U.S. Registration Requirements of Food Facilities

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act) added section 415 to the Federal Food, Drug, and Cosmetic Act (FD&C Act). Section 415 of the FD&C Act requires domestic and foreign facilities that manufacture, process, pack or hold food for human or animal consumption in the United States to register with the Food and Drug Administration (FDA).

The FDA Food Safety Modernization Act (FSMA) of 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 the FDA, including an assurance that the 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 the FDA to renew such registrations every other year, and provides the FDA with authority to suspend the registration of a food facility in certain circumstances.

Food Facility Registration Requirement

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

Why Facility Registration Is Required

Food facility registration will help the 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.

Which Facilities Must Register

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

• Domestic and foreign manufacturers or processors
• Domestic and foreign packers
• Domestic and foreign storage operations

Foods Handled by More Than One Foreign Facility

If a foreign facility that manufactures, processes, packs, or holds the food sends it to another foreign facility for further manufacturing/processing (including packaging) before the food is exported to the U.S., then only the second foreign facility is required to register with respect to that food.

If the second foreign facility performs only a minimal activity, such as putting on a label, then both facilities must register. Any foreign facility that packs or holds food after the last foreign manufacturer or processor of the food must also register.

Food Included in the Regulation

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

INCLUDED Foods	EXCLUDED Foods
• Dietary supplements and ingredients • Infant formula • Beverages • Fruits, vegetables and nuts • Fish and seafood • Dairy products and shell eggs • Raw agricultural commodities for use as food • Canned and frozen foods • Bakery goods, snack food, and candy • Food for animals (pet food, animal feed)	• Food contact substances • Pesticides

When Must a Facility Register or Renew its Registration?

A facility must register before it begins manufacturing/processing, packing, or holding food for consumption in the United States. A food facility is required to submit an initial registration to the FDA only once. Section 415(a)(3) of the FD&C Act, as amended by section 102 of FSMA, requires a facility to renew its registration with the FDA every other year during the period beginning on October 1 and ending on December 31 of each even-numbered year.

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 the 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 a facility, renew a registration, update required elements, or cancel registration 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. The FDA will consider a registration for a food facility to be expired if the registration is not renewed.

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.

REGISTERING A FACILITY

How to Register Your Facility

Registrants must use Form FDA 3537 to register, renew, or update a registration.

This form is available online

Online Registration

Registration must be completed 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.

Beginning January 4, 2020, registrants must submit registrations, registration renewals, updates, or cancellations to the FDA electronically, unless FDA has granted a waiver under 21 CFR 1.245.

Registration Help Desk

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.

The Registration Help Desk can be contacted by phone within the U.S. at 1-800-216-7331, outside the U.S. at 240-247-8804, by fax at 301-436-2804 and by email Furls@fda.gov or through the web site: https://www.accessdata.fda.gov/scripts/email/cfsan/bioterrorismact/helpf2.cfm and submitting the form.

Waivers from Electronic Submissions

In order to obtain a waiver from electronic submission of your registration, registration renewal, update, or cancellation, you must submit a written request to the FDA that explains why it is not reasonable for you to submit a registration, registration renewal, update, or cancellation electronically to the 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)

Registrants seeking a waiver should submit their request in advance of the biennial registration renewal due to an increased volume of industry queries during this timeframe.

Requests for the waiver form may be made by telephone by calling 1-877-216-7331 or 240-247-8804 (7:00 a.m. to 11:00 p.m. U.S. Eastern Standard Time) or by mail by sending your written request to:

U.S. Food and Drug Administration
Food Facility Registration HFS-681
5001 Campus Drive
College Park, MD 20740 USA

Information Required for Registration

The FDA requires the following information for facility registration:

• Facility name, full address, phone number

• 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)

• Name, address, phone number, and email address of the U.S. Agent for the facility

• An emergency contact phone number and email address

• Name, full address, phone number and email address of the owner, operator, or agent in charge.

• 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 the FDA will be permitted to inspect the facility as 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

Registration Confirmation

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

Verification process for the unique facility identifier (UFI) required in the facility's registration

Domestic and foreign facilities must submit a unique facility identifier (UFI) recognized as acceptable to FDA in the facility's registration. FDA intends to conduct the verification process for the UFI as follows:

• For registrations, after the submission of the registration, the FDA will verify the accuracy of the UFI recognized as acceptable by the FDA and will also verify that the facility-specific address associated with the UFI is the same address associated with the registration. The FDA will not confirm the registration or provide a registration number until the FDA verifies the accuracy of the facility's UFI and verifies that the facility-specific address associated with the UFI is the same address associated with the registration.

• For registration renewals, after the submission of the registration renewal, the FDA will provide an electronic confirmation of the registration renewal. When the facility's UFI is added or updated as part of the registration renewal, the FDA will verify the accuracy of the facility's UFI and will also verify that the facility-specific address associated with the UFI is the same address associated with the registration. The FDA will not provide a confirmation of the registration renewal until the FDA verifies the accuracy of the UFI and verifies that the facility specific address associated with the UFI is the same address associated with the registration.

Verification Procedures for U.S. Agents

For registrations, registration renewals, and updates to information about U.S. agents, the FDA will verify that the person identified as the U.S. agent for the foreign facility agreed to serve as the U.S. agent. The 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. For updates, the 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.

In most circumstances, the FDA will conduct this verification step by sending an email to the person identified as the U.S. agent. In some circumstances, however, the 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 the FDA that he has not agreed to serve as the facility's U.S. agent, the 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 the FDA has previously verified that the U.S. agent has agreed to serve as the U.S. agent for the facility, the FDA will not re-verify that the U.S. agent has agreed to serve as the U.S. agent for the foreign facility.

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

How to Update Registration Information

If any of the required information on your registration form changes — for example, if there is a 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 the FDA within 60 days.
A registration may be updated online at http://www.fda.gov/furls. 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.

Registration Cancellation

If a facility goes out of business or comes under new ownership, the registration must be cancelled within 60 days using Form FDA 3537a. This can be done electronically at http://www.fda.gov/furls.

Confidentiality of Registration Information

The list of registered facilities and registration-related information are not subject to disclosure under the Freedom of Information Act.

SUSPENSION OF REGISTRATION

Can the FDA suspend the registration of a food facility?

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

When can the FDA suspend the registration of a food facility?

The FDA can suspend a food facility's registration when the 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; and

2. A facility: (a) Created, caused or was otherwise responsible for that reasonable probability of causing serious adverse health consequences or death to humans or animals; or (b) Knew of, or had reason to know of, the reasonable probability, and packed, received, or held such food.

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.

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.

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

The 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 not later than two business days after the issuance of the suspension order or such other time period as agreed upon by the 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 reinstated. The FDA will reinstate a registration if it determines, based on evidence presented, that adequate grounds do not exist to continue the suspension.

What happens if FDA determines a suspension of registration remains necessary after a hearing?

The FDA will require the registrant subject to a suspension order to submit a corrective action plan to the FDA to demonstrate how the registrant plans to correct the conditions found by the FDA.

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

The FDA will vacate an order suspending a facility's registration and reinstate the registration of the facility subject to the order, if the 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) of the FD&C Act).