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Registration of Food Facilities: What You Need to Know About the FDA Regulation: Guidance for Industry

Small Entity Compliance Guide

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<http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm253380.htm>

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

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Registration of Food Facilities: What You Need to Know About the FDA Regulation: Guidance for Industry¹

Small Entity Compliance Guide

This guidance represents 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 as listed on the title page.

I. Introduction

This is a revision of the guidance “What You Need To Know About Registration of Food Facilities” that was issued in December 2012. We are issuing revised guidance because in the *Federal Register* of July 14, 2016 (81 FR 45911), we published a final rule pertaining to registration of food facilities entitled “Amendments to Registration of Food Facilities” (the final rule). The final rule amends the regulations at 21 CFR Part 1, Subpart H (21 CFR 1.225 through 1.245). The final rule became effective on September 12, 2016. This guidance reflects changes made by the final rule. We also have made editorial changes for clarity.

We have prepared this Small Entity Compliance Guide (SECG) in accordance with section 212 of the Small Business Regulatory Enforcement Fairness Act (Public Law 104-121, as amended by Public Law 110-28). This guidance document is intended to help small entities comply with the food facility registration regulations set forth in 21 CFR, Part 1, Subpart H (21 CFR 1.225 through 1.245). These regulations are binding and have the full force and effect of law.

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

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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 FDA guidances means that something is suggested or recommended, but not required.

II. Background

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act) (Pub. L. 107-188) added section 415 to the Federal Food, Drug, and Cosmetic Act (FD&C Act). 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.

On October 10, 2003, we issued an interim final rule (68 FR 58894) to implement section 415 of the FD&C Act. That rule established the food facility registration regulations in 21 CFR Part 1, Subpart H (21 CFR 1.225 through 1.243). Previously, this guidance restated FDA's food facility registration regulations. This guidance also served as FDA's SECG for 21 CFR Part 1, Subpart H.

The FDA Food Safety Modernization Act (FSMA), enacted on January 4, 2011, amended section 415 of the FD&C Act to require that facilities engaged in manufacturing, processing, packing, or holding food for consumption in the United States submit additional registration information to FDA, including an assurance that FDA will be permitted to inspect the facility at the times and in the manner permitted by the FD&C Act. Section 415 of the FD&C Act, as amended by FSMA, also requires food facilities required to register with FDA to renew such registrations every other year, and provides FDA with authority to suspend the registration of a food facility in certain circumstances.

On July 14, 2016, we published a final rule (81 FR 45912) that amended our food facility registration regulations to reflect, among other things, the FSMA amendments to section 415 of the FD&C Act. Accordingly, FDA has revised this guidance document intended to help small entities comply with 21 CFR Part 1, Subpart H (21 CFR 1.225 through 1.245).

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

III. Discussion

ABOUT REGISTRATION

Food Facility Registration Requirement

Domestic and foreign facilities that manufacture, process, pack, or hold food, as defined in 21 CFR 1.227, for human or animal consumption in the United States must register with FDA.

Why Facility Registration Is Required

Food facility registration will help FDA to:

- Determine the location and source of a potential bioterrorism incident or an outbreak of food-borne illness; and
- Quickly notify facilities that may be affected.

What It Costs

There is no fee for registration, registration renewal or updates to a registration.

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HOW REGISTRATION AFFECTS YOU

Which Facilities Must Register

If your facility is in one of the following food industry sectors, you must register your facility with FDA.

Food Industry Sectors Affected
<ul style="list-style-type: none">• Domestic and foreign manufacturers or processors²• Domestic and foreign packers²• Domestic and foreign storage operations²

<i>Foods Handled by More Than One Foreign Facility:</i>	
If...	Then...
A foreign facility that manufactures, processes, packs, or holds the food sends it to <i>another</i> foreign facility for further manufacturing/processing (including packaging) before the food is exported to the U.S.	Only the <i>second</i> foreign facility is required to register with respect to that food.
The second foreign facility performs only a minimal activity, such as putting on a label	<i>Both</i> facilities must register.
Any foreign facility packs or holds food <i>after</i> the last foreign manufacturer/processor of the food	The foreign packer or holder must also register.

² Domestic facilities must register whether or not food from the facility enters interstate commerce.

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Food Included in the Regulation

Registration pertains only to facilities that manufacture/process, pack, or hold food, as defined in 21 CFR 1.227, **for consumption** by humans or animals in the United States.

The following chart gives examples of the types of food that are included in or excluded from the “food” definition in the facility registration regulation. If your facility handles any of the included foods, it must be registered.

INCLUDED Foods	EXCLUDED Foods
<ul style="list-style-type: none">• Dietary supplements and dietary ingredients• Infant formula• Beverages (including alcoholic beverages and bottled water)• Fruits and vegetables• Fish³ and seafood• Dairy products and shell eggs• Raw agricultural commodities for use as food or components of food• Canned and frozen foods• Bakery goods, snack food, and candy (including chewing gum)• Live food animals• Food for animals (e.g., pet food, pet treats and chews, animal feed)	<ul style="list-style-type: none">• Food contact substances• Pesticides

Note: A facility that manufactures/processes, packs, or holds only a food contact substance or pesticide is NOT required to register with FDA.

³ Facilities that process only fish of the order Siluriformes (i.e., catfish, tra, swai, and basa) and products derived from these fish are not required to register as these facilities are regulated exclusively throughout the entire facility by the United States Department of Agriculture (USDA). See question B.6.2 from draft “Food Facility Registration Questions and Answers (Seventh Edition): Guidance for Industry”.

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Facilities That Do Not Have to Register

If your facility meets one of the following descriptions, it does NOT have to register with FDA.

These Facilities DON'T Have to Register

- **Private residences of individuals**, even though food may be manufactured/processed, packed, or held in them.
- **Non-bottled water drinking water collection and distribution establishments and structures**, such as municipal water systems.
- **Transport vehicles that hold food only in the usual course of their business as carriers.**
- **Primary production farm**⁴ — i.e., an operation under one management in one general (but not necessarily contiguous) physical location devoted to the growing of crops, the harvesting of crops (washing, trimming outer leaves, and cooling produce are part of harvesting), the raising of animals (including seafood), or any combination of these activities. The term “primary production farm” can include operations that pack or hold raw agricultural commodities, pack or hold processed food, or manufacture/process food under certain circumstances.
- **Secondary activities farm**⁴— i.e., an operation, not located on a primary production farm, devoted to harvesting, packing, and/or holding of raw agricultural commodities, as long as certain ownership criteria are met. A secondary activities farm may also pack or hold processed food or manufacture/process food under certain circumstances.
- **Restaurants** — i.e., facilities that prepare and sell food directly to consumers for immediate consumption, including pet shelters, kennels, and veterinary facilities that provide food to animals. Facilities that provide food to interstate conveyances, such as commercial aircraft, or central kitchens that do not prepare and serve food directly to consumers, are not restaurants for purposes of 21 CFR Part 1, Subpart H.

⁴ See the “farm” definition at 21 CFR 1.227. Note that in January 2018, FDA issued a guidance document in which we stated that we intend to initiate a rulemaking that could change the definition of a “farm.” We also stated that we do not anticipate that the rulemaking would result in an entity that currently is a “farm” becoming a “facility.” See “Policy Regarding Certain Entities Subject to the Current Good Manufacturing Practice and Preventive Controls, Produce Safety, and/or Foreign Supplier Verification Programs,” accessible at <https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm590646.htm>.

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- **Retail food establishments**⁵, such as grocery stores, convenience stores, vending machine locations, and certain farm-operated businesses, that sell food directly to consumers as their *primary function*, meaning that annual food sales directly to consumers are of greater dollar value than annual sales to other buyers. The term “retail food establishment” includes facilities that manufacture, process, pack, or hold food if the establishment’s primary function is to sell food from that establishment directly to consumers. A “farm-operated business” means a business that is managed by one or more farms and conducts manufacturing/processing not on the farm(s). Sale of food directly to consumers by a farm-operated business includes the sale of food directly to consumers at a roadside stand; through a community supported agriculture program; 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. In addition, 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; through a community supported agriculture program; 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.
- **Nonprofit food facilities**, which are charitable entities that meet the terms of § 501(c)(3) of the Internal Revenue Code and that prepare or serve food directly to the consumer or otherwise provide food or meals for consumption by humans or animals in the United States. This includes central food banks, soup kitchens, and nonprofit food delivery services.
- **Fishing vessels that do not process fish.** Such fishing vessels may engage in practices other than processing, such as harvesting and transporting fish, and heading, eviscerating, or freezing fish solely to prepare the fish for holding on board the vessel.
- **Facilities regulated exclusively and throughout the entire facility by the U.S. Department of Agriculture under one of its inspection acts**, that is, facilities processing only meat, poultry, or egg products that are inspected by USDA’s Food Safety and Inspection Service.

⁵ See the “retail food establishment” definition at 21 CFR 1.227.

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When Must My Facility Register?

Your facility must register before you begin manufacturing/processing, packing, or holding food for consumption in the United States.

How Often Must a Facility Register or Renew its Registration?

A food facility is required to submit an initial registration to FDA only once. Section 415(a)(3) of the FD&C Act, as amended by section 102 of FSMA, requires your facility to renew its registration with FDA every other year during the period beginning on October 1 and ending on December 31 of each even-numbered year.

Is a Facility Required to Resubmit all of the Registration Information during the Biennial Renewal Process?

No. FDA has an abbreviated biennial registration renewal process for a registrant of a facility that has not had any changes to its registration information since the registrant submitted the previous registration, registration renewal, or update for the facility.

Who May Register a Facility?

The owner, operator, or agent in charge of a facility, or an individual authorized by one of them, may register that facility.

Foreign facilities must designate a U.S. agent, who lives or maintains a place of business in the United States and is physically present in the United States, for purposes of communication between the facility and FDA. The U.S. agent also may be authorized to register the facility.

What If Your Facility Fails to Register, Renew, or Update its Registration?

Failure to register your facility, renew your registration, update required elements, or cancel registration in accordance with section 415 of the FD&C Act and applicable regulations is a prohibited act under the FD&C Act. The Federal government can bring a civil action against persons who commit a prohibited act, or it can bring a criminal action in Federal court to prosecute persons who are responsible for the commission of a prohibited act, or both.

FDA will consider a registration for a food facility to be expired if the registration is not renewed. 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.

If a foreign facility is required to register but fails to do so, food from that facility that is offered for import into the United States is subject to being held at the port of entry or a secure facility until the foreign facility is registered.

What if FDA cancels an expired registration for failure to renew?

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 and are subject to section 415 of the FD&C Act, you must re-register.

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SUSPENSION OF REGISTRATION

Can FDA suspend the registration of a food facility?

Yes. Section 415(b) of the FD&C Act, as amended by FSMA, provides that FDA may by order suspend the registration of a food facility registered under section 415 in certain circumstances.

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

FDA can suspend a food facility's registration when FDA determines that:

1. 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. A 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).

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).

What is the effect of an order suspending a food facility's registration?

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

Who may issue an order to suspend a food facility's registration?

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

If a facility's registration is suspended, does the registrant have an opportunity for an informal hearing?

FDA will provide the registrant subject to a suspension order with an opportunity for an informal hearing. If a request for a hearing is granted, the hearing must be held as soon as possible but not later than two business days after the issuance of the suspension order or such other time period as agreed upon by FDA and the registrant. Further, the hearing will be on actions required for reinstatement of registration and why the registration that is subject to suspension should be

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reinstated. FDA will reinstate a registration if it determines, based on evidence presented, that adequate grounds do not exist to continue the suspension of the registration (section 415(b)(2) of the FD&C Act).

What happens if FDA determines that a suspension of registration remains necessary after providing opportunity for an informal hearing?

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

When will FDA vacate an order suspending a food facility's registration?

FDA will vacate an order suspending a facility's registration and reinstate the registration of the facility subject to the order, if FDA determines that adequate grounds do not exist to continue the suspension actions required by the order (sections 415(b)(2) and 415(b)(3)(B) of the FD&C Act).

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REGISTERING YOUR FACILITY

How to Register Your Facility

Registrants must use Form FDA 3537 to register, renew, or update a registration. This form is available online and in paper form.

FDA will process paper submissions in the order received.

Note: FDA does not allow registration in person.

Online Registration

You can save time by registering online at <http://www.fda.gov/furls>. This web site offers online help and operates 24 hours a day, seven days a week. You can access the site wherever the Internet is available — including libraries, copy centers, schools, and Internet cafes.

A Registration Help Desk is available on business days, from 7:00 AM until 11:00 PM U.S. Eastern Standard Time to help you.

To Contact the Registration Help Desk:	
By phone	WITHIN THE U.S.: Call 1-800-216-7331 or 240-247-8804 OUTSIDE THE U.S.: Call 240-247-8804
By fax	Fax questions to 301-436-2804
By email	Furls@fda.gov or go to https://www.accessdata.fda.gov/scripts/email/cfsan/bioterrorismact/helpf2.cfm and complete the form

Paper Registration

If your facility does not have reasonable access to the Internet, you can request a copy of Form FDA 3537 from FDA by mail or phone. The form can be mailed or faxed to you. Fill out the form completely and legibly and mail it or fax it to:

To Submit a Paper Registration:	
By mail	Send to: U.S. Food and Drug Administration Food Facility Registration HFS-681 5001 Campus Drive College Park, MD 20740 USA
By fax	301-436-2804

Electronic submissions

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)).

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Waivers from Electronic Submissions

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. (21 CFR 1.245)

We encourage registrants seeking a waiver to submit their request in advance of the biennial registration renewal because we experience an increased volume of industry queries during this timeframe.

To Request the Form:	
By mail	Write to: U.S. Food and Drug Administration Food Facility Registration HFS-681 5001 Campus Drive College Park, MD 20740 USA
By phone	Call 1-877-216-7331 or 240-247-8804 (7:00 a.m. to 11:00 p.m. U.S. Eastern Standard Time)
Note: <i>Paper registration is less efficient than online registration. It takes longer to receive confirmation for paper registration. And, if your form contains omissions or errors, FDA will return it for corrections without registering your facility—resulting in further delay.</i>	

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Information Required for Registration

FDA requires you to provide the following information for facility registration.

Required Information
<ul style="list-style-type: none">• Facility name, full address, phone number• Beginning October 1, 2020, the facility’s unique facility identifier (UFI) recognized as acceptable by FDA• The preferred mailing address, if different from that of the facility• Parent company name, address, and phone number (if applicable)• Email address for the contact person of the facility or, in case of a foreign facility, the Name, address, phone number, and email address of the U.S. Agent for the facility• An emergency contact phone number and email address (for domestic facilities, the email address is only required if this is different from the contact person)• Name, full address and phone number of the owner, operator, or agent in charge. In addition, the email address of the owner, operator, or agent in charge is required, unless FDA has granted a waiver under 21 CFR 1.245• All trade names the facility uses• Applicable food product categories, as listed on the registration form• The type of activity conducted at the facility for each food product category identified• Assurance that FDA will be permitted to inspect the facility at the times and in the manner permitted by the FD&C Act• Certification that the information submitted is true and accurate and that the person submitting it is authorized to do so

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Optional Registration Information

FDA also requests optional registration information. Although you are not required by law to comply with this request, FDA encourages you to do so because such information will enable FDA to communicate more effectively with facilities that may be the target of, or otherwise affected by, a food-related emergency and such communication will benefit FDA and the registered facility.

Optional Information Requested

- 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 email 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
- Approximate dates of operation (if the facility's business is seasonal)

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Facility Registration Screen

Here is a sample screen from the FDA registration web site (<http://www.fda.gov/furls>).

U.S. Department of Health and Human Services

FDA FURLS | FFR Food Facility Registration

FURLS Home | FFR Home

Food Facility Registration

FFR Home

Welcome to the Food Facility Registration Module. Please select the menu option from the left to get started.

PAPERWORK REDUCTION ACT NOTICE

The burden for this collection of information is estimated to average between 1 and 12 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to the following address:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

For more information regarding food facility registration, please visit:
<http://www.fda.gov/Food/GuidanceRegulation/FoodFacilityRegistration/default.htm>

For assistance, please contact the FDA Industry Systems Help Desk:
1-800-216-7331
240-247-8804
furls@fda.gov

(Technical, Computer & General Questions)
Help desk hours are Monday to Friday from 7:30 am to 11:00 pm Eastern Standard Time

How Registration Is Confirmed

After you register your facility, FDA will confirm the registration, perform certain verification procedures and assign a registration number.

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:

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- 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.

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

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,

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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.

Verification Procedures for U.S. Agents

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.

<p>Note: Assignment of a registration number means only that the facility is registered. It does NOT convey FDA approval or endorsement of the facility or its products.</p>

Confidentiality of Registration Information

The list of registered facilities and certain registration-related information are not subject to disclosure under the Freedom of Information Act (see section 415(a)(5) of the FD&C Act). The provision of section 415(a)(5) does not apply if the information was obtained by FDA by other means or if the information has previously been lawfully disclosed to the public.

How to Update Registration Information

If any of the required information on your registration form changes — for example, if there is a

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new operator, agent in charge, or U.S. agent — the owner, operator, or agent in charge, or an individual authorized by one of them, must notify FDA within 60 days (21 CFR 1.234(a)).

To Update Your Registration:	
Online	Go to http://www.fda.gov/furls . ⁶
By paper	Use the paper registration process described on page 12

In the case of new ownership, the former owner must cancel the facility's registration within 60 days and the new owner must register the facility (21 CFR 1.234(b)).

How to Cancel Registration

If your facility goes out of business or comes under new ownership, you must cancel its registration within 60 days using Form FDA 3537a (21 CFR 1.235). You can do this electronically at <http://www.fda.gov/furls>, or you can request the form from FDA and use the paper registration process described on page 12.

FIND OUT MORE

How to Get More Information

Additional information is available at

<https://www.fda.gov/Food/GuidanceRegulation/FoodFacilityRegistration/default.htm>

and <http://www.fda.gov/Food/FoodSafety/FSMA/default.htm>.

⁶ Use the PIN that was issued with your facility's registration number. If you originally registered by paper, you will need to follow the online instructions to set up an account.

FDA’s Food Facility Registration Regulation At-a-Glance

WHAT It Is: Domestic and foreign facilities that manufacture, process, pack, or hold food, as defined in 21 CFR 1.227, for human or animal consumption in the U.S. must register with FDA.

WHY It’s Required: To help FDA to determine the location and source of a potential or actual bioterrorism incident or an outbreak of food-borne illness, and permit the Agency to notify quickly facilities that may be affected.

WHICH Facilities Must Register: Domestic and foreign food manufacturers/processors, packers, and storage operations that handle food for consumption in the U.S. For purposes of registration, “food” is defined in 21 CFR 1.227.

Examples of WHICH Foods Require Facility Registration:
<ul style="list-style-type: none">• Dietary supplements and dietary ingredients• Infant formula• Beverages (including alcoholic beverages and bottled water)• Fruits and vegetables• Fish⁷ and seafood• Dairy products and eggs• Raw agricultural commodities for use as food or components of food• Canned and frozen foods• Bakery goods, snack food, and candy (including chewing gum)• Live food animals• Food for animals (e.g., pet food, pet treats and chews, animal feed)

WHEN Facilities Must Register: Before your facility begins to manufacture, process, pack, or hold food for consumption in the United States.

WHO May Register: The owner, operator, or agent in charge of a facility, or an individual authorized by one of them, may register that facility.

Foreign facilities must designate a U.S. agent, who lives or maintains a place of business in the U.S. and is physically present in the U.S., for purposes of communication between the facility and FDA. The U.S. agent also may be authorized to register the facility.

⁷ Facilities that process only fish of the order Siluriformes (i.e., catfish, tra, swai, and basa) and products derived from these fish are not required to register as these facilities are regulated exclusively throughout the entire facility by the United States Department of Agriculture (USDA). See question B.6.2 from draft “Food Facility Registration Questions and Answers (Seventh Edition): Guidance for Industry”.

Contains Nonbinding Recommendations

HOW to Register:	
Online	Go to http://www.access.fda.gov/ (24 hours a day, 7 days a week).
By Mail or Fax	1. Request Form FDA 3537 from FDA (Call 1-877-216-7331 or 240-247-8804 (7:00 a.m. to 11:00 p.m. U.S. Eastern Standard Time)) 2. Mail or fax (Fax: 301-436-2804) completed form to: U.S. Food and Drug Administration HFS-681 5001 Campus Drive College Park, MD 20740

Get HELP: (business days, 7:00 AM to 11:00 PM U.S. EST)	
By phone	WITHIN THE U.S.: Call 1-800-216-7331 or 240-247-8804 OUTSIDE THE U.S.: Call 240-247-8804
By fax	Fax questions to 301-436-2804
By email	Email questions to furls@fda.gov

WHAT Information is Required:
<ul style="list-style-type: none"> • Facility name, full address, phone number • Beginning October 1, 2020, the facility’s unique facility identifier (UFI) recognized as acceptable by FDA • The preferred mailing address, if different from that of the facility • Parent company name, address and phone number (if applicable) • Email address for the contact person of the facility or, in case of a foreign facility, the name, address, phone number, and email address of the U.S. Agent for the facility • An emergency contact phone number and email address (for domestic facilities, the email address is only required if this is different from the contact person) • Name, full address and phone number of the owner, operator or agent in charge. In addition, the email address of the owner, operator, or agent in charge is required, unless FDA has granted a waiver under 21 CFR 1.245 • All trade names the facility uses • Applicable food product categories, as listed on the registration form • The type of activity conducted at the facility for each food product category identified • Assurance that FDA will be permitted to inspect the facility at the times and in the manner permitted by the FD&C Act • Certification that the information submitted is true and accurate and that the person submitting it is authorized to do so

HOW Registration Is Confirmed: FDA confirms the registration either electronically (online registration) or by mail (paper), and assigns a registration number.

WHAT IF...	
If...	Then...
Required registration info changes	You must notify FDA within 60 days.
There’s a change in ownership	The former owner must cancel registration within 60 days and the new owner must register.
Your facility goes out of business	You must cancel registration.
A domestic facility fails to register	The Federal government can bring a civil or criminal action against the owner, operator, or agent in charge.
A foreign facility fails to register and then tries to import food into the U.S.	The food will be held at the port of entry, unless otherwise directed by FDA or CBP.

Get More Information: For more information, go to <https://www.fda.gov/Food/GuidanceRegulation/FoodFacilityRegistration/default.htm>