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Guidance for Industry

What You Need To Know About Registration of Food Facilities

Small Entity Compliance Guide

Additional copies are available from:
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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

December 2012

Guidance for Industry[1]

What You Need To Know About Registration of Food Facilities Small Entity Compliance Guide

This guidance document is a restatement of the Food and Drug Administration's (FDA's) current requirements for registration of food[2] facilities presented in simplified format and language. As guidance, it is not binding on either FDA or the public.

FDA has prepared this guidance to restate the legal requirements in section 415 of the Federal Food, Drug, and Cosmetic Act (FD&C Act). Previously, this guidance restated the legal requirements of FDA's food facility registration regulation at 21 CFR Part 1, Subpart H (21 CFR 1.225 through 1.243), implementing section 415 of the FD&C Act, as added by the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. This guidance also served as FDA's Small Entity Compliance Guide (SECG) for 21 CFR Part 1, Subpart H in accordance with section 212 of the Small Business Regulatory Enforcement Fairness Act (Public Law 104-121). However, section 415 of the FD&C Act was amended by the FDA Food Safety Modernization Act (FSMA) in 2011. Accordingly, FDA is revising this document to provide guidance intended to help any entity comply with the requirements of section 415 of the FD&C Act, including the amendments to section 415 of the FD&C Act made by section 102 of FSMA. This document continues to serve as FDA's SECG for 21 CFR Part 1, Subpart H.

Introduction

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) directs the Food and Drug Administration (FDA), as the food regulatory agency of the Department of Health and Human Services, to take steps to protect the public from a threatened or actual terrorist attack on the U.S. food supply and other food-related emergencies.

To carry out certain provisions of the Bioterrorism Act, FDA established regulations requiring that:

- Food facilities register with FDA, and
- FDA be given advance notice on shipments of imported food.

These regulations became effective on **December 12, 2003.**

The FDA Food Safety Modernization Act (FSMA), enacted on January 4, 2011, amended section 415 of the Federal Food, Drug, and Cosmetic Act (FD&C Act), in relevant part, 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

[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.

[2] In this document, the term "food" refers to food for humans and animals, as defined in 21 CFR 1.227(b)(4).

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. Specifically, if FDA determines that food manufactured, processed, packed, received, or held by a registered food facility has a reasonable probability of causing serious adverse health consequences or death to humans or animals, FDA may by order suspend the registration of a facility that:

1. Created, caused, or was otherwise responsible for such reasonable probability; or
2. Knew of, or had reason to know of, such reasonable probability; and packed, received, or held such food.

Purpose of this Guidance

This guidance was created to inform domestic and foreign food facilities about the food facility registration requirements. It contains important information that may affect your firm.

The information in this guidance also appears online at .http://www.fda.gov/Food/FoodSafety/FSMA/ucm257978.htm

ABOUT REGISTRATION

Food Facility Registration Requirement

Domestic and foreign facilities that manufacture, process, pack, or hold food, as defined 21 CFR 1.227, for human or animal consumption in the U.S. must register with FDA effective December 12, 2003.

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 or updates to a registration.

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 effective December 12, 2003.

Food Industry Sectors Affected
• Domestic and foreign manufacturers or processors[*] • Domestic and foreign packers[*] • Domestic and foreign storage operations[*]

Foods Handled by More Than One Foreign Facility:	
If…	**Then…**
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.	Only the *second* 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	*Both* facilities must register.
Any foreign facility packs or holds food *after* the last foreign manufacturer/processor of the food	The foreign packer or holder must register.

[*] Domestic facilities must register whether or not food from the facility enters interstate commerce.

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 U.S.

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**
• Dietary supplements and dietary ingredients • Infant formula • Beverages (including alcoholic beverages and bottled water) • Fruits and vegetables • Fish 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)	• 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.

Facilities That Do Not Have to Register

If your facility is involved in one of the following activities, 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**. • **Farms** — i.e., facilities in one general location devoted to growing and harvesting crops (washing, trimming outer leaves, and cooling produce are part of harvesting) and/or raising animals (including seafood). The term "farm" includes facilities that pack or hold food, provided that all food used in those activities is grown, raised, or consumed on that farm or another farm under the same ownership, as well as facilities that manufacture/process food, provided that all food used in such activities is consumed on that farm or another farm under the same ownership. • **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 directly 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. • **Retail food establishments**, such as grocery stores, delis, roadside stands 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. • **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 U.S. 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,** that is, facilities handling only meat, poultry, or egg products.

Whether FSMA Changed the Scope of Facilities Required to Register

At this time, the same type of food facilities that were required to register with FDA under section 415 of the FD&C Act before FSMA are required to register with FDA and renew such registrations every other year. Those facilities are domestic and foreign facilities that manufacture, process, pack, or hold food for human or animal consumption in the United States (21 CFR 1.225). As noted above, for the purposes of section 415, the term "facility" does not include, in relevant part, farms, restaurants, and retail food establishments (section 415(c)(1) of the FD&C Act; 21 CFR 1.226).

When Your Facility Must Register

The deadline to register your facility with FDA was **December 12, 2003**. Facilities that go into business after December 12, 2003, must register before they begin manufacturing/processing, packing, or holding operations.

How Often Your Facility Must Register

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.

However, there was a delay in FDA's implementation of biennial registration renewal for the 2012 cycle, and registration renewal did not become available until October 22, 2012. FDA has provided guidance on its plans regarding the delay in the implementation of biennial registration renewal for the 2012 cycle in another food facility registration guidance entitled Guidance for Industry: Questions and Answers Regarding Food Facility Registration (Fifth Edition), available at http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodDefenseandEmergencyResponse/ucm331959.htm.

Is a facility required to resubmit all of the registration information during the biennial renewal process?

No. FDA will provide 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 or registration renewal for the facility.

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 registration. The U.S. agent may be authorized to register the facility.

What If Your Facility Fails to Register

Failure to register your facility, 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.

If a foreign facility is required to register but fails to do so, food from that facility that is offered for import into the U.S. is subject to refusal. The food may be held within the port of entry, unless directed elsewhere by FDA or the Customs and Border Protection Service (CBP).

SUSPENSION OF REGISTRATION (NEW)

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 at 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 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)(4) 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).

REGISTERING YOUR FACILITY

How to Register Your Facility

Registrants must use Form 3537 to register, renew, or update a registration. This form is available online and in paper form. A business with multiple facilities may also register on CD-ROM.

FDA will process paper and CD-ROM 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.access.fda.gov/. 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.

An Online 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 Online Registration Help Desk:	
By phone	WITHIN THE U.S.: Call 1-800-216-7331 or 301-575-0156 OUTSIDE THE U.S.: Call 301-575-0156
By fax	Fax questions to 301-436-2804
By email	Go to http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/RegistrationofFoodFacilities/OnlineRegistration/default.htm and complete the form

Paper Registration

If your facility does not have reasonable access to the Internet, you can request a copy of Form 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 to the above address, or fax it to 301-436-2804.

To Request the Form:	
By mail	Write to: U.S. Food and Drug Administration Food Facility Registration HFS-681 5100 Paint Branch Parkway College Park, MD 20993 USA
By phone	Call 1-877-216-7331 or 301-575-0156 (7:00 a.m. to 11:00 p.m. U.S. Eastern Standard Time)
Note: *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.*	

CD-ROM Registration

If your business has a large number of food facilities, you may wish to submit multiple registrations on a CD-ROM by mail. You can do so, provided that each registration uses the same preferred mailing address. The CD-ROM you use must have ISO 9660 (CD-R or CD-RW) data format.

To Register by CD-ROM:

1. Go to http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/RegistrationofFoodFacilities/ucm073728.htm and download the Portable Document Format (PDF) version of Form 3537.
2. Fill in a separate copy of the form electronically for each facility.
3. Use the same preferred mailing address for each facility.
4. Save the form for each facility under a different file name:

   a. The file name can be up to 32 characters long.

   b. Use the first part of the file name to identify the parent company.
5. Copy the files to a CD-ROM with ISO 9660 (CD-R or CD-RW) data format.
6. Enclose one signed copy of the certification statement that appears on the registration form (Box 13)
7. Mail the CD-ROM to:

   U.S. Food and Drug Administration/Food Facility Registration
   HFS-681
   5100 Paint Branch Parkway
   College Park, MD 20993

Note: If you send a CD-ROM that does not comply with the above specifications, FDA will return it without processing, which will delay registration.

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

Required Information
• Facility name, address, phone number, and emergency contact phone number • Parent company name, address, and phone number (if applicable) • Name, address and phone number of the owner, operator, or agent in charge • Email address for the contact person of the facility or, in case of a foreign facility, the U.S. Agent for the facility • All trade names the facility uses • Applicable food product categories, as listed on the registration form • Name, address, and phone number of a foreign facility's U.S. agent, and phone number of the facility's emergency contact if it is someone other than the U.S. agent • 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

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 • Preferred mailing address, if different from that of the facility • Fax number and email address of the owner, operator, or agent in charge of the facility • Fax number and email address of the parent company (if applicable) • For a foreign facility: the fax number of its U.S. agent • Type of activity conducted at the facility (e.g., processing, packing, etc.) • Type of storage (if it's a holding facility) • Approximate dates of operation (if the facility's business is seasonal)

Facility Registration Screen
Here is a sample screen from the FDA registration web site (www.access.fda.gov/).

How Registration Is Confirmed
After you register your facility, FDA will confirm the registration and assign a registration number.

If You Register…	You Will Receive Confirmation
Online	Electronically
By fax	By fax
By surface mail or CD-ROM	By surface mail

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.

Confidentiality of Registration Information
The list of registered facilities and submitted registration documents are not subject to disclosure under the Freedom of Information Act (see section 415(a)(5) of the FD&C Act). This confidentiality does not apply to information obtained by other means or that has previously been 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 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)).

You can submit information changes online (regardless of how you originally registered), by paper, or on CD-ROM.

To Update Your Registration:	
Online	Go to http://www.access.fda.gov/.*
By paper	Use the paper registration process described on page 11
By CD-ROM	Enter the changes on CD-ROM (see 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 before beginning operations (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 3537a (21 CFR 1.235). You can do this electronically at http://www.access.fda.gov/, or you can request the form from FDA and use the paper registration process described on page xx.

FIND OUT MORE

How to Get More Information
Additional information is available at www.fda.gov/oc/bioterrorism/bioact.html and http://www.fda.gov/Food/FoodSafety/FSMA/default.htm.

For more details and information on the specific requirements of the facility registration regulation, please refer to the Fact Sheet on FDA's Bioterrorism Regulation and the FDA Food Safety Modernization Act: Registration of Food Facilities at http://www.fda.gov/Food/FoodDefense/Bioterrorism/FoodFacilityRegistration/ucm081610.htm or http://www.fda.gov/Food/FoodSafety/FSMA/default.htm.

* Use the PIN that was issued with your facility's registration number. If you originally registered by paper or CD-ROM, 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 C.F.R. 1.227, for human or animal consumption in the U.S. must register with FDA ***effective December 12, 2003***.

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 foods for consumption in the U.S. as defined in 21 CFR 1.227.

Examples of WHICH Foods Require Facility Registration:
• Dietary supplements and dietary ingredients • Infant formula • Beverages (including alcoholic beverages and bottled water) • Fruits and vegetables • Fish 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: Effective December 12, 2003.

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 registration. The U.S. agent may be authorized to register the facility.

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 3537 from FDA (1-877-332-3882). 2. Mail or fax (Fax: 301-436-2804) completed form to: U.S. Food and Drug Administration HFS-681 Fishers Lane Rockville, MD 20857 U.S.A.
On CD-ROM (For multiple facilities using the same mailing address)	• Download Form 3537 at http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/RegistrationofFoodFacilities/ucm073728.htm • Create separate electronic files for each facility. • Submit files on CD-ROM (ISO 9660 CD-R or CD-RW format). • Include a signed certification statement. • Mail to the above address.

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 301-575-0156 OUTSIDE THE U.S.: Call 301-575-0156
By fax	Fax questions to 301-436-2804
By email	Email questions to furls@fda.gov

WHAT Information is Required:
• Facility name, address, phone number and emergency contact phone number
• Parent company name, address and phone number (if applicable)
• Name, address and phone number of the owner, operator or agent in charge
• Email address for the contact person of the facility or, in case of a foreign facility, the U.S. agent for the facility
• All trade names the facility uses
• Applicable food product categories, as listed on the registration form
• Name, address, phone number and emergency contact phone number of a foreign facility's U.S. agent
• 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 or CD-ROM registration), and assigns a registration number.

WHAT IF…

If…	**Then…**
Required registration info changes	You must notify FDA within 60 days (online or by mail or fax).
There's a change in ownership	The former owner must cancel registration within 60 days and the new owner must re-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 Info: For more information, go to www.fda.gov/oc/bioterrorism/bioact.html