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Questions and Answers Regarding Food Facility Registration (Seventh Edition): Guidance for Industry

Draft Guidance

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For questions regarding this draft document, contact FDA's Technical Assistance Network by submitting the form available at <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm459719.htm>.

**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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This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or we) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance listed on the title page.

I. INTRODUCTION

On October 10, 2003, the Food and Drug Administration (FDA or we) 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) (68 FR 58894). 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 United States to register with FDA. This guidance was developed to answer frequently asked questions relating to the registration requirements of section 415 of the FD&C Act.

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 Title 21, Code of Federal Regulations (CFR), Section 10.115 (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. The sixth edition was issued as Level 1 guidance and included one additional question and answer relating to a proposed change to the "farm" definition in 21 CFR 1.227 (79 FR 58524; September 29, 2014). The new question and answer was identified with the date that it was added to the guidance. The sixth edition was immediately effective because FDA had determined that prior public participation was not feasible or appropriate.

¹ This guidance has been jointly prepared by the Office of Compliance in the Center for Food Safety and Applied Nutrition, the Office of Surveillance and Compliance in the Center for Veterinary Medicine, and the Office of Regulatory Affairs at the U.S. Food and Drug Administration.

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This revision (Seventh Edition) is being issued as Level 1 draft guidance pursuant to 21 CFR 10.115 and includes additional questions and answers relating to the Amendments to Registration of Food Facilities final rule (Registration Final Rule) (81 FR 45912; July 14, 2016) that revised FDA’s registration regulations and other questions and answers regarding food facility registration. The new questions and answers are identified with the date that they were added to the guidance. We also revised information in existing questions and answers, deleted some questions and answers, and made editorial changes (e.g., reorganized existing questions and answers) to improve clarity. For the revised questions and answers, we have not added a date indicating when the questions and answers were revised.

“I”, “you,” “your” or “registrant” are used in this guidance to refer to the owner, operator, or agent in charge of a facility that manufacturers/processes, packs, or holds food for consumption in the United States.

FDA’s guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe our 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

A.1 Who must register under the food facility registration requirements?

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 United States, you must register with FDA, unless you are exempt under 21 CFR 1.226 from the requirement 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 (21 CFR 1.225(b)). 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 (see 21 CFR 1.225(c) and 1.230(a)). A foreign facility’s U.S. agent may, but is not required to, register the facility (21 CFR 1.230).

B. Who is Exempt from Registration?

1. Farms

B.1.1 [Added December 2016] Are farms exempt from registration?

Under 21 CFR 1.226(b), farms are not required to register. “Farm” is defined in 21 CFR 1.227 as:

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(1) Primary production farm. A primary production farm is an operation under one management in one general (but not necessarily contiguous) physical location devoted to the growing of crops, the harvesting of crops, the raising of animals (including seafood), or any combination of these activities. The term “farm” includes operations that, in addition to these activities:

(i) Pack or hold raw agricultural commodities;

(ii) Pack or hold processed food, provided that all processed food used in such activities is either consumed on that farm or another farm under the same management, or is processed food identified in paragraph (1)(iii)(B)(1) of this definition; and

(iii) Manufacture/process food, provided that:

(A) All food used in such activities is consumed on that farm or another farm under the same management; or

(B) Any manufacturing/processing of food that is not consumed on that farm or another farm under the same management consists only of:

(1) Drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins), and packaging and labeling such commodities, without additional manufacturing/processing (an example of additional manufacturing/processing is slicing);

(2) Treatment to manipulate the ripening of raw agricultural commodities (such as by treating produce with ethylene gas), and packaging and labeling treated raw agricultural commodities, without additional manufacturing/processing; and

(3) Packaging and labeling raw agricultural commodities, when these activities do not involve additional manufacturing/processing (an example of additional manufacturing/processing is irradiation); or

(2) Secondary activities farm. A secondary activities farm is an operation, not located on a primary production farm, devoted to harvesting (such as hulling or shelling), packing, and/or holding of raw agricultural commodities, provided that the primary production farm(s) that grows, harvests, and/or raises the majority of the raw agricultural commodities harvested, packed, and/or held by the secondary activities farm owns, or jointly owns, a majority interest in the secondary activities farm. A secondary activities farm may also conduct those additional activities allowed on a primary production farm as described in paragraph (1)(ii) and (iii) of this definition.

Therefore, if your farm operation conducts activities that fall within the definition of “farm” in 21 CFR 1.227, the farm is exempt from registration. However, if your farm is a “farm mixed-type facility,” you must register. For a discussion of “farm mixed-type facility,” please see Question B.1.5 in this document.

For more information on activities that are within the “farm” definition, please see our draft guidance entitled, “Classification of Activities as Harvesting, Packing, Holding, or Manufacturing/Processing for Farms and Facilities” (81 FR 58421; August 25, 2016).

B.1.2 Is an establishment that conditions seed and sells seed to farmers for cultivation a facility that is required to register if some of the seed sold is intended to be used as animal

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food?

A facility that manufactures/processes, packs, or holds food for consumption in the United States is required to register. “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. An establishment that conditions and sells seed to farmers for planting purposes is typically excluded from the requirements for registration. However, an establishment that conditions seed for planting purposes 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. Whether a particular establishment is required to register will depend on the specific nature of the establishment. This would include situations where seeds are sent for use as animal food because they become cracked, damaged, culled, or are otherwise not suitable for cultivation. However, some establishments may direct such cracked, damaged, culled, or excess seeds for incineration and landfilling. If the seed is reasonably expected only to be cultivated or destroyed (e.g., by incineration or landfill), the establishment is not required to register. (See Comment 3 in the Registration Final Rule; 81 FR 45912 at 45919).

B.1.3 Is a farm that grows tomatoes and sells them directly to consumers from a roadside stand located on the farm exempt from registration?

Yes. Assuming that the farm on which the tomatoes are grown otherwise satisfies the definition of “farm” (21 CFR 1.227), 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.1.4 If a farm located in a foreign country ships food directly to the United States, is it required to register?

No. A “farm” located in a foreign country that ships food directly to the United States is exempt from the registration requirements of section 415 of the FD&C Act (21 U.S.C. 350d; 21 CFR 1.227). However, if prior to shipping to the United States, 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 Question C.3.8 in this document.

B.1.5 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?

Yes. The term “mixed-type facility” means an establishment that engages in both activities that are exempt from registration and activities that require the establishment to be registered. An example of such a facility is a “farm mixed-type facility,” which is an establishment that is a farm, but also conducts activities outside the farm definition that require the establishment to be registered (21 CFR 1.227). In this example, the farm mixed-type facility is required to register

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because its processing activities are not covered by the “farm” definition in 21 CFR 1.227.

B.1.6 Is use of chlorinated water to wash lettuce on a farm considered "processing," necessitating registration of the farm?

If the farm is washing lettuce using water directly from a public or other water supply that is chlorinated for other purposes, FDA will consider this activity “harvesting” or “packing” within the meaning of “farm” in 21 CFR 1.227. Accordingly, an establishment using chlorinated water in this manner is a farm and is not required to register.

B.1.7 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?

We consider labeling, including stickering, to be a “manufacturing/processing” activity. However, placing labels (e.g., stickers) directly on raw agricultural commodities (RACs), on boxes or other containers holding packed RACs, or on consumer packages containing RACs, is within the “farm” definition. (See “farm” definition in 21 CFR 1.227 at (1)(iii)(B)(3)).

B.1.8 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 register?

No. The packing shed would not have to register because it would be considered a secondary activities farm. According to 21 CFR 1.227, a “secondary activities farm” is an operation, not located on a primary production farm, devoted to harvesting (such as hulling or shelling), packing, and/or holding of RACs, provided that the primary production farm(s) that grows, harvests, and/or raises the majority of the RACs harvested, packed, and/or held by the secondary activities farm owns, or jointly owns, a majority interest in the secondary activities farm.

B.1.9 [Added December 2016] Does a farm that packs fresh produce from other farms have to register? Does a farm that packs its own produce have to register?

No. According to the definition of “farm” in 21 CFR 1.227, an establishment devoted to the growing of crops, the harvesting of crops, the raising of animals, or any combination of these activities, would remain within the “farm” definition if it packs or holds RACs, regardless of whether the farm packs or holds RACs grown on that farm, RACs grown on a another farm under the same management, or RACs grown on another farm under different management. Any such operation that meets the “farm” definition is not subject to the requirement to register under section 415 of the FD&C Act.

B.1.10 Does a farm need to register 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?

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No. The “farm” definition provides for farms to pack food (21 CFR 1.227 at (1)(i)). Wrapping produce and placing it into cartons for transporting the food off the farm is packing and is within the “farm” definition.

B.1.11 Is a farm required to register if the owner of the farm 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.

No. The farm in this example is exempt from registration. Moreover, the farm is exempt from registration regardless of whether the clamshell is the container that the consumer receives. If the strawberries are placed into clamshells that are not the containers that will be received by the consumer, such activity is “packing” under 21 CFR 1.227. The definition of a “farm” in 21 CFR 1.227 includes farms that pack RACs, and so the farm would not have to register. Alternatively, placing strawberries into a container that directly contacts the food and that the consumer receives is “packaging” under 21 CFR 1.227, which is an example of manufacturing/processing. However, the definition of “farm” provides that a farm may package and label RACs that are not consumed on that farm or on another farm under the same management as long as the packaging and labeling do not involve additional manufacturing/processing, so the farm in such case would not have to register.

Furthermore, the truck that transports the workers and the filled containers off the farm is not a facility that is required to register because it is holding the food only in its usual course of business as a carrier (21 CFR 1.227, definition of “facility”).

B.1.12 On some farms, vegetables are removed from the ground, field trimmed, washed, and then transferred to a truck in the field where they are placed in a consumer package, cooled, and held before being moved off the farm by a transport vehicle. The truck (i.e., mobile operation) that packages and cools the RACs is a separate operation (i.e., is under different management) from the operation that performs the other activities, and the truck performs this function on multiple farms. Is the operation performing activities before the vegetables are transferred to the truck for cooling and packaging or the truck operation where the vegetables are cooled and packaged required to register with FDA?

The operation removing vegetables from the ground, field trimming, washing, and transferring them to a truck is a primary production farm. All of these activities, as conducted by the operation, are performed on RACs and can be classified as “harvesting” and/or “holding” within the farm definition. Therefore, it is not required to register.

The mobile operation also is not required to register. The cooling conducted by the mobile operation is considered to be a “harvesting” activity because it is performed on RACs in the same general physical location where the RACs were grown or raised. This harvesting activity makes the mobile operation a primary production farm, and primary production farms may also package RACs (providing the packaging involves no additional manufacturing/processing) within the farm definition.

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B.1.13 Is a truck-mounted operation that removes carrots from the ground, chops them into roughly 1-inch pieces, and then places them into consumer-ready bags before transporting them off the farm for distribution required to register?

The truck-mounted operation is a farm mixed-type facility because it is a farm, but it also conducts activities outside the farm definition that require registration. Removing carrots from the ground is considered harvesting and makes the operation a primary production farm. Chopping the carrots into 1-inch pieces is a “manufacturing/processing” activity that is outside the farm definition and triggers the registration requirement. Once chopped, the carrots are not RACs and therefore placing them in consumer-ready bags is packaging processed food, another “manufacturing/processing” activity outside of the farm definition.

B.1.14 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?

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). “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.” Bottling wine 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 register. Furthermore, the exception in 21 CFR 1.227 for farms (both primary production farms and secondary activity farms) that perform packaging and labeling without additional manufacturing/processing only applies to packaging and labeling of RACs, and wine is a processed food.

B.1.15 Are maple syrup producers “farms” and, thus, exempt from registering?

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). Therefore, the farm is exempt from registration. However, concentrating sugar maple sap by heating is a form of “manufacturing/processing” (21 CFR 1.227). Accordingly, a facility that concentrates sugar maple sap is performing a “manufacturing/processing” activity and is required to register, unless all of the concentrated sap is consumed on the farm or another farm under the same management.

B.1.16 Does a farm need to register if it grows a crop, harvests it, and holds it for a period of time before shipping it to a distributor (e.g., grain elevator) or manufacturer/processor?

No. Holding a harvested crop for a period of time before providing it to a distributor or manufacturer/processor does not result in the farm being required to register. (For a full discussion of what constitutes a farm, see Question B.1.1).

B.1.17 If a farm grows hay and sells the hay as animal food to a dairy farm that is not

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under the same management, does the hay farm need to register? Does the dairy farm need to register? Is registration dependent on how long the farm holds the hay before it sells it?

No. The farm growing and selling the hay is a “farm” because the associated activities are considered part of either growing, harvesting, or holding a RAC, which are activities that fall within the “farm” definition in 21 CFR 1.227. Therefore, the farm is not required to register. (See Question B.1.1). The dairy farm would not be required to register solely on the basis of buying or receiving the hay, but for more information on dairy farms specifically, see Question B.1.23. Registration is not dependent on how long the farm holds the hay before it sells it because the duration of holding the hay does not affect whether the operation is a farm.

B.1.18 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?

Even though the potato crop has been sold to a potato processor, until the potatoes are removed from the farm and stored at an off-farm facility, there is no requirement that the farmer or processor register the farm as a food facility. 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.

B.1.19 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. Do any of these activities constitute manufacturing/processing, thus necessitating registration for this farm?

No. Cutting (or otherwise separating) the edible portion of a RAC from the crop plant and removing or trimming part of the RAC (e.g., foliage, husks, roots or stems) are harvesting activities that are traditionally performed on farms for the purpose of removing RACs from the place they were grown or raised and preparing them for use as food. Washing the leaves in this context would be considered part of harvesting. Drying/dehydrating a RAC to create a distinct commodity is a manufacturing/processing activity; however, it is provided for in the “farm” definition, as long as there is no additional manufacturing/processing (e.g., chopping) done to the RAC. Therefore, if the peppermint farmer cuts, trims, and washes the leaves, and then places the harvested leaves in a barn to allow them to dehydrate, and no additional manufacturing/processing is conducted on the peppermint, the farm would not be required to register.

B.1.20 [Added December 2016] Am I required to register my farm if I sell grain stored on my farm to a neighboring farm, and the grain could be used by the neighboring farm as animal food?

No. A farm that grows grain, stores it on the farm, and then sells that grain to a neighboring farm

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or another person is acting within the definition of “farm” in 21 CFR 1.227. The farm would still be exempt from registration even if the neighboring farm or other person uses the grain as human or animal food at a later time.

B.1.21 [Added December 2016] Am I required to register if I extract and bottle honey produced on my farm (i.e., remove the wax seal and spin the honey out of the honeycomb, then bottle the honey)?

No. Many activities associated with beekeeping and honey production are within the “farm” definition and therefore do not require registration. In this case, extracting honey is considered harvesting and bottling honey is packaging a RAC, which is a type of manufacturing/processing included within the “farm” definition.

B.1.22 [Added December 2016] Is a business that is not owned by farmers, and not located on a primary production farm, that collects honeycombs or honey from multiple farms, packs it (e.g., in 10-gallon containers), and sends it to a processing facility required to register?

Yes. The operation is a packing facility that does not meet the definition of a “secondary activities farm” (see 21 CFR 1.227) and is required to register.

B.1.23 [Added December 2016] If cows are milked on a farm and the milk is then picked up from the farm and transported by tanker to a cooperative, is the farm required to register?

If the cows are milked, and the milk is stored in refrigerated storage tanks at the dairy farm to be picked up by a milk tanker for processing, the dairy farm is not required to register, because the milking of cows and storing of milk are activities that fall within the definition of “farm” in 21 CFR 1.227. FDA considers milking of cows to be “harvesting” when applied to animals, because it is akin to harvesting crops. However, if the dairy farm manufactures/processes the milk, for example, by pasteurizing it, and all milk used in such activities is not consumed on that farm or another farm under the same management, the dairy farm would be a mixed-type facility and would have to register.

B.1.24 [Added December 2016] If a farmer makes silage and sells that silage to another farmer for use as animal food, would the farmer be required to register?

Silage is a processed food made by fermenting (ensiling) green vegetation (e.g., alfalfa, clover, corn). A farm may manufacture/process food and remain within the “farm” definition, if all the food that is manufactured/processed is consumed on that farm or another farm under the same management. If the processed food is consumed on a farm under different management, then the farm manufacturing the food becomes a farm mixed-type facility and is required to register. Therefore, in this example, the silage farmer would be required to register because the farmer is selling silage to another farm under different management.

B.1.25 [Added December 2016] Does a farm that mills and bags animal food for sale have to

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register?

An on-farm operation that manufactures and processes food for livestock or poultry (e.g., a feed mill) does not remain within the definition of “farm” in 21 CFR 1.227 if the sale of that food is to a farm under different management, even if the raw ingredients are grown on the farm that has the feed mill. The establishment is a farm mixed-type facility and required to register. (See Question B.1.5).

However, a farm that includes an operation that manufactures/processes and packs animal food (e.g., mills and bags animal food) can be within the definition of “farm” in 21 CFR 1.227 as long as all of that animal food is consumed on that farm or another farm under the same management. Because it is a farm, it is not required to register.

B.1.26 [Added December 2016] If a farm accumulates animal carcasses and sends the carcasses to a rendering plant to be added to animal food, is the farm required to register?

No. A farm may hold RACs and remain within the “farm” definition. Unprocessed animal carcasses destined for rendering into animal food are a RAC. The definition of “farm” in 21 CFR 1.227 allows holding of one’s own RACs and others’ RACs. Therefore, even if a farm is accumulating carcasses from other farms, that fact would not require it to register.

B.1.27 [Added December 2016] Am I required to register if I grow vegetable/fruit crops and send the oversupply from these crops to animal food without further manufacturing or processing?

No. The farm is not required to register, because these activities—growing, harvesting, and holding unprocessed fruits and vegetables for food use (human and/or animal)—fall within the definition of “farm” in 21 CFR 1.227.

B.1.28 Does an agricultural feed cooperative that manufactures animal food (e.g., operates a feed mill) and is recognized as a cooperative under U.S. laws have to register?

Whether the agricultural feed cooperative manufacturing operation has to register depends on whether the operation meets one of the exemptions in 21 CFR 1.226, such as being a farm.

Example 1: A cooperative consists of member farms that own and manage a feed mill, and the feed mill sells animal food to the member farms and other non-member farms. The cooperative feed mill would not meet the “retail food establishment” exemption because it is selling to farms (businesses) rather than to consumers. It would not meet the definition of a “farm” because the manufactured/processed food is not consumed on farms under the same management, since the feed mill is not under one management with the various individual farms that are purchasing the animal food from the feed mill. The feed mill would be required to register

Example 2: A cooperative manages a feed mill and also manages an operation in the same general (but not necessarily contiguous) physical location as the feed mill, devoted to raising

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animals that are eating all the food produced by the feed mill. The feed mill does not sell the manufactured/processed food to any other buyers. The operation managed by the cooperative would meet the definition of a “farm” in 21 CFR 1.227 and the feed mill that is part of that operation would not be required to register.

B.1.29 [Added December 2016] Algae may be grown in shallow outdoor ponds, inside greenhouses, or in fermentation-type vessels. Do such facilities have to register? Does an operation that both grows and processes algae have to register?

An operation that grows algae for use in human or animal food and that is under one management in one general (but not necessarily contiguous) physical location, whether the algae is grown outdoors or indoors, is growing a crop and would be considered a primary production farm (see the definition of “farm” in 21 CFR 1.227). A farm that also processes algae would be a farm mixed-type facility, an establishment that engages in both activities that are exempt from registration under section 415 of the FD&C Act and activities that require the establishment to register (see the definition of “mixed-type facility” in 21 CFR 1.227). A farm is exempt from registration. As noted in Question B.1.5, a farm mixed-type facility is required to register.

2. Retail Food Establishments

B.2.1 Does a warehouse club that sells to both consumers and businesses need to register?

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.2.2 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 register?

The supermarket is exempt from registration as a “retail food establishment” (21 CFR 1.227) if its primary function is to sell food products directly to consumers from the supermarket. 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.

B.2.3 Are retail food establishment storerooms, distribution centers, or warehouses considered "holding facilities" that are required to register?

If a facility is a "retail food establishment" under 21 CFR 1.226(c) and 1.227, storerooms for the retail food establishment that are co-located with, and thus, part of, the retail food establishment,

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are not required to register. 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" in 21 CFR 1.227 because it does not sell food from the facility directly to consumers. Thus, the distribution centers and warehouses are required to register.

B.2.4 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?

No. A "retail food establishment" may manufacture/process, pack, or hold food if the establishment's primary function is to sell food from that establishment directly to consumers (see definition of "retail food establishment" in 21 CFR 1.227).

B.2.5 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 register?

No. The bakery is a "retail food establishment" and does not need to register. 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.2.6 [Added December 2016] Are self-service ice vending machines required to register?

No. Under 21 CFR 1.227, a "retail food establishment" includes grocery stores, convenience stores, and vending machines. Therefore, vending machines that sell food products directly to consumers as their primary function are exempt from registration as retail food establishments.

B.2.7 [Added December 2016] How did the Registration Final Rule amend the definition of "retail food establishment?"

As a result of section 102 of FSMA, the Registration Final Rule amended the definition of "retail food establishment" in 21 CFR 1.227 to clarify that:

- Sale of food directly to consumers from an establishment located on a farm includes sales by that establishment directly to consumers:
 - At a roadside stand (a stand situated on the side of or near a road or thoroughfare at which a farmer sells food from his or her farm directly to consumers) or farmers' market (a location where one or more local farmers assemble to sell food from their farms directly to consumers);
 - Through a community supported agriculture program. Community supported agriculture (CSA) program 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. This includes CSA programs in

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- which a group of farmers consolidate their crops at a central location for distribution to shareholders or subscribers; and
- At other such direct-to-consumer sales platforms, including door-to-door sales; mail, catalog and Internet order, including online farmers markets and online grocery delivery; religious or other organization bazaars; and State and local fairs.
- Sale of food directly to consumers by a farm-operated business includes the sale of food by that farm-operated business directly to consumers:
 - At a roadside stand (a stand situated on the side of or near a road or thoroughfare at which a farmer sells food from his or her farm directly to consumers) or farmers' market (a location where one or more local farmers assemble to sell food from their farms directly to consumers);
 - Through a community supported agriculture program. Community supported agriculture (CSA) program 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. This includes CSA programs in which a group of farmers consolidate their crops at a central location for distribution to shareholders or subscribers; and
 - At other such direct-to-consumer sales platforms, including door-to-door sales; mail, catalog and Internet order, including online farmers markets and online grocery delivery; religious or other organization bazaars; and State and local fairs.
 - A "farm-operated business" means a business that is managed by one or more farms and conducts manufacturing/processing not on the farm(s).

For example, an establishment located on a farm that sells apples it grows and apple pies it manufactures directly to consumers at a farmer's market would consider those sales in determining its primary function. At the same time, if a farmer manufactures or manages the manufacturing of jellies from the apples that he grows at an off-farm location, such as an incubator kitchen, and sells those jellies directly to consumers at a farmer's market, the jelly-making operation would be a farm-operated business and may consider those sales in determining its primary function.

We recognize that some farmers rent space at off-farm manufacturing/processing facilities, like shared kitchens, to conduct value-added processing. The "business" we are referring to in "farm-operated business" is the business entity conducting the manufacturing/processing operations. The ownership of the physical building, e.g., the ownership of the shared kitchen, where the manufacturing/processing occurs is not relevant. Thus, if an apple grower leases space at an off-farm incubator kitchen to manufacture apple jellies, ownership of the incubator kitchen building would not be relevant. Because the apple farmer manages the off-farm apple jelly manufacturing operation, the apple jelly manufacturing operation is a farm-operated business and eligible for the retail food establishment exemption from registration.

In addition, we recognize that some farms are members of cooperatives that pool RACs grown,

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harvested, or raised by member farms for value-added processing. The phrase “one or more farms” in the explanation of the meaning of “farm-operated business” allows cooperatives comprised of multiple farms performing certain manufacturing/processing activities to be eligible for the retail food establishment exemption from registration (see Comment 9 in the Registration Final Rule; 81 FR 45912 at 45921 to 45922).

B.2.8 [Added December 2016] Are farmers’ markets and roadside stands considered retail food establishments, including those markets and stands that sell food not manufactured or grown on the farm selling those foods?

Farmers’ markets and roadside stands may be retail food establishments even when they sell food products not manufactured or grown on the farm that is selling those foods. The test for whether such farmers’ markets and roadside stands are retail food establishments is whether they sell food directly to consumers as their primary function. The food sold directly to consumers can be produced by the farmers selling the food, but need not be (see Comment 10 in the Registration Final Rule; 81 FR 45912 at 45922).

B.2.9 [Added December 2016] Is there a limitation on the distance of roadside stands or farmers’ markets from the farms on which the food is produced?

No. For purposes of the definitions for farmers’ markets and roadside stands, as used in the definition of “retail food establishment” in 21 CFR 1.227, there is no limitation on the distance between the farmers’ market or roadside stand and the farms on which the food is produced (see Comment 12 in the Registration Final Rule; 81 FR 45912 at 45923).

B.2.10 What does “community supported agriculture program” mean for purposes of the “retail food establishment” definition?

The term “community supported agriculture (CSA) program,” which is used in the definition of “retail food establishment” in 21 CFR 1.227, 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. This includes CSA programs in which a group of farmers consolidates their crops at a central location for distribution to shareholders or subscribers.

B.2.11 [Added December 2016] For purposes of the “retail food establishment” definition, can CSAs sell food other than crops?

Yes. CSA activities are not limited to only selling “crops.” For example, a farm mixed-type facility may sell strawberries it grows and strawberry jam that it manufactures directly to consumers through a CSA. Whether the on-farm manufacturing establishment is a retail food establishment, and thus exempt from registration, would depend on whether its primary function is to sell food directly to consumers. The sale of food directly to consumers through a platform that resembles a CSA but does not sell crops could still be used in determining the establishment’s primary function. It may be possible for an establishment to consider sales through that platform in determining its primary function if the establishment either: (1) is

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located on a farm; or (2) is a farm-operated business and the requirements applicable to farm-operated businesses are met (see Comment 13 in the Registration Final Rule; 81 FR 45912 at 45923).

B.2.12 [Added December 2016] May sales from my on-farm manufacturing operation that are made via mail, catalog or Internet order, or through online farmers' markets or online grocery delivery be considered sales of food directly to consumers?

Yes. Sales of food directly to consumers from an establishment located on a farm or from a farm-operated business includes sales by such establishments directly to consumers at such direct-to-consumer platforms as mail, catalog, and Internet order, including online farmers markets and online grocery delivery.

B.2.13 [Added December 2016] If I supply food directly to consumers via the Internet or mail-order, am I a retail food establishment?

Maybe. Facilities that sell food directly to consumers via the Internet or mail-order may be retail food establishments, provided they meet the other criteria of the “retail food establishment” definition in 21 CFR 1.227 (see Comment 82 in the Interim Final Rule; 68 FR 58894 at 58914 to 58915).

B.2.14 [Added December 2016] For purposes of the “retail food establishment” definition, can sales at produce auctions, food hubs, and buying clubs be considered sales that are directly to consumers?

Sales at such platforms can be to different types of entities. In some cases, sales may be to consumers. However, sales may also be to restaurants, wholesalers and other businesses. An establishment’s direct sales to individual consumers at these platforms can be counted as sales to consumers. However, a direct sale to a business at these platforms cannot be counted as sales to consumers. Furthermore, a direct sale to a separate business that runs these platforms, rather than to specific buyers, would not be counted as sales to consumers because businesses (including businesses that run produce auctions) are not consumers (see Comments 15 and 17 in the Registration Final Rule; 81 FR 45912 at 45924).

B.2.15 [Added December 2016] Is there an income limitation included in the “retail food establishment” definition?

No. There is no income limitation for establishments to qualify as retail food establishments. As long as an establishment’s primary function is to sell food directly to consumers, it is a retail food establishment. 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 (21 CFR 1.227).

B.2.16 [Added December 2016] What types of facilities that sell animal food would be considered retail food establishments?

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A “retail food establishment” is an establishment that 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 (see 21 CFR 1.227). A pet store that sells animal food directly to consumers is an example of a type of animal food establishment that may be a retail food establishment. In some instances, a farm supply store, specialty bakery, hobby store, or other retail store that sells animal food, such as pet treats, (and also may sell human food) may be a retail food establishment if the annual monetary value of sales of food products directly to consumers (such as pet owners or other individuals) exceeds the annual monetary value of sales of food products to all other buyers (such as farms, which are considered businesses).

B.2.17 [Added December 2016] Do off-farm feed mills that sell all their animal food to the public need to register or do they qualify for a retail food establishment exemption?

Feed mills that manufacture/process, pack, or hold animal food for consumption in the United States are required to register, unless an exemption in 21 CFR 1.226 applies (e.g., the retail food establishment or farm exemptions). To be considered a “retail food establishment,” the annual monetary value of sales of food products directly to consumers must exceed the annual monetary value of sales of food products to all other buyers. In most instances, off-farm feed mills selling food to the public would not meet the retail food establishment definition because they typically sell most of their animal food to farms, which are considered businesses, and not consumers.

B.2.18 [Added December 2016] I have a farm supply store that sells to both farms (i.e., businesses) and pet owners (i.e., consumers). What percentage of animal food sales to farms would require my store to register?

To be considered a “retail food establishment” as defined in 21 CFR 1.227, the establishment’s primary function must be to sell food directly to consumers. A retail food establishment’s primary function is to sell food directly to consumers if the annual monetary value of sales of food directly to consumers exceeds the annual monetary value of sales of food to all other buyers (see 21 CFR 1.227). The term “consumers” does not include businesses, such as farms. Therefore, if more than 50% of a farm supply store’s annual monetary value of sales of food is to consumers, such as pet owners and other individuals, then the farm supply store would meet the definition of a “retail food establishment” and would not be required to register. However, if more than 50% of a farm supply store’s annual monetary value of sales of food is to other buyers, such as farms, then the farm supply store would not meet the definition of a “retail food establishment” and would be required to register.

B.2.19 [Added December 2016] Can I manufacture/process some of the animal food I sell at retail, in addition to selling prepackaged or bulk animal food and still be considered a retail food establishment?

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A retail food establishment may manufacture/process food and remain within the “retail food establishment” definition of 21 CFR 1.227 if the establishment’s primary function is to sell food, including food it manufactures/processes, directly to consumers. A retail food establishment’s primary function is to sell food directly to consumers if the annual monetary value of sales of food directly to consumers exceeds the annual monetary value of sales of food to all other buyers (such as to farms, which are considered businesses).

3. Restaurants

B.3.1 Are central kitchens that prepare food for a chain of restaurants considered to be restaurants and, therefore, exempt from registration?

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. Thus, they are not exempt, as restaurants, from registration.

B.3.2 Are pet shelters, kennels, and veterinary facilities in which food is provided to animals exempt from registration?

The definition of “restaurant” includes pet shelters, kennels, and veterinary facilities in which food is provided to animals (21 CFR 1.227). Therefore, these facilities are not required to register.

4. Nonprofit Food Establishments

B.4.1 Are exporters of food for charity exempt from the registration requirements?

Yes. An establishment, including a non-profit facility, is not required to register if all food manufactured/processed, packed, or held at the facility is not for consumption in the United States (21 CFR 1.225 and 1.227).

B.4.2 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?

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 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)).”

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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.

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.

In addition, a "restaurant" (21 CFR 1.227) 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) 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."

B.4.3 [Added December 2016] If I prepare food for organizations like “Meals on Wheels,” am I required to register?

If your facility meets the definition of “nonprofit food establishment” in 21 CFR 1.227, then you do not have to register. The exemption from registration for nonprofit food establishments can extend to a wide range of charitable entities, including those that prepare meals for consumption

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through partner organizations, such as “Meals on Wheels” programs and soup kitchens, regardless of whether the organization preparing the meal is the same organization that is delivering or serving the meal to the consumer. The definition of “nonprofit food establishment” in 21 CFR 1.227 includes central food banks, food pantries and meal delivery services. However, an entity that does not satisfy the criteria of 26 U.S.C. 501(c)(3) would not meet the definition of “nonprofit food establishment.” For instance, an entity that prepares meals at their facility and sells them to other unaffiliated businesses or organizations (including non-profit organizations) that subsequently offer/deliver those meals to individual consumers would not be a “nonprofit food establishment” if the net earnings of the entity inure to the benefit of a private individual (such that the entity does not meet the criteria of 26 U.S.C. 501(c)(3)). Such an entity would be required to register, provided that none of the other exemptions in 21 CFR 1.226 apply.

B.4.4 [Added December 2016] Are food banks required to register?

If a food bank meets the definition of “nonprofit food establishment,” as defined in 21 CFR 1.227, the food bank does not have to register. “Nonprofit food establishment” is defined 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)).” Distributing donated or rescued food, either directly to the consumer or to other charitable organizations, such as food pantries, soup kitchens or meal delivery services, are activities within the definition of non-profit food establishment because the food is provided for consumption by humans or animals.

In addition, some food pantries where individuals can visit to obtain food may also be considered non-profit food establishments, provided they meet the definition in 21 CFR 1.227.

5. Fishing Vessels

B.5.1 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 register?

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 1.226(f)).

6. Facilities Regulated Exclusively by the United States Department of Agriculture (USDA)

B.6.1 Are facilities that process deer, elk, and bison required to register with FDA?

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Yes. Facilities that process deer, elk, and bison are required to register as a food facility with FDA. Deer, elk, and bison are species that are foods under FDA’s jurisdiction. A facility that processes deer, elk, or bison, as well as meat or poultry products under USDA jurisdiction, would not be exempt from registration because they are not regulated exclusively, throughout the entire facility, by USDA (21 CFR 1.226(g)).

B.6.2 [Added December 2016] Are facilities that process fish of the order Siluriformes and products derived from these fish required to register as food facilities with FDA?

No. On December 2, 2015, the United States Department of Agriculture’s Food Safety Inspection Service (FSIS) amended its regulations to establish a mandatory inspection program for fish of the order Siluriformes and products derived from these fish (see 80 FR 75590; December 2, 2015). Siluriformes include catfish, tra, swai and basa. Effective March 1, 2016, FSIS assumed primary responsibility for the regulation of domestic and imported Siluriformes (fish), and products derived from these fish. A facility that only processes Siluriformes would be exempt from registration because it is regulated exclusively, throughout the entire facility, by USDA (21 CFR 1.226(g)). However, a facility that processes other fish, as well as Siluriformes under USDA jurisdiction, would not be exempt from registration because they are not regulated exclusively, throughout the entire facility, by USDA (21 CFR 1.226(g)).

B.6.3 [Added December 2016] Are establishments that operate under USDA FSIS inspection and also produce finished pet food required to register?

Yes. Facilities that manufacture, process, pack, or hold finished pet food must be registered as a food facility with FDA. Pet food is regulated by FDA. A facility that manufactures, processes, packs, or holds finished pet food, as well as meat or poultry products under USDA jurisdiction, would not be exempt from registration because they are not regulated exclusively, throughout the entire facility, by USDA (21 CFR 1.226(g)).

C. Definitions

1. Facility

C.1.1 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?

No. A private residence is not a facility as defined in 21 CFR 1.227. 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 example, 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.

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C.1.2 [Added December 2016] Are small food producers or hobbyists who make food out of their home and also sell the food at farmers’ markets or to other consumers required to register?

Under 21 CFR 1.227, a private residence is not a “facility” and thus, is not required to register. 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. 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. Accordingly, if the activities of small food producers or hobbyists meet customary expectations for a private residence, the producers or hobbyists would not be required to register.

C.1.3 [Added December 2016] If berries are harvested, then made into jam at a private residence for sale at markets and to retail stores, does the producer have to register the private residence as a facility?

Under 21 CFR 1.227, a private residence is not a “facility” and thus, is not required to register. 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. 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. Accordingly, if the activities of the jam producer meet customary expectations for a private residence, the producer would not be required to register.

C.1.4 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?

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 and, thus, would not have to register.

C.1.5 A number of maple sugar makers operate from their own property, on which their private residence is also located. Are these maple sugar makers required to register the facility that is on their property and used for maple sugar production?

Under 21 CFR 1.227, a private residence is not a “facility” and thus, is not required to register. 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 maple 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 register. If, however, a separate building located on the real property of the private residence site is used as a maple 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

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(e.g., as a farm or retail food establishment; see 21 CFR 1.227).

C.1.6 Are facilities that import food into the United States solely for export from a bonded warehouse required to register? Does the bonded warehouse that holds the food have to register?

No. Facilities that manufacture/process, pack, or hold food entering the United States solely for the purpose of exportation or trans-shipment to another country (i.e., none of the food is for consumption in the United States) are not required to register (see 21 CFR 1.225). 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 United States solely for future export is subject to the Prior Notice of Imported Food regulation (see 21 CFR part 1, subpart I).

C.1.7 A university research facility may sell some of its animals into commercial channels for food use. Does the facility have to register?

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

C.1.8 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?

“Facility” is defined to include structures under one ownership at one general physical location (21 CFR 1.227). 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 register.

C.1.9 [Added December 2016] Are distribution/warehouse facilities that supply animal food products to retail food establishments (e.g., farm supply stores and pet shops) required to register?

The distribution/warehouse facilities would be required to register because these facilities hold animal food for consumption in the United States, unless one of the exemptions in 21 CFR 1.226 applies. Generally, the retail food establishment exemption would not be applicable because the distributor/warehouse's primary function is not selling directly to consumers. The distributor/warehouse is distributing the animal food to retail food establishments, which are considered businesses and not consumers.

For situations where a retail food establishment has a co-located storage building, see Question B.2.3.

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C.1.10 [Added December 2016] If I operate a feed mill that manufactures, warehouses, and distributes animal food in packaged form and/or in bulk, does my facility have to register?

Yes. The feed mill would be required to register because the feed mill manufactures, processes, packs, or holds animal food for consumption in the United States, unless the feed mill meets one of the exemptions in 21 CFR 1.226 (see also sections II.B.1 Farms and II.B.2 Retail Food Establishments).

C.1.11 [Added December 2016] I am an animal food distributor that stores and distributes bagged livestock and pet food. Does my facility have to register?

Yes. The animal food distributor would be required to register because the animal food distributor holds animal food for consumption in the United States, unless the distributor meets one of the exemptions in 21 CFR 1.226 (see also Question B.2.18).

C.1.12 [Added December 2016] Are facilities that manufacture food additives and color additives for food use required to register as a food facility?

Food additives and color additives for food use are “food” as defined in section 201(f) of the FD&C Act (21 U.S.C. 321(f)). Therefore, many food additive and color additive facilities are required to register because these facilities manufacture/process, pack, or hold food for consumption in the United States. However, if a food additive is not intended to have a technical effect in or on the food and meets the definition of a food contact substance in section 409(h)(6) of the FD&C Act (21 U.S.C. 348(h)(6)), it is excluded from the definition of “food” for purposes of food facility registration (see 21 CFR 1.227). (See, for example, Questions C.2.5, C. 2.6, C.2.10, and C.2.12.). Consequently, facilities that manufacture food contact substances are not required to register.

2. Food

C.2.1 Are facilities that manufacture/process, pack, or hold fertilizers required to register?

Fertilizers are not food for consumption. Thus, facilities that hold fertilizers are not required to register.

C.2.2 Are pharmaceuticals considered "food" for purposes of the food facility registration requirement?

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 used for food or drink or for components of food or drink. Therefore, facilities that manufacture, process, pack, or hold such products are not required to register 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 FDA's Center for Drug Evaluation and Research regarding facility registration. You may email the eDRLS team at edrfs@fda.hhs.gov. Animal drug manufacturers may wish to consult with FDA's Center for Veterinary Medicine regarding drug establishment registration by

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emailing askCVM@fda.hhs.gov .

C.2.3 Are dietary supplements and components of dietary supplements considered "food" for purposes of the food facility registration requirement?

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 are “foods.” Accordingly, a facility that manufactures/processes, packs, or holds a dietary supplement or a component of a dietary supplement is required to register as a food facility unless it qualifies for an exemption from registration (21 CFR 1.226).

Products marketed as nutritional supplements or feed supplements for animals are considered to be “foods” or “new animal drugs” depending on the intended use. Facilities manufacturing/processing, packing, or holding animal food for consumption in the United States must register.

C.2.4 Are pet rawhide chew manufacturing facilities required to register?

Yes. These facilities are required to register because rawhide chews are consumed by animals and thus are "food," as defined in 21 CFR 1.227.

C.2.5 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?

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 excludes food contact substances, as defined in section 409(h)(6) of the FD&C Act (21 U.S.C. 348(h)(6)), but includes food additives (see 21 U.S.C. 321(f)). Consequently, facilities that manufacture chemicals used in the production of food contact substances are not required to register with FDA. However, if substance X is intended to have a technical effect in or on the food, it is "food" (i.e., a food additive), as defined in 21 CFR 1.227 and section 201(f) of the FD&C Act, 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 the facility with FDA.

C.2.6 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?

The answer to this question depends upon the use of the enzymes in question. As explained in Question C.2.5 in this document, for the purposes of food facility registration, the definition of “food” excludes food contact substances (21 CFR 1.227). If an enzyme produced by the facility

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is added to food and is intended to have a technical effect in the food, the facility is required to register. If the manufactured enzymes are used to manufacture a substance that will be a food contact substance (or component of a food contact substance), the facility is not required to register.

C.2.7 Are facilities that manufacture gum base substances, such as polyvinyl acetate used to produce chewing gum base, required to register?

Yes. Chewing gum is "food" (section 201(f)(2) of the FD&C Act; 21 CFR 1.227). 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 register, unless the facility is exempt from registration under 21 CFR 1.226.

C.2.8 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 register?

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 register as a food facility.

C.2.9 Does a facility need to register if it manufactures raw materials for dietary supplements?

Yes. Dietary supplements and dietary supplement components are "food" (sections 201(f) and 201(ff) of the FD&C Act and 21 CFR 1.227). 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 register as a food facility.

C.2.10 Are facilities that manufacture food packaging required to register as food facilities?

No. The definition of "food" in 21 CFR 1.227, 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, including food packaging or bottled water containers or closures, is not required to register.

C.2.11 Are facilities that manufacture/process, pack, or hold food used in research and development or as food samples required to register with FDA?

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

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that manufactures/processes, packs, or holds food used in research and development or as product samples is required to register with FDA. However, if the food is not for consumption in the United States by humans or animals, the facility is not required to register.

C.2.12 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 register?

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 that manufactures/processes, packs, or holds 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 register.

3. Holding

C.3.1 Is a local collecting facility for grains exempt from the registration requirement?

All establishments at which food is manufactured/processed, packed, or held are required to register, unless otherwise exempt (21 CFR 1.225 and 1.226). If the local "collecting facility" is storing or holding the grain, e.g., collecting grain in a silo or grain elevator, the facility must be registered with FDA unless they meet an exemption in 21 CFR 1.226. For example, if the collecting facility is storing grain grown on the farm where it is located (a primary production farm) or meets the definition of a secondary activities farm (i.e., the "collecting facility" is majority owned by farmers and the majority of grain stored comes from the farmers that own the facility), it is not required to register (21 CFR 1.226 and 1.227).

C.3.2 If an establishment only receives packaged produce RACs for shipping and holds them in cold storage, is it required to register?

If the cold storage operation meets the requirements to be a secondary activities farm (i.e., it is majority owned by farmers and the majority of packaged produce RACs stored comes from the farmers that own the cold storage operation), it is not required to register (21 CFR 1.226 and 1.227). However, if the operation does not meet the requirements to be a secondary activities farm or holds processed foods in addition to the packaged produce RACs, it must register (21 CFR 1.225 and 1.227).

C.3.3 If finished food products for consumption in the United States are held at a third party facility before consolidation for import into the United States, must this facility register?

Yes. The facility is holding food for consumption in the United States, and therefore is required

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to register, unless an exemption applies (21 CFR 1.225 and 1.226).

C.3.4 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?

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.

C.3.5 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 register with FDA as food facilities?

No. Post offices and express courier facilities are not required to register 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 1.227 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 United States 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. 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 register as food facilities.

C.3.6 Truck terminals and freight forwarders may have food on their premises as part of the shipment process. Are these types of establishments required to register with FDA as food facilities?

No. Truck terminals and other stationary facilities that serve merely to assist transportation

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vehicles in the process of transporting food are not required to register with FDA. As with post offices and similar facilities discussed in Question C.3.5 in this document, 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 register 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; 68 FR 58894 at 58904). However, FDA further considered this issue, as well as related ones, and determined that the earlier guidance should be revised.

C.3.7 Is a vessel carrier that only transports food from one facility to another considered to be a facility that must be registered?

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. Therefore, a vessel carrier is not a facility that must be registered.

C.3.8 Are foreign storage facilities that hold finished food products prior to export to the United States required to register?

Yes. Generally, a foreign storage facility that holds food prior to export to the United States is required to register with FDA. However, if the food subsequently undergoes manufacturing/processing of more than a *de minimis* nature in another foreign facility, the foreign storage facility prior to that manufacturing/processing facility is not required to register.

C.3.9 Do the facilities of both the exporter and the importer of food for consumption in the United States need to register if they each hold food?

Yes. The facilities of both the exporter and the importer are required to register if they hold food for consumption in the United States. However, as indicated in the response to Question C.3.8 in this document, the foreign facility need not register 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 United States (21 CFR 1.226(a)).

C.3.10 Does a cruise ship have to register if it is holding food for consumption for passengers and returns to the United States with food not consumed on the cruise?

Restaurants are not required to register (21 CFR 1.226(d)). “Restaurant” is defined in 21 CFR 1.227 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 register because it is not manufacturing/processing, packing, or holding food for consumption in the United States. In addition, even if a cruise ship carries food as cargo, it is not required to register because, in such circumstances, it would be considered a transport vehicle (21 CFR 1.227).

C.3.11 [Added December 2016] Is a stockyard or livestock market required to register?

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Yes. A stockyard or livestock market would be required to register (unless an exemption in 21 CFR 1.226 applies) if they are holding live animals for human or animal consumption. Generally, stockyards and livestock markets consist of a series of pens or yards where market animals are collected and held. These animals are either sold to feedlots/ veal finishing farms or purchased by packing houses for slaughter. Neither a livestock market nor a stockyard is a “farm” as defined in 21 CFR 1.227, because they do not raise animals.

C.3.12 [Added December 2016] Do receiving stations (domestic and foreign) that are stand-alone operations need to register if the receiving stations only collect and clean fruit prior to storage? There is a processing facility at the same location under separate ownership.

If the stand-alone receiving facility that collects and cleans fruit (and does not conduct any other activities except storage) is majority owned by one or more primary production farms, the majority of the RACs held by that receiving station come from the primary production farm(s), and the receiving station does not conduct any manufacturing/processing other than the activities allowed within the “farm” definition in 21 CFR 1.227, then the receiving station does not have to register. If the stand-alone receiving facility does not meet the definition of a secondary activities farm in 21 CFR 1.227, then it must register because it is holding food.

C.3.13 [Added December 2016] Must I register my facility as a warehouse if we only hold food for a short period of time (i.e., a few hours to one day before food is transported)?

There is no timeframe (maximum or minimum) associated with holding. Consequently, a facility that holds food for consumption in the United States is not exempt from food facility registration requirements based on how long it holds food.

C.3.14 [Added December 2016] Do I have to register if my establishment fumigates food?

The definition of “holding” provides that holding includes “activities performed incidental to storage of a food (e.g., activities performed for the safe or effective storage of that food, such as fumigating food during storage, and drying/dehydrating raw agricultural commodities when the drying/dehydrating does not create a distinct commodity) . . . but does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act” (see definition of “holding” in 21 CFR 1.227).

Generally a facility that fumigates food is manufacturing/processing, packing or holding food and therefore is required to register. If the fumigation is performed on a farm for the safe or effective storage of a RAC, this activity would not be one that requires the farm to register because fumigation is considered a “holding” activity and holding RACs is within the farm definition.

4. Manufacturing/Processing

C.4.1 Is a cotton gin that separates cotton fibers from cotton seeds and then sells these seeds to a manufacturer who then processes the seeds into animal food for sale to livestock operations required to register?

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An off-farm cotton gin is a facility that must register if the owner, operator, or agent in charge of the facility reasonably believes that the cotton seeds are reasonably expected to be directed to an animal food use or as an ingredient in animal food. FDA believes that the owner, operator, or agent in charge of a cotton gin facility generally knows or should know that the cotton seeds are reasonably likely to be used as components of animal food (e.g., as an ingredient in cotton seed meal). Off-farm cotton ginning is either a packing activity (if done for safe or effective packing) or a manufacturing/processing activity, depending on circumstances. A facility that manufactures/processes, packs, or holds food for consumption in the United States is required to register. A facility that subsequently processes the cotton seed into animal food is also required to register.

However, if the off-farm cotton ginner and the establishment that processes the cotton seed into animal food (animal food manufacturer) are both located in a foreign country, the cotton ginner would not be required to register because the animal food manufacturer conducts further manufacturing/processing of the cotton seeds prior to export to the United States. The foreign animal food manufacturer must be registered unless, before the animal food is exported to the United States, the animal 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 register.

C.4.2 Do all manufacturing/processing sites under one ownership have to register, even if only one is involved with foods for consumption in the United States?

No. Only facilities that manufacture/process, pack, or hold food for consumption in the United States are required to register. Thus, facilities that manufacture/process, pack, or hold food that will be consumed outside of the United States do not need to register.

C.4.3 [Added December 2016] Am I required to register my facility if my facility manufactures/processes human food that results in human food by-products that we pack or hold for processing by another facility that manufactures/processes animal food?

Yes. Your facility is required to register because you manufacture/process, pack, or hold food for consumption by humans and animals in the United States. There is not a separate registration process for human and animal food. (See also Question F.3.4).

C.4.4 [Added December 2016] Am I required to register if I use heat to pasteurize the honey I produce on my farm?

Under 21 CFR 1.227, heating honey for pasteurization is considered manufacturing/processing. Therefore, if you use heat to pasteurize the honey you produce on your farm, you must register unless: (1) all the honey that has undergone manufacturing/processing is consumed on your farm or another farm under the same management, or (2) your manufacturing/processing operation meets the definition of a retail food establishment.

C.4.5 [Added December 2016] If I bottle water from a spring, must I register?

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Bottling water from a spring is considered manufacturing/processing under 21 CFR 1.227. Facilities engaged in bottling water from a spring are required to register. However, the bottler would not have to register the spring as a facility.

5. Packing

See Questions and Answers B.1.8 – B.1.12 and B.1.22 under section II.B.1 in this document.

6. Trade Names

C.6.1 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?

Under 21 CFR 1.227, 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 (21 CFR 1.232(a)(5)). A facility's registration is not required to include all brand names for products manufactured/processed, packed, or held at the facility.

7. U.S. Agent

C.7.1 [Added December 2016] Who can be a U.S. agent and what are the roles and responsibilities of the U.S. agent?

A U.S. agent may be an individual, partnership, corporation, or association. A U.S. agent must have a place of business or residence in the United States and be physically present in the United States. For example, a foreign facility may use its U.S. importer as its U.S. agent. As established in 21 CFR 1.227, the U.S. agent acts as a communications link between FDA and a foreign facility for both routine and emergency communications. The U.S. agent will be the person FDA contacts when an emergency occurs, unless the registration specifies another emergency contact. In functioning as the communications link with FDA, a U.S. agent may choose to initiate communications with FDA, and FDA may likewise choose to initiate communications with the U.S. agent. Further, as stated in the definition for "U.S. agent" in 21 CFR 1.227, FDA will treat representations by the U.S. agent as those of the foreign facility, and will consider information or documents provided to the U.S. agent the equivalent of providing the information or documents to the foreign facility.

C.7.2 For foreign facilities, may the U.S. agent for the facility also serve as the facility's emergency contact?

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 and 1.232(c)).

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C.7.3 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?

No. 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. As we stated in Question C.7.1 in this document, a U.S. agent may be an individual, partnership, corporation, or association. The U.S. agent must have a place of business or residence in the United States and be physically present in the United States.

C.7.4 May a foreign government official residing in the United States, 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?

FDA is concerned that acting as a U.S. agent may conflict with the duties of foreign government representatives (see Comment 90 in the preamble to the Interim Final Rule; 68 FR 58894 at 58916). 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.

C.7.5 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?

No. Under 21 CFR 1.227, 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 (see 21 CFR 1.227 and Comment 86 in the preamble to the Interim Final Rule; 68 FR 58894 at 58915).

C.7.6 Is a power of attorney required for a U.S. agent to work on behalf of the facility?

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

C.7.7 May a foreign food processor change U.S. agents after registration?

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. At this time, updates may be submitted electronically at <http://www.access.fda.gov>. 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 section II.E.3 in this document.

After January 4, 2020, you must submit updates electronically, unless FDA has granted a waiver

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under 21 CFR 1.245 (see also section II.N of this document for a discussion on waivers).

C.7.8 May the emergency contact for a foreign facility have a phone number outside the United States?

Yes. A foreign facility's emergency contact may have a phone number outside the United States. 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 United States. The U.S. agent must have a U.S. phone number. In addition, 21 CFR 1.232(c) requires an e-mail address for the U.S. agent be provided in the foreign facility's registration.

C.7.9 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?

Under 21 CFR 1.227, there are two qualifications for a U.S. agent. The agent: (1) must reside or maintain a place of business in the United States; and (2) must be physically present in the United States. 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.

C.7.10 How does a foreign facility "authorize" someone in the United States to be their agent (e.g., letter to FDA, notarized document)?

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, as long as the U.S. agent has agreed to serve as the U.S. agent for the foreign facility. 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 will verify that the person identified as the U.S. agent for the foreign facility has agreed to serve as the U.S. agent (see 21 CFR 1.231). (See also section II.E.6 of this document for a discussion of the verification procedures for U.S. agents).

C.7.11 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?

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).

C.7.12 May foreign facilities belonging to the same parent company use different U.S. agents for registration purposes?

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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.

C.7.13 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?

Routine registration and emergency communications under the registration regulation relate to facilities, not to specific shipments. FDA expects that food facility registration requirements will have no impact on customary communications regarding the disposition of a particular food shipment. A firm's commercial business in the United States need not be conducted exclusively through the U.S. agent designated for registration purposes (21 CFR 1.227). Ordinarily, for example, for questions relating to an imported 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.

C.7.14 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?

The owner, operator, or agent in charge of the foreign facility, or an individual authorized by one of them (e.g., the U.S. agent), 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. This e-mail should include the information previously provided on the registration form regarding the U.S. agent (i.e., name, address, phone number, email address) 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.

C.7.15 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?

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 1.232(c)(2) 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.

C.7.16 Can a person in the United States, who has not been designated as the U.S. agent for

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a foreign facility, perform the registration function for that facility?

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 1.225 and 1.230). The authorized individual may be, but is not required to be, the U.S. agent for the facility.

C.7.17 Under 21 CFR 1.232(c), the registration for a foreign facility is required to include the "name, full address, phone number, and e-mail address of the foreign facility's U.S. agent. . . ." "U.S. agent" is defined in 21 CFR 1.227 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 foreign facility's U.S. agent must reside or maintain a place of business in the United States and must be physically present in the United States (21 CFR 1.227). 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 Form FDA 3537 or in response to the appropriate prompt when a facility is registered electronically. As previously stated in our response to Question C.7.10, FDA will verify that the person identified as the U.S. agent for the foreign facility has agreed to serve as the U.S. agent (see 21 CFR 1.231).

C.7.18 What will happen to an article of food that is offered for import into the United States from a facility that does not provide a U.S. agent?

When FDA determines a foreign food facility has not registered in accordance with section 415 of the FD&C Act because it does not provide a U.S. agent, FDA may hold shipments offered for import from that facility at the U.S. port of arrival until the facility amends their registration to list a U.S. agent who has affirmatively agreed to serve as such.

C.7.19 [Added December 2016] Are the U.S. agent for food facility registration and the U.S. agent for purposes of the foreign supplier verification program (FSVP) the same?

No. Although Congress used the term "United States agent" in both section 805(a)(2)(B) (pertaining to who serves as the "importer" for purposes of fulfilling FSVP requirements) and section 415(a)(1)(B) of the FD&C Act (pertaining to food facility registration), we do not interpret the use of the term "United States agent" in section 805(a)(2)(B) to mean the U.S. agent for a foreign facility under section 415(a)(1)(B) (see Comment 22 in the Registration Final Rule; 81 FR 45912 at 45926).

C.7.20 [Added December 2016] Can the U.S. agent for food facility registration and the U.S. agent for purposes of the FSVP be the same person?

Yes. There is no prohibition on the same person serving as both the U.S. agent for purposes of

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food facility registration and the U.S. agent for purposes of satisfying the FSVP “importer” requirements—provided that such person meets the relevant requirements of both the FSVP regulation (21 CFR part 1, subpart L) and the food facility registration regulation.

C.7.21 [Added December 2016] Can the U.S. agent for a foreign food facility access the facility’s FDA Unified Registration and Listing Systems (FURLS) and help desk on behalf of the foreign facility?

Yes. The U.S. agent of a foreign facility may view the information submitted in the foreign facility’s registration (21 CFR 1.227). The U.S. agent will be able to view the information electronically via FURLS Food Facility Registration Module. U.S. agents may contact FDA’s help desk with questions about foreign facilities that they represent. In addition, a U.S. agent

may contact FDA’s help desk on behalf of the foreign facility (see Comment 25 in the Registration Final Rule; 81 FR 45912 at 45927).

8. Other Definitions

C.8.1 How does FDA define "owner," "operator," and "agent in charge?"

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).

C.8.2 How does FDA define "parent company?"

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 or Renew Your Registration?

1. When Must You Register?

D.1.1 When must you register initially under the food facility registration requirements?

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

2. Biennial Registration Renewal

D.2.1 When does a facility that is required to register with FDA need to submit a registration renewal to FDA?

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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.

FDA will consider a registration for a food facility to be expired if the registration is not renewed as required (21 CFR 1.241(b)). FDA will consider a food facility with an expired registration to have failed to register in accordance with section 415 (21 CFR 1.241(b)). 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)).

D.2.2 [Added November 2016] Do new food facilities need to wait until October 1 of a biennial renewal year to register?

No. The owner, operator, or agent in charge of a facility that begins to manufacture/process, pack, or hold food for consumption in the United States must register before the facility begins such activities (21 CFR 1.230). An owner, operator, or agent in charge of a facility may authorize an individual to register the facility on its behalf (21 CFR 1.230). If the initial registration is submitted prior to October 1 of a biennial renewal year, a renewal still must be submitted for the facility during the period beginning on October 1 and ending on December 31.

D.2.3 [Added November 2016] Does FDA intend to inform food facilities about the registration renewal period?

Prior to the beginning of the biennial registration renewal (or “registration renewal”) period on October 1, FDA intends to send an email to all registered facilities and U.S. agents for the facilities notifying them of the upcoming registration renewal period. In these emails, we plan to provide general information about the registration renewal process, including the deadline for renewals. Once the renewal period begins, if a facility has not submitted a renewal, we plan to continue to send emails reminding the facility of the upcoming deadline through the end of the registration renewal period on December 31.

D.2.4 [Added November 2016] Will a food facility be issued a new registration number during the registration renewal process?

No. A food facility will not be issued a new registration number when it renews a current registration.

D.2.5 [Added November 2016] Am I required to provide my registration number and pin number when I submit my registration renewal?

When you submit a registration renewal via mail or fax, you are asked to provide your facility registration number and pin number (or PIN). For electronic submissions, Account holders in FURLS will not need to provide a registration number or pin because that information is linked to the Account.

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D.2.6 [Added November 2016] Does FDA consider a registration renewal expired if it was properly submitted on or prior to the December 31 deadline but was not timely administered or accepted by FDA on or prior to the December 31 deadline?

In the Registration Final Rule, we added 21 CFR 1.241(b) to specify that FDA will consider a registration for a food facility to be expired if the registration is not renewed, as required by 21 CFR 1.230(b). If a food facility registration or renewal registration is submitted (or postmarked, for paper submissions) on or before the renewal deadline and includes all required information, we will not consider such a registration to be expired. Furthermore, 21 CFR 1.241(c) provides that FDA will cancel a registration if the facility's registration has expired because the facility has failed to renew its registration in accordance with 21 CFR 1.230(b). For registrations that we do not consider to be expired, we will not cancel the registrations under 21 CFR 1.241(c) (see Comment 26 in the Registration Final Rule; 81 FR 45912 at 45927 to 45928).

3. Abbreviated Registration Renewal Process

D.3.1 [Added November 2016] Will I have to resubmit all of my registration information when I renew my registration?

FDA is providing an abbreviated registration renewal process for facilities that do not have information changes under 21 CFR 1.232 since the submission of the preceding registration, registration renewal, or update (see 21 CFR 1.230(c)).

If you use the abbreviated registration renewal process, you must confirm that no changes have been made to the information required under 21 CFR 1.232 since you submitted the preceding registration, registration renewal, or update, and you must certify that the information submitted is truthful and accurate. Each electronic abbreviated registration renewal must include the name of the individual submitting the abbreviated renewal. For registrations submitted by mail or fax, each abbreviated registration renewal must also include the individual's signature (see 21 CFR 1.230(c)).

For abbreviated registration renewals not submitted by the owner, operator, or agent in charge of the facility, the abbreviated renewal must provide the email address of the individual who authorized submission of the abbreviated renewal, unless FDA has granted a waiver under 21 CFR 1.245 (21 CFR 1.230(c)).

E. How and Where Do You Register or Renew Your Registration?

1. General Questions

E.1.1 How can registration be submitted?

You, or an individual you authorize, can submit a facility's registration or registration renewal electronically or by U.S. mail or fax.

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E.1.2 Does FDA require registration to be submitted in an electronic format?

No. Registration by a paper system is still available. FDA regulations requires that owners, operators, or agents in charge must submit their registration, registration renewal, update, and cancellation to FDA electronically beginning on January 4, 2020, unless FDA has granted a waiver under 21 CFR 1.245 (21 CFR 1.231(a)(2); 21 CFR 1.234(d); 21 CFR 1.235(d)). If FDA has granted a waiver, registrations and registration renewals may be submitted through mail or fax (see 21 CFR 1.231(a)(2); 21 CFR 1.234(d); 21 CFR 1.235(d)). However, FDA continues to encourage use of the electronic format because it is more efficient and provides for immediate submission of the registration information.

2. Electronic Registration and Registration Renewal

E.2.1 [Added November 2016] How can I submit my registration or registration renewal electronically?

You, or an individual you authorize, can submit a facility's registration or registration renewal electronically at <http://www.access.fda.gov>.

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).

3. Registration or Registration Renewal by Mail or Fax

E.3.1 How can I submit my registration or registration renewal by mail or fax?

Beginning January 4, 2020, registrants must submit their registration or registration renewal to FDA electronically, unless FDA has granted a waiver under 21 CFR 1.245 (see 21 CFR 1.231). If FDA has granted a waiver under 21 CFR 1.245, the registrant may register or renew by mail or by fax. If you submit a registration or registration renewal by mail or fax, you must use the paper version of Form FDA 3537. That version is available for download at

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

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

U.S. Food and Drug Administration
Food Facility Registration (HFS-681)
5001 Campus Dr.
College Park, MD 20740

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

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You may also use the paper form to update or cancel your registration information, if FDA has granted a waiver under 21 CFR 1.245 (see 21 CFR 1.234(d); 21 CFR 1.235(d)).

4. Unique Facility Identifier and Verification Procedures for FDA

E.4.1 [Added November 2016] How will FDA conduct the verification process for the unique facility identifier (UFI) required in the facility's registration?

Under 21 CFR 1.232(a)(2), domestic and foreign facilities must submit a unique facility identifier (UFI) recognized as acceptable to FDA in the facility's registration (see also section F.2 of this document for further discussion of the UFI requirement).

Please note, however, that the requirement for providing a UFI in food facility registration submissions will not begin until October 1, 2020.

As outlined in 21 CFR 1.231(a)(3) and (b)(5), beginning October 1, 2020, FDA intends to conduct the verification process for the UFI as follows:

- For electronic registrations, after you submit your registration, FDA will verify the accuracy of your UFI recognized as acceptable by FDA and will also verify that the facility-specific address associated with the UFI is the same address associated with your registration. FDA will not confirm your registration or provide you with a registration number until FDA verifies the accuracy of your facility's UFI and verifies that the facility-specific address associated with the UFI is the same address associated with your registration.
- For electronic registration renewals, after you submit your electronic registration renewal, FDA will provide you with an electronic confirmation of your registration renewal. When you add or update your facility's UFI as part of the registration renewal, FDA will verify the accuracy of your facility's UFI and will also verify that the facility-specific address associated with the UFI is the same address associated with your registration. FDA will not provide you with a confirmation of your registration renewal until FDA verifies the accuracy of your UFI and verifies that the facility-specific address associated with the UFI is the same address associated with your registration.
- For registrations submitted by mail or fax, after you submit your registration, FDA will verify the accuracy of your facility's UFI and will also verify that the facility-specific address associated with the UFI is the same address associated with your registration. FDA will not confirm your registration or provide you with a registration number until FDA verifies the accuracy of your facility's UFI and verifies that the facility-specific address associated with the UFI is the same address associated with your registration.
- For registration renewals submitted by mail or fax, after you submit your registration renewal, FDA will provide you with a confirmation of your registration renewal. When you add or update your facility's UFI as part of your registration renewal, FDA will verify the accuracy of your facility's UFI and will also verify that the facility-specific address associated with the UFI is the same address associated with your registration. FDA will not provide you with a confirmation of your registration renewal until FDA

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verifies the accuracy of your UFI and verifies that the facility-specific address associated with the UFI is the same address associated with your registration.

5. Verification Procedures for Submissions Not Made by the Owner, Operator, or Agent in Charge of the Facility

E.5.1 [Added November 2016] How will FDA conduct the verification process for submissions not made by the owner, operator, or agent in charge of the facility?

For registrations or registration renewals not submitted by the owner, operator, or agent in charge of the facility, FDA will verify that the individual identified as having authorized the submission in fact authorized the submission on behalf of the facility. FDA will not confirm a registration, provide a registration number, or provide confirmation of a registration renewal until that individual confirms that he or she authorized the submission (see 21 CFR 1.231(a)(4) and (b)(6)). In most circumstances, FDA will conduct this verification step by sending an email to the individual identified as having authorized the submission. In some circumstances, however, FDA may determine that it is appropriate to use other methods to conduct the verification step, such as U.S. mail or phone.

For updates and cancellations, FDA will not provide a confirmation of the registration update or cancellation until the individual confirms that he or she authorized the submission (21 CFR 1.234(c)(3) and (d)(6) (for updates) and 1.235(c)(3) and (d)(6) (for cancellations)). We will provide the owner, operator, or agent in charge of the facility 30 calendar days to respond to our verification request.

If we do not receive a response to our verification request within that time, the registration, registration renewal, update, or cancellation submission will be removed from our database and a new submission will be required. For registration renewals, updates, or cancellations, if FDA has previously verified that the authorizing individual has authorized the individual submitting the renewal to make registration submissions on behalf of the facility, FDA will not re-verify that the authorizing individual in fact authorized the submission.

FDA will continue its current practice of individually contacting facilities if specific questions arise regarding the facility's registration.

6. Verification Procedures for U.S. Agents

E.6.1 [Added November 2016] How will FDA conduct the verification process for U.S. agents?

For registrations, registration renewals, and updates to information about U.S. agents, FDA will verify that the person identified as the U.S. agent for the foreign facility agreed to serve as the U.S. agent (see 21 CFR 1.231(a)(5) and (b)(7) (for registrations and registration renewals) and 1.234(c)(2) and (d)(5) (for updates)). FDA will not confirm a registration or registration renewal or provide a registration number until the person identified as the U.S. agent for the foreign facility confirms that the person agreed to serve as the U.S. agent (21 CFR 1.231(a)(5) and

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(b)(6)). For updates, FDA will not provide a confirmation of the registration update until the person identified as the U.S. agent for the foreign facility confirms that the person agreed to serve as the U.S. agent (21 CFR 1.234(c)(2) and (d)(5)).

In most circumstances, FDA will conduct this verification step by sending an email to the person identified as the U.S. agent. In some circumstances, however, FDA may determine that it is appropriate to use other methods to conduct the verification step, such as U.S. mail or phone.

If the individual listed as the 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 an individual who has agreed to serve as the facility's U.S. agent. For registration renewals, if FDA has previously verified that the U.S. agent has agreed to serve as the U.S. agent for the facility, FDA will not re-verify that the U.S. agent has agreed to serve as the U.S. agent for the foreign facility.

We will provide the person identified as the U.S. agent 30 calendar days to respond to our verification request. If we do not receive a response to our verification request within that time, the registration, registration renewal, or update submission will be removed from our database and a new submission will be required.

E.6.2 What will happen when the person listed as the U.S. agent for the facility does not agree to serve as the facility's U.S. agent?

After you submit your registration, FDA will verify that the person identified as the U.S. agent for your foreign facility has agreed to serve as your U.S. agent. FDA will not confirm your registration or provide you with a registration number until that person confirms that the person has agreed to serve as your U.S. agent (see 21 CFR 1.231(a)(5) and (b)(7)).

If the person listed as the U.S. agent informs FDA that the person 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 a person that has in fact agreed to serve as the facility's U.S. agent.

7. Requirement to Update Incorrect Registration Information

E.7.1 [Added November 2016] If I provide incorrect information at the time I submit my registration or registration renewal, do I have to immediately update my submission?

Yes. If any information previously submitted was incorrect at the time of submission, you must immediately update your facility's registration as specified in 21 CFR 1.234 (21 CFR 1.231(a)(6) and (b)(9)).

F. What Information Is Required in the Registration?

1. General questions

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F.1.1 What information is required in the registration of a food facility?

As outlined in 21 CFR 1.232, the following information is required for domestic and foreign food facility registrations:

- Facility name, address, phone number, and emergency contact phone number;
- Preferred mailing address, if different from that of the facility;
- Parent company name, address, and phone number (if the facility is a subsidiary of the parent company);
- All trade names the facility uses;
- Name, address, and phone number of the owner, operator, or agent in charge;
- Email address of the owner, operator, or agent in charge, unless FDA has granted a waiver under 21 CFR 1.245;
- Applicable food product categories of any food manufactured/processed, packed, or held at the facility, as identified on Form FDA 3537;
- The type(s) of activity at the facility for each food product category, as provided in 21 CFR 1.232(a)(8);
- A statement in which the owner, operator, or agent in charge provides an assurance that FDA will be permitted to inspect the facility at the times and in the manner permitted by the FD&C Act;
- A statement in which the owner, operator, or agent in charge certifies that the information submitted is true and accurate. If the individual submitting the form is not the owner, operator, or agent in charge of the facility, the registration must also include a statement in which the individual certifies that the information submitted is true and accurate, certifies that he/she is authorized to submit the registration, and identifies by name, address, and telephone number, the individual who authorized submission of the registration. In addition, the registration must identify the individual who authorized submission of the registration by email address, unless FDA has granted a waiver under 21 CFR 1.245.

In addition, beginning October 1, 2020, the facility's UFI recognized as acceptable by FDA will be required to be submitted with the registration information (21 CFR 1.232(a)(2)). Each registration submission must include the name of the individual submitting the registration. For the paper option, the registration must also include the individual's signature (see 21 CFR 1.230).

For a domestic facility, the registration must also include:

- The email address for the contact person of the facility;
- An emergency contact phone number and email address if different from the email address for the contact person.

For a foreign facility, the registration must also include:

- The name, full address, phone number, and email address of the foreign facility's U.S.

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- agent;
- An emergency contact phone number and email address.

F.1.2 [Added December 2016] If a mobile facility (e.g., a truck-mounted operation) is required to register, what address should it use?

When registering, the owner, operator, or agent in charge of the mobile facility must provide FDA with the information required in 21 CFR 1.232. 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 (see Comment 38; 68 FR 58894 at 58904).

2. Unique Facility Identifier (UFI)

F.2.1 [Added November 2016] When will I be required to submit a UFI in my registration submission?

As previously stated in the answer to Question F.1.1 in this document, beginning October 1, 2020, the facility's UFI recognized as acceptable by FDA will be required to be submitted with the registration information (21 CFR 1.232(a)(2)). After a food facility provides a UFI, it will be required to update its registration with any changes to the identifier in accordance with 21 CFR 1.234.

F.2.2 [Added November 2016] If I have a UFI recognized as acceptable by FDA, may I include it in my registration submission before October 1, 2020?

At this time, Form FDA 3537 does not provide a data field to include UFI information. We will consider adding an optional UFI data field on Form FDA 3537 in advance of the October 1, 2020 date to allow facilities to voluntarily submit UFI information.

F.2.3 [Added November 2016] Which UFI or UFIs are recognized as acceptable to FDA for food facility registration purposes?

At this time, FDA recognizes the Data Universal Numbering System D-U-N-S (DUNS) number as an acceptable UFI. DUNS numbers are assigned and managed by Dun & Bradstreet. However, as stated previously in this document, the requirement to submit a UFI will not begin until October 1, 2020. If FDA recognizes as acceptable any additional UFIs before the October 1, 2020 date, we will update the response to this question.

F.2.4 [Added November 2016] How do I obtain a UFI recognized as acceptable by FDA?

At this time, the DUNS number is the preferred UFI recognized as acceptable to FDA for food facility registration. The DUNS number is assigned and managed by Dun & Bradstreet and is available free of charge. Information on how to obtain a DUNS number will be available on the FDA Web site. You can obtain a DUNS number through the Internet or by phone.

However, as stated previously in this document, the requirement to submit a UFI will not begin until October 1, 2020. If FDA recognizes as acceptable additional UFIs before the October 1,

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2020 date, we will update the response to this question.

F.2.5 [Added November 2016] Who can I contact if I want to use a different UFI than the one(s) FDA recognizes as acceptable?

If you would like FDA to consider the use of an alternative identifier for food facility registration other than the one(s) FDA recognizes as acceptable in this document, you may contact FDA at the FURLS Helpdesk (email to FURLS@fda.gov or by phone at 1-800-216-7331 or 301-575-0156).

F.2.6 [Added November 2016] If I provide a UFI with my registration submission, do I also have to include my food facility registration number?

Yes. If you submit an update or a registration renewal, you are also asked to provide your facility registration number on Form FDA 3537.

F.2.7 [Added November 2016] If I am the owner, operator, or agent in charge of multiple food facilities, do I have to provide separate UFIs for each of my facilities?

Yes. The registration for each facility must include a UFI recognized as acceptable by FDA (see 21 CFR 1.232(a)(2)).

F.2.8 [Added November 2016] Do I have to provide a new UFI for the facility if there is a change in ownership?

If a facility comes under new ownership, the former owner must cancel the old registration in accordance with 21 CFR 1.235, and the new owner must submit a new registration for the facility as specified in 21 CFR 1.231 (see 21 CFR 1.234(b)). If a facility cancels its registration due to a change in ownership, the new owner, operator, or agent in charge must provide the appropriate UFI when registering the facility under the new ownership (see 21 CFR 1.232).

3. Food Product Categories

F.3.1 [Added November 2016] Am I required to provide information about food product categories in my registration submission?

Yes. Your food facility registration must include the applicable food product categories of any food manufactured/processed, packed, or held at the facility as identified on Form FDA 3537 (21 CFR 1.232(a)(7)). See the 2016 Edition of the “Necessity of the Use of Food Categories in Food Facility Registrations and Updates to Food Categories: Guidance for Industry,” issued in September 2016, for the updated food product categories.

F.3.2 [Added November 2016] If my facility is a warehouse/holding facility, do I have to constantly update the food product categories in my registration if this information frequently changes?

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For warehouse facilities engaged in ongoing operations that frequently change food product categories, these facilities may select all of the food product categories that are normally part of their operations. If the warehouse has updates to the food product categories it handles, the facility is required to update its registration in accordance with 21 CFR 1.234 (see Comment 60 in the Registration Final Rule; 81 FR 45912 at 45937).

F.3.3 [Added November 2016] Do I submit registration information about the ingredients used at my facility for manufacturing finished foods, or the finished products that I manufacture?

You are required to provide the applicable food product categories of any food manufactured/processed, packed, or held at the facility, as identified on Form FDA 3537 (21 CFR 1.232(a)(7)). If you are a manufacturer/processor, you should provide food product category information about the foods that you manufacture/process, not the ingredients that you use in your manufacturing/processing. For example, if you manufacture chocolate chip cookies and you use butter as one of the ingredients for the cookies, you should not provide food product category information about the butter. Instead, you should provide food product category information about the cookies. Specifically, you should select the food product category of bakery products, dough mixes, or icings. (See also the Food Product Categories Guidance at <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm324778.htm> for more information and updates to the food product categories identified on Form FDA 3537.)

F.3.4 [Added November 2016] If my facility is subject to FDA’s human food Current Good Manufacturing Practice regulations in subpart B of 21 CFR part 117 and manufactures/processes human food that results in human food by-products that we pack or hold and then send either to another facility that manufactures/processes animal food or to a farmer for use as animal food, do I provide animal food product category information in my registration?

Yes. Your food facility registration must include applicable food product categories of any food manufactured/processed, packed, or held at the facility as identified on Form FDA 3537 (21 CFR 1.232(a)(7)). If your facility’s human food manufacturing results in by-product that you pack or hold for distribution as animal food, you must select the applicable animal food product categories for the by-products that you pack or hold.

4. Activity Type Information

F.4.1 [Added November 2016] Am I required to provide activity type information in my registration submission?

Yes. Your food facility registration must include information about the type of activity conducted at your facility for each food product category identified (21 CFR 1.232(a)(8)). The activity type options are as follows:

- Ambient human food storage warehouse/holding facility;

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- Refrigerated human food warehouse/holding facility;
- Frozen human food warehouse/holding facility;
- Interstate conveyance caterer/catering point;
- Contract sterilizer;
- Labeler/relabeler;
- Manufacturer/processor;
- Acidified food processor;
- Low-acid food processor;
- Farm mixed-type facility;
- Packer/repacker;
- Salvage operator (reconditioner);
- Animal food warehouse/holding facility;
- Other activity.

F.4.2 [Added November 2016] What does FDA consider the different activity types specified in 21 CFR 1.232(a)(8) to mean?

FDA's considers the activity types to have the following meanings:

- Ambient human food storage warehouse/holding facility: A facility that holds or stores food for human consumption at ambient air temperatures (approximately 21° C/70° F). Examples include storage tanks and grain elevators.
- Refrigerated human food warehouse/holding facility: A facility that holds or stores food products for human consumption at refrigerated temperatures (approximately 4° C/40° F to 0° C/32° F).
- Frozen human food warehouse/holding facility: A facility that holds or stores food for human consumption at frozen temperatures (approximately 0° C/32° F or below).
- Interstate conveyance caterer/catering point: A facility that prepares complete or partial meals or drinks from raw or partially processed materials for service to passengers or crew aboard an interstate conveyance or for consumption by these groups at a location other than where prepared.
- Contract Sterilizer: A facility that performs contract operations such as sterilization or irradiation of foods or components of foods, or that provides other microbial reduction treatments such as steam treatment or propylene oxide (PPO) treatment.
- Labeler/Relabeler: A facility that affixes the original labeling to a food product or changes in any way the labeling on a food product without affecting the product or its container.
- Manufacturer/Processor: A non-farm facility that makes food from one or more ingredients, or synthesizes, prepares, treats, modifies, or manipulates food, including food crops or ingredients. For purposes of this activity type option, examples of manufacturing/processing activities include: baking, boiling, bottling, canning, cooking, cooling, cutting, distilling, drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins), evaporating,

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eviscerating, extracting juice, extruding (of animal food), formulating, freezing, grinding, homogenizing, irradiating, labeling, milling, mixing, packaging (including modified atmosphere packaging), pasteurizing, peeling, pelleting (of animal food), rendering, treating to manipulate ripening, trimming, washing, or waxing.

- Acidified food processor: An establishment that manufactures/processes acidified foods as defined in 21 CFR 114.3(b) and is subject to the requirements of 21 CFR parts 108 and 114.
- Low-acid food processor: An establishment that manufactures/processes thermally processed low-acid food (as defined in 21 CFR 113.3(n)) packaged in a hermetically sealed container (as defined in 21 CFR 113.3(j)) and is subject to the requirements of 21 CFR parts 108 and 113.
- Farm Mixed-Type Facility: An establishment that is a farm, but also conducts activities outside the farm definition that require the establishment to be registered under section 415 of the FD&C Act.
- Packer/Repacker: A facility that packs a food product or products into different containers without making any change in the form of the product.
- Salvage Operator (Reconditioner): A facility that deals in the resale and reconditioning of damaged foods.
- Animal food warehouse/holding facility (e.g., storage facilities, including storage tanks, grain elevators): A facility that holds or stores food for animal consumption at any temperature.
- Other activity: Any other activity conducted at the facility not otherwise specified in 21 CFR 1.232(a)(8).

F.4.3 [Added November 2016] When do I select both low-acid food processor and acidified food processor as activity types on the registration form?

The low-acid food processor and acidified food processor activity types should both be selected if the facility manufactures acidified foods subject to the requirements in 21 CFR parts 108 and 114, as well as thermally processed low-acid foods packaged in hermetically sealed containers that are subject to the requirements of 21 CFR parts 108 and 113. For example, a facility that processes a thermally processed low-acid food such as green beans in water in a can and an acidified food such as pearl onions in brine in a glass jar would select both the low-acid food processor and acidified food processor activity types on the food facility registration form. The facility is engaging in both acidified food and low-acid food processing.

F.4.4 [Added November 2016] When is the requirement to provide activity type information effective?

You must provide activity type information, as specified in 21 CFR 1.232(a)(8), when you submit your registration, registration renewal, or update, after September 12, 2016, the effective date of the Registration Final Rule (81 FR 45912).

F.4.5 [Added November 2016] Do foreign facilities have to provide activity type information about all foods associated with the facility, or only about foods exported for

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consumption in the United States?

Foreign facilities that are required to register are only required to provide activity type information about food that the facility manufactures/processes, packs, or holds for consumption in the United States (see Comment 66 in the Registration Final Rule; 81 FR 45912 at 45938).

5. Requirement to Provide Assurance that FDA Will Be Permitted to Inspect

F.5.1 [Added November 2016] Is a foreign facility required to provide assurance that FDA will be permitted to inspect the facility?

Yes. Section 415(a)(2) of the FD&C Act, as amended by section 102(b) of FSMA, requires that food facility registrations contain an assurance that FDA will be permitted to inspect the facility at the times and in the manner permitted by the FD&C Act. The assurance is required for food facilities in order to complete their food facility registration.

G. What Optional Items Are Included in the Registration?

G.1 What optional information may be provided in the registration?

As stated in 21 CFR 1.233, FDA encourages, but does not require, registrants to submit items that are indicated as optional on Form FDA 3537.

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

- Facility fax number;
- Fax number and e-mail address for the preferred mailing address, if different from that of the facility;
- Fax number of the owner, operator, or agent in charge of the facility;
- Fax number and e-mail address of the parent company (if applicable);
- Individual name and title for the facility emergency contact;
- For a foreign facility: Title and fax number of its U.S. agent;
- Fax number of the authorizing individual; and
- Approximate dates of operation (if the facility's business is seasonal).

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

H.1 When must I update the information submitted in a food facility's registration?

You, or an individual you authorize, must submit an update to the facility's registration within 60 calendar days of any change to any of the required information (21 CFR 1.234(a)). 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 United

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States (21 CFR 1.234(b)).

H.2 [Added November 2016] I have changes to my registration information. Must I update my registration now, or can I wait until the beginning of the biennial registration renewal period beginning on October 1 of each even-numbered year?

The owner, operator, or agent in charge of a facility is required to submit an update to a facility's registration to FDA within 60 calendar days of a change to any of the required registration information previously submitted under 21 CFR 1.232(21 CFR 1.234(a)). If a change occurs to a facility's previously submitted required registration information before the start of or during the biennial registration renewal period, a registrant may submit an update for such change as part of the facility's registration renewal by including the update information in the registration renewal, provided that such update is submitted within 60 calendar days of the change. If a facility submits an update to FDA before the start of the next biennial registration renewal period, which takes place from October 1 – December 31 of each even-numbered year, the facility will still be required to submit a registration renewal to FDA during the biennial registration renewal period.

H.3 [Added November 2016] If I am the owner, operator, or agent in charge of a facility, may I authorize another individual to update the facility's registration?

Yes. Under 21 CFR 1.234(a), the owner, operator, or agent in charge of a facility may authorize an individual to update a facility's registration. The authorized individual may be, but is not required to be, the U.S. agent for the facility.

H.4 [Added November 2016] Am I required to include the email address of the individual who authorized the update in my registration update?

For updates not submitted by the owner, operator, or agent in charge, the update must include the email address of the individual who authorized the update, unless FDA has granted a waiver under 21 CFR 1.245 (see 21 CFR 1.234).

H.5 [Added November 2016] When must I submit my update to FDA electronically?

Updates must be submitted electronically to FDA beginning January 4, 2020, unless FDA has granted a waiver under 21 CFR 1.245. If FDA has granted a waiver, you may submit your update by mail or fax (see 21 CFR 1.234(d)).

H.6 [Added November 2016] Am I required to provide my registration number and pin number when I update my registration?

If you submit an update to your registration via mail or fax, you are asked to provide your facility registration number and pin number (or PIN) on Form FDA 3537. For electronic submissions, Account holders in FURLS will not need to provide a registration number or pin because that information is linked to the Account.

H.7 [Added November 2016] What do I do if I don't know my facility's registration number or pin number?

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If a registrant does not know their registration number and/or pin number, the owner, operator, or agent in charge should mail or fax a letter on company letterhead including the company's name, address, email address (if available), and facility telephone number to:

U.S. Food and Drug Administration
Food Facility Registration (HFS-681)
5001 Campus Dr.
College Park, MD 20740

You may send the fax to (301) 436-2804. Alternatively, the owner, operator, or agent in charge may send an email to FURLS@fda.gov to request their registration number and/or pin number. The email should include the company's name, address, and facility telephone number. We will verify that the individual requesting the registration number and/or pin number is the owner, operator, or agent in charge of the facility. Upon successful verification of the requester, the registration number and/or pin number will be sent to the owner, operator, or agent in charge of the facility by email, or U.S. mail, as appropriate.

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

I.1 How and when must a facility cancel its registration?

The owner, operator, or agent in charge of the facility, or an individual 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 an individual authorized by one of them, can submit the cancellation electronically at <http://www.fda.gov/furls>. Alternatively, you can obtain a paper copy of the cancellation form, Form FDA 3537a, and use the paper process to fax or mail the cancellation to FDA. Beginning January 4, 2020, you must submit your cancellation electronically, unless FDA has granted a waiver under 21 CFR 1.245 (21 CFR 1.235(d)). If FDA has granted a waiver, you may submit your cancellation by mail or fax.

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

U.S. Food and Drug Administration
Food Facility Registration (HFS-681)
5001 Campus Dr.
College Park, MD 20740

I.2 [Added November 2016] What information must be submitted in a cancellation?

As specified in 21 CFR 1.235(b), the cancellation for a facility's registration must include the

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following information:

- The facility's registration number;
- Whether the facility is domestic or foreign;
- The facility name and address;
- The name, address, and email address (if available) of the individual submitting the cancellation;
- For registration cancellations not submitted by the owner, operator, or agent in charge of the facility, the email address of the individual who authorized submission of the registration cancellation, unless FDA has granted a waiver under 21 CFR 1.245; and
- A statement certifying that the information submitted is true and accurate, and that the person submitting the cancellation is authorized by the facility to cancel its registration.

I.3 [Added November 2016] When will my registration be considered canceled?

For electronic cancellations, once you complete your electronic cancellation, FDA will provide you with an electronic confirmation of your cancellation (21 CFR 1.235(c)(2)). Your registration will be considered cancelled once FDA sends you your cancellation confirmation (21 CFR 1.235(c)(4)). For cancellations submitted by mail or fax, the registration will be considered cancelled once FDA enters the facility's cancellation data into the registration system (21 CFR 1.235(d)(7)). FDA will send the registrant a cancellation confirmation (21 CFR 1.235(d)(7)).

As we stated in the answer to Question E.5.1 of this document, for registration cancellations not submitted by the owner, operator, or agent in charge of the facility, after submission of the registration cancellation, FDA will verify that the individual identified as having authorized submission of the cancellation in fact authorized the submission on behalf of the facility (21 CFR 1.235(c)(3); 21 CFR 1.235(d)(6)). FDA will not confirm the registration cancellation until that individual confirms that he or she authorized the registration cancellation (21 CFR 1.235(c)(3); 21 CFR 1.235(d)(6)).

I.4 [Added November 2016] Can FDA cancel my registration?

Yes. As described in 21 CFR 1.241(c), FDA may cancel registrations in certain circumstances. Specifically, 21 CFR 1.241(c) provides that FDA will cancel a registration if FDA independently verifies:

- the facility is no longer in business;
- the facility has changed owners, and the owner, operator, or agent in charge of the facility fails to cancel the registration;
- the registration is for a facility that does not exist;
- the facility is not required to register;
- the information about the facility's address was not updated in a timely manner in accordance with 21 CFR 1.234(a); or
- the registration was submitted to FDA by a person not authorized to submit the registration under 21 CFR 1.225.

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In addition, FDA will consider a registration for a food facility to be expired if the registration is not renewed, as required by 21 CFR 1.230(b), and FDA will consider a food facility with an expired registration to have failed to register in accordance with section 415 of the FD&C Act (21 CFR 1.241(b)). Furthermore, 21 CFR 1.241(c) provides that FDA will cancel a registration if the facility's registration has expired because the facility has failed to renew the registration in accordance with 21 CFR 1.230(b).

21 CFR 1.241(c) states that if we cancel a facility's registration, we will send a confirmation of the cancellation using contact information submitted by the facility in the registration database.

I.5 [Added November 2016] If FDA cancels my registration, will I be informed before the registration is canceled?

We anticipate that in many cases it will be appropriate for FDA to send notices to facilities facing potential cancellation indicating our intent to cancel their registrations and the basis for such cancellations. We also anticipate that, when appropriate, if the circumstances meriting possible cancellation are corrected within 30 days after notice is provided, we will not cancel the registration. We further anticipate that if facilities do not respond within 30 days, or if corrective action is otherwise not taken within that time period, we will consider the lack of response or lack of corrective action as independent verification that the facility should no longer be registered and will then cancel the registration. If a facility believes its registration was cancelled in error, the facility may contact FDA. We also anticipate that it will generally not be appropriate to provide the 30-day window for corrective action if the basis for cancellation is an expired registration due to failure to renew a registration in accordance with 21 CFR 1.230(b). In those circumstances, a facility would have already received notice of its obligation to renew. Leading up to and throughout the registration renewal period, we plan to notify registrants of their obligation to renew registrations and the deadline for doing so. We also plan to notify registrants that failure to renew their registrations in accordance with 21 CFR 1.230(b) will cause FDA to consider the registrations expired. Additionally, we plan to notify registrants that we will consider a food facility with an expired registration to have failed to register in accordance with section 415 of the FD&C Act.

If FDA cancels a facility's registration, FDA will send a confirmation of the cancellation to the facility (see 21 CFR 1.241(c)).

I.6 [Added November 2016] What must I do if FDA cancels my registration because FDA considers it to be expired?

If FDA cancels your registration because FDA considers it to be expired and you continue to manufacture/process, pack, or hold food for consumption in the United States, you must re-register according to 21 CFR 1.230, and you must include all the information specified in 21 CFR 1.232.

I.7 [Added November 2016] If I have registered with FDA but am not required to do so, do I have to cancel the registration, or will FDA cancel the registration?

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Yes, you must cancel your registration within 60 calendar days of the reason for cancellation (see 21 CFR 1.235(a)). However, as specified in 21 CFR 1.241(c), we will cancel registrations if we independently verify that a facility is not required to register.

I.8 [Added November 2016] If FDA cancels a registration, what will FDA do with the information about those facilities that have previously registered?

We will archive information from inactive food facility registrations as appropriate.

J. What Other Registration Requirements Apply?

J.1 What other registration requirements apply to foods?

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.

Also, shell egg producers with 3,000 or more laying hens at a particular farm that does not sell all their eggs directly to consumers and that produces shell eggs for the table market are required to register their farms with FDA (see 21 CFR 118.11 (a)).

In addition, section 412(c)(1)(A) of the FD&C Act requires a person who introduces or delivers for introduction any new infant formula into interstate commerce to register with FDA the name of the person and their place of business, and all establishments at which the person intends to manufacture the new infant formula.

In addition, certain medicated feed mills are required to be licensed with FDA and registered as a drug establishment. For more information about which medicated feed mills must meet these requirements and how to become licensed and registered as a drug establishment, please see: <http://www.fda.gov/AnimalVeterinary/Products/AnimalFoodFeeds/MedicatedFeed/default.htm>.

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

K.1 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?

The failure of an owner, operator, or agent in charge of a facility to register its facility, renew the registration of its facility, update required registration elements of its facility's registration, or to cancel its registration in accordance with the requirements in 21 CFR part 1, subpart H is a prohibited act under section 301(dd) of the FD&C Act (21 U.S.C. 331(dd)). See 21 CFR 1.241(a). The United States can bring a civil action in Federal court to enjoin a person who commits a prohibited act. The United States also can bring a criminal action in Federal court to

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prosecute a person who is responsible for the commission of a prohibited act (21 CFR 1.241(a)). In addition, under section 306 of FD&C Act, FDA can seek debarment of any person who has been convicted of a felony relating to importation of food into the United States.

If food being imported or offered for import into the United States is from a foreign facility for which registration has not been submitted, the food must be held at the port of entry 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 and/or U.S. Customs and Border Protection (CBP) (section 801(l) of the FD&C Act).

K.2 [Added November 2016] If a foreign facility has not renewed its registration by December 31 of a biennial renewal period, will the facility still be able to import food into the United States?

If a foreign facility required to register does not renew its registration by December 31 of a biennial renewal period, the registration for the facility will be considered expired and FDA will cancel the registration. FDA will enforce the registration requirements of section 415 of the FD&C Act and implementing regulations in 21 CFR part 1, subpart H as appropriate in each situation. FDA's prior notice for imported foods system is the agency's primary tool for ensuring that foreign facilities that offer food for import into the United States are registered under section 415 of the FD&C Act. (See 21 CFR 1.285 and CPG Sec. 110.310 Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness Response Act of 2002). If FDA determines that a foreign food facility is not registered in accordance with section 415 and 21 CFR part 1, subpart H, including because the facility has failed to renew its registration as required, the food being imported or offered for import into the United States from the foreign facility is subject to being held at the port of entry (as defined in 19 CFR 101.1), in accordance with section 801(l) of the FD&C Act, unless CBP concurrence is obtained for the export of the food and the food is immediately exported from the port of arrival (as defined in 21 CFR 1.276(b)(11) (see 21 CFR 1.285(b)). Food held in this circumstance shall not be entered and shall not be delivered to the importer, owner, or ultimate consignee until the foreign facility is registered in accordance with section 415 and 21 CFR part 1, subpart H, and the appropriate registration number is provided in prior notice as specified in 21 CFR 1.285(i). FDA may allow the food held at the port of entry to be moved to a secure facility, as appropriate (21 CFR 1.285(c)(2)). However, FDA ordinarily will not allow the food to be transferred by any person from the port of entry into the United States or from the secure facility.

K.3 [Added November 2016] If a foreign facility has not renewed its registration by December 31 of a biennial renewal period, will the facility's designated U.S. agent continue to be designated as the U.S. agent for the facility?

Once a registration expires for failure to renew the registration, FDA will cancel the registration (see 21 CFR 1.241(c)). Once the registration is cancelled, the U.S agent no longer serves as the U.S. agent (as defined in 21 CFR 1.227) for that facility.

L. What Does Assignment of a Registration Number Mean?

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L.1 When is a food facility registration number assigned?

FDA assigns a registration number to confirm that a food facility is registered. A facility's registration is not confirmed until after we verify certain information included in the registration. Specifically, we will not confirm a registration until we verify a facility's UFI and facility-specific address, that the person identified as the U.S. agent agreed to serve as the U.S. agent (for foreign facility registrations), and that registrations not submitted by an owner, operator, or agent in charge were in fact authorized by the individual identified as having authorized the submission. See 21 CFR 1.231. Upon successful verification of this information, the registration number is assigned, and the registrant is notified of the registration number and pin number for the facility either in an email or a letter sent through U.S. mail.

L.2 What does assignment of a registration number mean?

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.

M. Is Food Registration Information Available to the Public?

M.1 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?

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 (FOIA) (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.

M.2 Is a registered facility responsible for ensuring that the companies with which they deal are registered?

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 United States 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.

M.3 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?

Section 415(a)(5) of the FD&C Act provides that certain registration-related information, including the registration number, is not subject to disclosure under FOIA. However, this does not prevent a facility itself from disclosing such information. In fact, for imports, a facility will

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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 (see 21 CFR part 1, subpart I). 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.

M.4 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?

Section 415(a)(5) of the FD&C Act provides that certain food facility registration information is not subject to disclosure under FOIA. 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 United States.

M.5 Will FDA require the food facility registration number to be displayed as part of a food label?

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.

N. Waiver Request

N.1 [Added November 2016] What is the process for submitting a waiver from electronic submission for my registration, registration renewal, update, or cancellation?

Beginning January 4, 2020, registrants must submit registrations, registration renewals, updates, or cancellations to FDA electronically, unless FDA has granted a waiver under 21 CFR 1.245 (see 21 CFR 1.231(a)(2) and (b), 1.234(d), and 1.235(d)).

If you are submitting a waiver from electronic submission of your registration, registration renewal, update, or cancellation, you must submit a written request to FDA that explains why it is not reasonable for you to submit a registration, registration renewal, update, or cancellation electronically to FDA. Possible reasons for why it may not be reasonable will depend on the circumstances, but in some cases may include conflicting religious beliefs or lack of reasonable access to the Internet.

N.2 [Added November 2016] What is the process for submitting a waiver from providing the email address of the owner, operator, or agent in charge of the facility, or the individual who authorized the submission, in my registration, registration renewal, update, or cancellation?

Under 21 CFR 1.232(a)(6), you must provide the email address of the owner, operator, or agent

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in charge of the facility unless FDA has granted a waiver from such requirement. In addition, under 21 CFR 1.230(b) and (c), 1.232(a)(10), 1.234(a), and 1.235(b)(5), registration renewals, abbreviated registration renewals, registrations, updates, and cancellations not submitted by the owner, operator, or agent in charge must include the email address for the individual who authorized the submission, unless FDA has granted a waiver under 21 CFR 1.245.

If you are submitting a waiver from the email requirement, you must submit a written request to FDA that explains why it is not reasonable for you to submit the required email address information (21 CFR 1.245).

N.3 [Added November 2016] Who must submit the waiver request to FDA?

The owner, operator, or agent in charge of the facility or the U.S. agent for a foreign facility may submit the waiver request to FDA.

N.4 [Added November 2016] How and where can I submit my waiver request?

The waiver request must be submitted in writing to the following address:

U.S. Food and Drug Administration
Center for Food Safety and Applied Nutrition
5001 Campus Dr. (HFS-681)
College Park, MD 20740

You may also submit your request by email to FURLS@fda.gov. The waiver request should include the facility name(s) and address(es) and the name of the owner, operator, or agent in charge of the facility. In addition, if the waiver request is being submitted by a U.S. agent on behalf of a foreign facility, the request should include the name of the U.S. agent authorized by the owner, operator, or agent in charge of the facility to submit the waiver request. Once FDA receives and reviews the request, we will notify you if the waiver has been granted or denied.

For requests regarding a waiver from submitting a registration, registration renewal, update, or cancellation to FDA electronically, if we grant your waiver, we will send you a paper copy of Form FDA 3537 or Form FDA 3537a, if requested.

N.5 [Added November 2016] If I have multiple facilities, may I submit one waiver request for all of my facilities?

Yes. You may submit one waiver request for all of your facilities if you have multiple facilities. You should include the facility names, addresses, and the name of the owner, operator, or agent in charge of each facility in your waiver request. If the waiver request is being submitted by a U.S. agent on behalf of a foreign facility, the request should include the name of the U.S. agent authorized by the owner, operator, or agent in charge of the facility to submit the waiver request.

N.6 [Added November 2016] How will FDA review my waiver request?

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FDA will consider whether to grant or deny your waiver based on the information you include in your request. We will consider each request on a case-by-case basis.

N.7 [Added November 2016] Do I have to submit additional waiver requests after a request has already been granted?

No. Once FDA grants a waiver, we will consider the waiver to be in effect for as long as the reasons for the waiver remain unchanged and the registration has not been cancelled, unless you have informed FDA that the waiver is no longer needed. If the registration for the facility has been cancelled, a new waiver request should be submitted.

O. General Registration Questions

O.1 Will the food facility regulations be published in other languages?

No. FDA has no plans to publish the Amendments to Registration of Food Facilities Final Rule or the regulations at 21 CFR part 1, subpart H in any language other than English.

O.2 [Added November 2016] Is there a fee for registration, updating a registration, renewing a registration, or canceling a registration?

No. There is no fee associated with initial registration, updating a registration, renewing a registration, or canceling a registration.

O.3 [Added November 2016] Do I have to use a third-party service when submitting a registration?

No. FDA does not require a food facility to use a third party to make registration submissions. A food facility owner, operator, or agent in charge of the facility is responsible for meeting the registration requirements (see section 415(a) of the FD&C Act; and 21 CFR part 1, subpart H). The owner, operator, or agent in charge may authorize an individual to make registration submissions on behalf of the facility (see, e.g., 21 CFR 1.230(a)). The authorized individual may be, but is not required to be, the U.S. agent for a foreign facility. Although third parties such as U.S. agents may charge a fee for their registration-related services, there is no fee assessed by FDA for registrations.

O.4 [Added November 2016] Are qualified facilities that are exempt from the Preventive Controls for Human Food or Animal Food final rules still required to register?

Yes. Qualified facilities, as defined in 21 CFR 117.3 (human food) or 21 CFR 507.3 (animal food), are food facilities that are required to register under section 415 of the FD&C Act.

O.5 [Added November 2016] I am a farmer and my produce is packed in a packinghouse that is a separate business from my farm. My farm business and the packinghouse business are under common ownership. That is, there is a single, separate business that

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owns a majority interest in my farm, and a majority interest in the packinghouse. The packinghouse only packs produce from my farm. The packinghouse would qualify as a secondary activities farm except that the packinghouse is not majority-owned by the farms whose produce it packs. FDA has extended the compliance date with respect to the requirements for hazard analysis and risk-based preventive controls for businesses such as mine to consider modifying the farm definition. During the extended timeframe to comply with the requirements for hazard analysis and risk-based preventive controls, does my business need to register?

In a final rule published in the *Federal Register* of August 24, 2016 (81 FR 57784), FDA extended the date for certain facilities to comply with some or all requirements for hazard analysis and risk-based preventive controls in some circumstances. These facilities include certain facilities that would qualify as secondary activities farms except for the ownership of the facility, certain facilities that color RACs, and facilities solely engaged in the ginning of cotton. For some of these issues, FDA stated that it was considering whether future rulemaking to modify the “farm” definition is appropriate to address the issue. FDA does not intend to prioritize enforcing the registration requirement for these businesses.

P. Suspension of Registration

P.1 Can FDA suspend the registration of a food facility?

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.

P.2 When can FDA suspend the registration of a facility registered under section 415 of the FD&C Act?

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).

P.3 When are registered food facilities subject to the suspension of registration provisions of section 415 of the FD&C Act?

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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).

Q. Compliance Dates

Q.1 [Added November 2016] When must I comply with the requirements of the Amendments to Registration of Food Facilities final rule?

You must comply with the requirements of the Registration Final Rule on September 12, 2016, unless otherwise stated in the final rule.

Q.2 [Added November 2016] When must I comply with the UFI requirement?

Beginning October 1, 2020, you must provide the facility's UFI recognized as acceptable by FDA in your registration submission, as specified in 21 CFR 1.232(a)(2).

Q.3 [Added November 2016] When must I comply with the electronic submission requirement?

Beginning January 4, 2020, you must submit your registration, registration renewal, updates, and cancellations to FDA electronically unless FDA has granted a waiver from such requirement (see 21 CFR 1.231(a)(2) and (b), 1.234(d), and 1.235(d)). Furthermore, as we stated in the Registration Final Rule, FDA must have already granted a waiver in order for the electronic submission requirement to not apply (see 81 FR 45912 at 45943 to 45944).

III. References

We have placed the following references on display in the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. You may see them at that location between 9 a.m. and 4 p.m., Monday through Friday. As of December 1, 2016, FDA had verified the Web site address for the references it makes available as hyperlinks from the Internet copy of this guidance, but FDA is not responsible for any subsequent changes to Non-FDA Web site references after December 1, 2016.

1. U.S. Food and Drug Administration. 2016. "Classification of Activities as Harvesting, Packing, Holding, or Manufacturing/Processing for Farms and Facilities." Accessed online at <http://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/ucm517567.htm>.
2. U.S. Food and Drug Administration. 2016. "Necessity of the Use of Food Categories in Food Facility Registrations and Updates to Food Categories: Guidance for Industry." Accessed online at

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<http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm324778.htm>.

3. U.S. Food and Drug Administration. 2016. Information on Medicated Feeds. Accessed online at <http://www.fda.gov/AnimalVeterinary/Products/AnimalFoodFeeds/MedicatedFeed/default.htm>.