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

Draft Guidance

This guidance is being distributed for comment purposes only.

Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance within 90 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number FDA-2012-D-1002 listed in the notice of availability that publishes in the *Federal Register*.

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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Questions and Answers Regarding Food Facility Registration (Seventh Edition): Guidance for Industry[1]

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or we) on this topic.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.

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).

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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?

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.

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.

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 renewa1 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.

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 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 (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 is the status of a foreign facility's registration 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 has agreed to serve as your U.S. agent (see 21 CFR 1.231(a)(5) and (b)(7)).

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 affirmatively 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

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

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, 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?

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;
- 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, 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 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 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 31of 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?

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 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.

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?

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 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?

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 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 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?

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 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?

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 September 28, 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 September 28, 2016.

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

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