2004] 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 (See 21 CFR 1.281(a)(6)) and thus, be unable to import the shipment.

- 17.2 **Q:** [Added February, 2004] We have received a lot of requests from our customers to send them our registration number. Can we reveal our registration number?

A: Section 415(a)(4) of the FD&C Act prohibits FDA from publicly disclosing certain registration-related information. 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 product manufacture by the facility. The Bioterrorism 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. This type of agreement could limit the opportunity for an unauthorized entity to use a facility's registration number.

- 17.3 **Q:** [Added February, 2004] 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: As noted, § 415(a)(4) of the FD&C Act prohibits disclosure of such information by FDA. 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.

- 17.4 **Q:** [Added February, 2004] Will FDA require the registration number to be displayed as part of a product label?

A: No. There is no requirement to list on the label for a product the registration number (or numbers) for the facility (or facilities) associated with the product. FDA, however, discourages facilities from including their registration numbers on

the labels of their products to prevent others from using the registration number for improper purposes.

N. General Registration Questions

18.1 Q: [Added February, 2004] Will the 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.

* This is a revision of the third edition of the FDA guidance "Questions and Answers Regarding Registration of Food Facilities," which FDA issued on February 17, 2004.

⁽¹⁾This guidance has been prepared by the Center for Food Safety and Applied Nutrition (CFSAN) at the U.S. Food and Drug Administration.