

(iii) If the product is a drug or biological product, a description of the product's strength and dosage form or, if the product is a device, the product's model number; and

(iv) If the export is to a country not listed in section 802(b)(1) of the act, the country that is to receive the exported article. The notification may, but is not required to, identify countries listed in section 802(b)(1) of the act or state that the export is intended for a listed country without identifying the listed country.

(2) The notification shall be sent to the following addresses:

(i) For biological products and devices regulated by the Center for Biologics Evaluation and Research—Division of Case Management (HFM-610), Office of Compliance and Biologics Quality, Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448.

(ii) For human drug products, biological products, and devices regulated by the Center for Drug Evaluation and Research—Division of New Drugs and Labeling Compliance, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002.

(iii) For devices—Food and Drug Administration, Center for Devices and Radiological Health, Division of Program Operations, 10903 New Hampshire Ave., Bldg. 66, rm. 5429, Silver Spring, MD 20993-0002.

(e) *Recordkeeping requirements for products subject to section 802(g) of the act.* (1) Any person exporting a product under any provision of section 802 of the act shall maintain records of all drugs, biological products, and devices exported and the countries to which the products were exported. In addition to the requirements in paragraph (b) of this section, such records include, but are not limited to, the following:

(i) The product's trade name;

(ii) If the product is a drug or biological product, the product's abbreviated or proper name or, if the product is a device, the type of device;

(iii) If the product is a drug or biological product, a description of its strength and dosage form and the prod-

uct's lot or control number or, if the product is a device, the product's model number;

(iv) The consignee's name and address; and

(v) The date on which the product was exported and the quantity of product exported.

(2) These records shall be kept at the site from which the products were exported or manufactured, and be maintained for the same period of time as required for records subject to good manufacturing practice or quality systems regulations applicable to the product. The records shall be made available to FDA, upon request, during an inspection for review and copying by FDA.

[66 FR 65447, Dec. 19, 2001, as amended at 69 FR 48774, Aug. 11, 2004; 70 FR 14980, Mar. 24, 2005; 74 FR 13112, Mar. 26, 2009; 75 FR 20914, Apr. 22, 2010]

EFFECTIVE DATE NOTE: At 77 FR 5176, Feb. 2, 2012, §1.101 was amended by revising paragraph (a) and the heading of paragraph (b), effective Apr. 2, 2012. For the convenience of the user, the revised text is set forth as follows:

§ 1.101 Notification and recordkeeping.

(a) *Scope.* This section pertains to notifications and records required for human drug, biological product, device, animal drug, food, cosmetic, and tobacco product exports under sections 801 or 802 of the Federal Food, Drug, and Cosmetic Act or (21 U.S.C. 381 and 382) or section 351 of the Public Health Service Act (42 U.S.C. 262).

(b) *Recordkeeping requirements for human drugs, biological products, devices, animal drugs, foods, cosmetics, and tobacco products exported under or subject to section 801(e)(1) of the Federal Food, Drug, and Cosmetic Act.* * * *

* * * * *

Subparts F–G [Reserved]

Subpart H—Registration of Food Facilities

SOURCE: 68 FR 58960, Oct. 10, 2003, unless otherwise noted.

§ 1.225

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GENERAL PROVISIONS

§ 1.225 Who must register under this subpart?

(a) You must register your facility under this subpart if you are the owner, operator, or agent in charge of either a domestic or foreign facility, as defined in this subpart, and your facility is engaged in the manufacturing/processing, packing, or holding of food for consumption in the United States, unless your facility qualifies for one of the exemptions in § 1.226.

(b) 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.

(c) 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.

§ 1.226 Who does not have to register under this subpart?

This subpart does not apply to the following facilities:

(a) A foreign facility, if food from such facility undergoes further manufacturing/processing (including packaging) by another facility outside the United States. A facility is not exempt under this provision if the further manufacturing/processing (including packaging) conducted by the subsequent facility consists of adding labeling or any similar activity of a *de minimis* nature;

(b) Farms;

(c) Retail food establishments;

(d) Restaurants;

(e) Nonprofit food establishments in which food is prepared for, or served directly to, the consumer;

(f) Fishing vessels, including those that not only harvest and transport fish but also engage in practices such as heading, eviscerating, or freezing intended solely to prepare fish for holding on board a harvest vessel. However, those fishing vessels otherwise engaged in processing fish are subject to this subpart. For the purposes of this section, “processing” means handling, storing, preparing, shucking, changing into different market forms, manufacturing, preserving, packing, labeling, dockside unloading, holding, or heading, eviscerating, or freezing other

than solely to prepare fish for holding on board a harvest vessel;

(g) Facilities that are regulated exclusively, throughout the entire facility, by the U.S. Department of Agriculture under the Federal Meat Inspection Act (21 U.S.C. 601 *et seq.*), the Poultry Products Inspection Act (21 U.S.C. 451 *et seq.*), or the Egg Products Inspection Act (21 U.S.C. 1031 *et seq.*);

§ 1.227 What definitions apply to this subpart?

(a) *The act* means the Federal Food, Drug, and Cosmetic Act.

(b) In addition, for the purposes of this subpart:

(1) *Calendar day* means every day shown on the calendar.

(2) *Facility* means any establishment, structure, or structures under one ownership at one general physical location, or, in the case of a mobile facility, traveling to multiple locations, that manufactures/processes, packs, or holds food for consumption in the United States. Transport vehicles are not facilities if they hold food only in the usual course of business as carriers. A facility may consist of one or more contiguous structures, and a single building may house more than one distinct facility if the facilities are under separate ownership. The private residence of an individual is not a facility. Nonbottled water drinking water collection and distribution establishments and their structures are not facilities.

(i) *Domestic facility* means any facility located in any State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico that manufactures/processes, packs, or holds food for consumption in the United States.

(ii) *Foreign facility* means a facility other than a domestic facility that manufactures/processes, packs, or holds food for consumption in the United States.

(3) *Farm* means a facility in one general physical location devoted to the growing and harvesting of crops, the raising of animals (including seafood), or both. Washing, trimming of outer leaves of, and cooling produce are considered part of harvesting. The term “farm” includes:

(i) Facilities that pack or hold food, provided that all food used in such activities is grown, raised, or consumed on that farm or another farm under the same ownership; and

(ii) 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.

(4) *Food* has the meaning given in section 201(f) of the act (21 U.S.C. 321(f)),

(i) Except for purposes of this subpart, it does not include:

(A) *Food* contact substances as defined in section 409(h)(6) of the act (21 U.S.C. 348(h)(6)), or

(B) Pesticides as defined in 7 U.S.C. 136(u).

(ii) Examples of food include fruits, vegetables, fish, dairy products, eggs, raw agricultural commodities for use as food or as components of food, animal feed (including pet food), food and feed ingredients, food and feed additives, dietary supplements and dietary ingredients, infant formula, beverages (including alcoholic beverages and bottled water), live food animals, bakery goods, snack foods, candy, and canned foods.

(5) *Holding* means storage of food. Holding facilities include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks.

(6) *Manufacturing/processing* means making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food, including food crops or ingredients. Examples of manufacturing/processing activities are cutting, peeling, trimming, washing, waxing, eviscerating, rendering, cooking, baking, freezing, cooling, pasteurizing, homogenizing, mixing, formulating, bottling, milling, grinding, extracting juice, distilling, labeling, or packaging.

(7) *Nonprofit food establishment* means a charitable entity that prepares or serves food directly to the consumer or otherwise provides food or meals for consumption by humans or animals in the United States. The term includes central food banks, soup kitchens, and nonprofit food delivery services. To be considered a nonprofit food establish-

ment, the establishment must meet the terms of section 501(c)(3) of the U.S. Internal Revenue Code (26 U.S.C. 501(c)(3)).

(8) *Packaging* (when used as a verb) means placing food into a container that directly contacts the food and that the consumer receives.

(9) *Packing* means placing food into a container other than packaging the food.

(10) *Restaurant* means a facility that prepares and sells food directly to consumers for immediate consumption. "Restaurant" does not include facilities that provide food to interstate conveyances, central kitchens, and other similar facilities that do not prepare and serve food directly to consumers.

(i) Entities in which food is provided to humans, such as cafeterias, lunchrooms, cafes, bistros, fast food establishments, food stands, saloons, taverns, bars, lounges, catering facilities, hospital kitchens, day care kitchens, and nursing home kitchens are restaurants; and

(ii) Pet shelters, kennels, and veterinary facilities in which food is provided to animals are restaurants.

(11) *Retail food establishment* means an establishment that sells food products directly to consumers as its primary function. A retail food establishment may manufacture/process, pack, or hold food if the establishment's primary function is to sell from that establishment food, including food that it manufactures/processes, packs, or holds, directly to consumers. A retail food establishment's primary function is to sell food directly to consumers if the annual monetary value of sales of food products directly to consumers exceeds the annual monetary value of sales of food products to all other buyers. The term "consumers" does not include businesses. A "retail food establishment" includes grocery stores, convenience stores, and vending machine locations.

(12) *Trade name* means the name or names under which the facility conducts business, or additional names by which the facility is known. A trade name is associated with a facility, and a brand name is associated with a product.

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(13) *U.S. agent* means a person (as defined in section 201(e) of the act (21 U.S.C. 321(e))) residing or maintaining a place of business in the United States whom a foreign facility designates as its agent for purposes of this subpart. A U.S. agent cannot be in the form of a mailbox, answering machine or service, or other place where an individual acting as the foreign facility's agent is not physically present.

(i) The U.S. agent acts as a communications link between FDA and the foreign facility for both emergency and routine communications. The U.S. agent will be the person FDA contacts when an emergency occurs, unless the registration specifies under §1.233(e) another emergency contact.

(ii) FDA will treat representations by the U.S. agent as those of the foreign facility, and will consider information or documents provided to the U.S. agent the equivalent of providing the information or documents to the foreign facility.

(iii) Having a single U.S. agent for the purposes of this subpart does not preclude facilities from having multiple agents (such as foreign suppliers) for other business purposes. A firm's commercial business in the United States need not be conducted through the U.S. agent designated for purposes of this subpart.

(14) *You or registrant* means the owner, operator, or agent in charge of a facility that manufactures/processes, packs, or holds food for consumption in the United States.

PROCEDURES FOR REGISTRATION OF FOOD FACILITIES

§ 1.230 When must you register?

The owner, operator, or agent in charge of a facility that manufactures/processes, packs or holds food for consumption in the United States must register the facility no later than December 12, 2003. 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 on or after December 12, 2003, must register before the facility begins such activities. An owner, operator, or agent in charge of a facility

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may authorize an individual to register the facility on its behalf.

§ 1.231 How and where do you register?

(a) *Electronic registration.* (1) To register electronically, you must register at <http://www.fda.gov/furls>, which is available for registration 24 hours a day, 7 days a week. This website is available from wherever the Internet is accessible, including libraries, copy centers, schools, and Internet cafes. An individual authorized by the owner, operator, or agent in charge of a facility may also register a facility electronically.

(2) FDA strongly encourages electronic registration for the benefit of both FDA and the registrant.

(3) Once you complete your electronic registration, FDA will automatically provide you with an electronic confirmation of registration and a permanent registration number.

(4) You will be considered registered once FDA electronically transmits your confirmation and registration number.

(b) *Registration by mail or fax.* If, for example, you do not have reasonable access to the Internet through any of the methods described in paragraph (a) of this section, you may register by mail or fax.

(1) You must register using Form 3537. You may obtain a copy of this form by writing to the U.S. Food and Drug Administration (HFS-681), 5600 Fishers Lane, Rockville, MD 20857 or by requesting a copy of this form by phone at 1-800-216-7331 or 301-575-0156.

(2) When you receive the form, you must fill it out completely and legibly and either mail it to the address in paragraph (b)(1) of this section or fax it to 301-436-2804 or 1-800-573-0846.

(3) If any required information on the form is incomplete or illegible when FDA receives it, FDA will return the form to you for revision, provided that your mailing address or fax number is legible and valid. When returning a registration form for revision, FDA will use the means by which the form was received by the agency (*i.e.*, by mail or fax).

(4) FDA will enter complete and legible mailed and faxed registration submissions into its registration system, along with CD-ROM submissions, as soon as practicable, in the order FDA receives them.

(5) FDA will then mail to the address or fax to the fax number on the registration form a copy of the registration as entered, confirmation of registration, and your registration number. When responding to a registration submission, FDA will use the means by which the registration was received by the agency (*i.e.*, by mail or fax).

(6) If any information you previously submitted was incorrect at the time of submission, you must immediately update your facility's registration as specified in § 1.234.

(7) Your facility is considered registered once FDA enters your facility's registration data into the registration system and the system generates a registration number.

(c) *Registration by CD-ROM for multiple submissions.* If, for example, you do not have reasonable access to the Internet through any of the methods provided under paragraph (a) of this section, you may register by CD-ROM.

(1) Registrants submitting their registrations in CD-ROM format must use ISO 9660 (CD-R or CD-RW) data format.

(2) These files must be submitted on a portable document format (PDF) rendition of the registration form (Form 3537) and be accompanied by one signed copy of the certification statement that appears on the registration form (Form 3537).

(3) Each submission on the CD-ROM must contain the same preferred mailing address in the appropriate block on Form 3537.

(4) A CD-ROM may contain registrations for as many facilities as needed up to the CD-ROM's capacity.

(5) The registration on the CD-ROM for each separate facility must have a unique file name up to 32 characters long, the first part of which may be used to identify the parent company.

(6) You must mail the CD-ROM to the U.S. Food and Drug Administration (HFS-681), 5600 Fishers Lane, Rockville, MD 20857.

(7) If FDA receives a CD-ROM that does not comply with these specifica-

tions, it will return the CD-ROM to the submitter unprocessed.

(8) FDA will enter CD-ROM submissions that comply with these specifications into its registration system, along with the complete and legible mailed and faxed submissions, as soon as practicable, in the order FDA receives them.

(9) For each facility on the CD-ROM, FDA will mail to the preferred mailing address a copy of the registration(s) as entered, confirmation of registration, and each facility's assigned registration number.

(10) If any information you previously submitted was incorrect at the time of submission, you must immediately update your facility's registration as specified in § 1.234.

(11) Your facility is considered registered once FDA enters your facility's registration data into the registration system and the system generates a registration number.

(d) *Fees.* No registration fee is required.

(e) *Language.* You must submit all registration information in the English language except an individual's name, the name of a company, the name of a street, and a trade name may be submitted in a foreign language. All information, including these items, must be submitted using the Latin (Roman) alphabet.

[68 FR 58960, Oct. 10, 2003, as amended at 69 FR 29428, May 24, 2004; 73 FR 15883, Mar. 26, 2008]

§ 1.232 What information is required in the registration?

Each registrant must submit the following information through one of the methods described in § 1.231:

(a) The name, full address, and phone number of the facility;

(b) The name, address, and phone number of the parent company, if the facility is a subsidiary of the parent company;

(c) For domestic and foreign facilities, the names, addresses, and phone numbers of the owner, operator, and agent in charge.

(d) For a foreign facility, the name, address, phone number, and, if no emergency contact is designated under § 1.233(e), the emergency contact phone

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number of the foreign facility's U.S. agent;

(e) For a domestic facility, an emergency contact phone number;

(f) All trade names the facility uses;

(g) Applicable food product categories as identified in §170.3 of this chapter, unless you check either "most/all human food product categories," according to §1.233(j), or "none of the above mandatory categories" because your facility manufactures/processes, packs, or holds a food that is not identified in §170.3 of this chapter;

(h) The name, address, and phone number for the owner, operator, or agent in charge;

(i) 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. Each registration must include the name of the individual registering the facility submitting the registration, and the individual's signature (for the paper and CD-ROM options).

[68 FR 58960, Oct. 10, 2003, as amended at 69 FR 29428, May 24, 2004]

§ 1.233 What optional items are included in the registration form?

FDA encourages, but does not require, you to submit the following items in your facility's registration. These data will enable FDA to communicate more quickly with facilities that may be the target of a terrorist threat or attack, or otherwise affected by an outbreak of foodborne illness. This information includes:

(a) Fax number and e-mail address of the facility;

(b) Preferred mailing address, if different from that of the facility;

(c) Fax number and e-mail address of the parent company, if the facility is a subsidiary of the parent company;

(d) For a domestic facility, emergency contact name, title, and e-mail address;

(e) For a foreign facility, an emergency contact name, title, phone number and e-mail address. FDA will consider the facility's U.S. agent the facility's emergency contact unless the facility chooses to designate another person to serve as an emergency contact under this section;

(f) For a foreign facility, title, fax number, and e-mail address of the U.S. agent;

(g) Type of activity conducted at the facility (e.g., manufacturing/processing or holding);

(h) Food categories not identified in §170.3 of this chapter, which are provided in Form 3537 sections 11a (e.g., infant formula, animal byproducts and extracts) and 11b (e.g., grain products, amino acids);

(i) Type of storage, if the facility is primarily a holding facility;

(j) A food product category of "most/all human food product categories," if the facility manufactures/processes, packs, or holds foods in most or all of the categories identified in §170.3 of this chapter;

(k) Approximate dates of operation, if the facility's business is seasonal;

(l) The fax number and e-mail address of the owner, operator, or agent in charge; and

(m) The fax number and e-mail address of the individual who authorized submission of the registration.

§ 1.234 How and when do you update your facility's registration information?

(a) *Update requirements.* The owner, operator, or agent in charge must submit an update to a facility's registration within 60 calendar days of any change to any of the information previously submitted under §1.232 (e.g., change of operator, agent in charge, or U.S. agent), except a change of the owner. The owner, operator, or agent in charge may authorize an individual to update a facility's registration.

(b) *Cancellation due to ownership changes.* If the reason for the update is that the facility has a new owner, the former owner must cancel the facility's

registration as specified in §1.235 within 60 calendar days of the change and the new owner must re-register the facility as specified in §1.231. The former owner may authorize an individual to cancel a facility's registration.

(c) *Electronic update.* (1) To update your registration electronically, you must update at <http://www.fda.gov/furls>.

(2) Once you complete your electronic update, FDA will automatically provide you with an electronic confirmation of your update.

(3) Your registration will be considered updated once FDA transmits your update confirmation, unless notified otherwise.

(d) *Update by mail or fax.* If, for example, you do not have reasonable access to the Internet through any of the methods described in §1.231(a), you may update your facility's registration by mail or by fax:

(1) You must update your registration using Form 3537. You may obtain a copy of this form by writing to the U.S. Food and Drug Administration (HFS-681), 5600 Fishers Lane, Rockville, MD 20857 or by requesting the form by phone at 1-877-FDA-3882 (1-877-332-3882).

(2) When you receive the form, you must legibly fill out the sections of the form reflecting your updated information and either mail it to the address in paragraph (d)(1) of this section or fax it to 301-436-2804 or 1-800-573-0846.

(3) If the information on the form is incomplete or illegible when FDA receives it, FDA will return the form to you for revision, provided that your mailing address or fax number is legible and valid. When returning a registration form for revision, FDA will use the means by which the registration was received by the agency (*i.e.*, by mail or fax).

(4) FDA will enter complete and legible updates into its registration system, along with CD-ROM submissions, as soon as practicable, in the order FDA receives them.

(5) FDA will then mail to the address or fax to the fax number on the registration form a copy of the update as entered and confirmation of the update. When responding to an update submission, FDA will use the means by

which the form was received by the agency (*i.e.*, by mail or fax).

(6) If any update information you previously submitted was incorrect at the time of submission, you must immediately resubmit your update.

(7) Your registration will be considered updated once FDA enters your facility's update data into the registration system and the system generates an update confirmation.

(e) *Update by CD-ROM for multiple submissions.* If, for example, you do not have reasonable access to the Internet through any of the methods provided under §1.231(a), you may update your facilities' registrations by CD-ROM.

(1) Registrants submitting their updates in CD-ROM format must use ISO 9660 (CD-R or CD-RW) data format.

(2) Update files must be submitted on a PDF rendition of FDA's registration form (Form 3537) and be accompanied by one signed copy of the certification statement on the registration form (Form 3537).

(3) Each submission on the CD-ROM must contain the same preferred mailing address in the appropriate block on Form 3537.

(4) The CD-ROM may contain updates for as many facilities as needed up to the CD-ROM's capacity.

(5) The update for each facility on the CD-ROM must have a unique file name up to 32 characters long, the first part of which may be used to identify the parent company.

(6) You must mail the CD-ROM to U.S. Food and Drug Administration (HFS-681), 5600 Fishers Lane, Rockville, MD 20857.

(7) If FDA receives an update CD-ROM that does not comply with these specifications, it will return the CD-ROM to the registrant unprocessed.

(8) FDA will enter CD-ROM update submissions into its registration system, along with the complete and legible mailed and faxed update submissions, as soon as practicable, in the order FDA receives them.

(9) For each facility on the CD-ROM, FDA will mail to the preferred mailing address a copy of the update(s) as entered and confirmation of the update.

(10) If any update information you previously submitted was incorrect at

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the time of submission, you must immediately resubmit your update.

(11) Your registration will be considered updated once FDA enters your facility's update data into the registration system and the system generates an update confirmation.

[68 FR 58960, Oct. 10, 2003 as amended at 73 FR 15883, Mar. 26, 2008]

§ 1.235 How and when do you cancel your facility's registration information?

(a) *Notification of registration cancellation.* A facility canceling its registration must do so within 60 calendar days of the reason for cancellation (*e.g.*, facility ceases operations, ceases providing food for consumption in the United States, or the facility is sold to a new owner).

(b) *Cancellation requirements.* The cancellation of a facility's registration must include the following information:

(1) The facility's registration number;

(2) Whether the facility is domestic or foreign;

(3) The facility name and address;

(4) The name, address, and e-mail address (if available) of the individual submitting the cancellation; and

(5) 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.

(c) *Electronic cancellation.* (1) To cancel your registration electronically, you must cancel at <http://www.fda.gov/furls>.

(2) Once you complete your electronic cancellation, FDA will automatically provide you with an electronic confirmation of your cancellation.

(3) Your registration will be considered cancelled once FDA transmits your cancellation confirmation.

(d) *Cancellation by mail or fax.* If, for example, you do not have reasonable access to the Internet through any of the methods described in § 1.231(a), you may cancel your facility's registration by mail or fax.

(1) You must cancel your registration using Form 3537a. You may obtain a copy of this form by writing to the U.S.

Food and Drug Administration (HFS-681), 5600 Fishers Lane, Rockville, MD 20857, or by requesting the form by phone at 1-877-FDA-3882 (1-877-332-3882).

(2) When you receive the form, you must completely and legibly fill out the form and either mail it to the address in paragraph (d)(1) of this section or fax it to 301-436-2804 or 1-800-573-0846.

(3) If the information on the form is incomplete or illegible when FDA receives it, FDA will return the form to you for revision, provided that your mailing address or fax number is legible and valid. When returning a cancellation form for revision, FDA will use the means by which the cancellation was received by the agency (*i.e.*, by mail or fax).

(4) FDA will enter complete and legible mailed and faxed cancellations into its registration system, along with CD-ROM cancellations, as soon as practicable, in the order FDA receives them.

(5) FDA will then mail to the address or fax to the fax number on the cancellation form a copy of the cancellation as entered and confirmation of the cancellation. When responding to a cancellation, FDA will use the means by which the form was received by the agency (*i.e.*, by mail or fax).

(6) If any information you previously submitted was incorrect at the time of submission, you must immediately resubmit your cancellation.

(7) Your registration will be considered cancelled once FDA enters your facility's cancellation data into the registration system and the system generates a confirmation.

(e) *Cancellation by CD-ROM for multiple submissions.* If, for example, you do not have reasonable access to the Internet through any of the methods described in § 1.231(a), you may cancel your facilities' registrations using a CD-ROM.

(1) Registrants submitting their cancellations in CD-ROM format must use ISO 9660 (CD-R or CD-RW) data format.

(2) Cancellation files must be submitted on a PDF rendition of the cancellation form (Form 3537a) and be accompanied by one signed copy of the

certification statement on the cancellation form.

(3) Each submission on the CD-ROM must contain the same preferred mailing address in the appropriate block on Form 3537.

(4) The CD-ROM may contain cancellations for as many facilities as needed up to the CD-ROM's capacity.

(5) The cancellation for each facility on the CD-ROM must have a unique file name up to 32 characters long, the first part of which may be used to identify the parent company.

(6) You must mail the CD-ROM to U.S. Food and Drug Administration (HFS-681), 5600 Fishers Lane, Rockville, MD 20857.

(7) If FDA receives a CD-ROM that does not comply with these specifications, it will return the CD-ROM to the registrant unprocessed.

(8) FDA will enter CD-ROM submissions that meet the specifications into its registration system, along with complete and legible mailed and faxed submissions, as soon as practicable, in the order FDA receives them.

(9) For each facility on the CD-ROM, FDA will mail to the preferred mailing address a copy of the cancellation(s) as entered and confirmation of the cancellation.

(10) If any information you previously submitted was incorrect at the time of submission, you must immediately resubmit your cancellation.

(11) Your registration will be considered cancelled once FDA enters your facility's cancellation data into the registration system and the system generates a confirmation.

[68 FR 58960, Oct. 10, 2003 as amended at 73 FR 15883, Mar. 26, 2008]

ADDITIONAL PROVISIONS

§ 1.240 What other registration requirements apply?

In addition to the requirements of this subpart, you must comply with the registration regulations found in part 108 of this chapter, related to emergency permit control, and any other Federal, State, or local registration requirements that apply to your facility.

§ 1.241 What are the consequences of failing to register, update, or cancel your registration?

(a) Section 301 of the act (21 U.S.C. 331) prohibits the doing of certain acts or causing such acts to be done. Under section 302 of the act (21 U.S.C. 332), the United States can bring a civil action in Federal court to enjoin a person who commits a prohibited act. Under section 303 of the act (21 U.S.C. 333), the United States can bring a criminal action in Federal court to prosecute a person who is responsible for the commission of a prohibited act. Under section 306 of the act (21 U.S.C. 335a), FDA can seek debarment of any person who has been convicted of a felony relating to importation of food into the United States. Failure of an owner, operator, or agent in charge of a domestic or foreign facility to register its facility, to update required elements of its facility's registration, or to cancel its registration in accordance with the requirements of this subpart is a prohibited act under section 301(dd) of the act.

(b) FDA will cancel a registration if the agency independently verifies that the facility is no longer in business or has changed owners, and the owner, operator, or agent in charge of the facility fails to cancel the registration, or if FDA determines that the registration is for a facility that does not exist. If FDA cancels a facility's registration, FDA will mail a confirmation of the cancellation to the facility at the address provided in the facility's registration.

(c) If an article of food is imported or offered for import into the United States and a foreign facility that manufactured/processed, packed, or held that article of food has not registered in accordance with this subpart, the disposition of the article of food shall be governed by the procedures set out in subpart I of this part.

§ 1.242 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.

§ 1.243 Is food registration information available to the public?

(a) The list of registered facilities and registration documents submitted under this subpart are not subject to disclosure under 5 U.S.C. 552 (the Freedom of Information Act). 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 (the Freedom of Information Act).

(b) Paragraph (a) of this section does not apply to any information obtained by other means or that has previously been disclosed to the public as defined in § 20.81 of this chapter.

Subpart I—Prior Notice of Imported Food

SOURCE: 73 FR 66402, Nov. 7, 2008, unless otherwise noted.

GENERAL PROVISIONS

§ 1.276 What definitions apply to this subpart?

(a) *The act* means the Federal Food, Drug, and Cosmetic Act.

(b) The definitions of terms in section 201 of the act (21 U.S.C. 321) apply when the terms are used in this subpart, unless defined in this section.

(1) *Calendar day* means every day shown on the calendar.

(2) *Country from which the article originates* means FDA Country of Production.

(3) *Country from which the article is shipped* means the country in which the article of food is loaded onto the conveyance that brings it to the United States or, in the case of food sent by international mail, the country from which the article is mailed.

(4) *FDA Country of Production* means: (i) For an article of food that is in its natural state, the country where the article of food was grown, including harvested or collected and readied for shipment to the United States. If an article of food is wild fish, including seafood that was caught or harvested outside the waters of the United States by a vessel that is not registered in the United States, the FDA Country of Production is the country in which the

vessel is registered. If an article of food that is in its natural state was grown, including harvested or collected and readied for shipment, in a Territory, the FDA Country of Production is the United States.

(ii) For an article of food that is no longer in its natural state, the country where the article was made; except that, if an article of food is made from wild fish, including seafood, aboard a vessel, the FDA Country of Production is the country in which the vessel is registered. If an article of food that is no longer in its natural state was made in a Territory, the FDA Country of Production is the United States.

(5) *Food* has the meaning given in section 201(f) of the act, except as provided in paragraph (b)(5)(i) of this section.

(i) For purposes of this subpart, food does not include:

(A) Food contact substances as defined in section 409(h)(6) of the act (21 U.S.C. 348(h)(6)); or

(B) Pesticides as defined in 7 U.S.C. 136(u).

(ii) Examples of food include fruits, vegetables, fish, including seafood, dairy products, eggs, raw agricultural commodities for use as food or as components of food, animal feed (including pet food), food and feed ingredients, food and feed additives, dietary supplements and dietary ingredients, infant formula, beverages (including alcoholic beverages and bottled water), live food animals, bakery goods, snack foods, candy, and canned foods.

(6) *Full address* means the facility's street name and number; suite/unit number, as appropriate; city; Province or State as appropriate; mail code as appropriate; and country.

(7) *Grower* means a person who engages in growing and harvesting or collecting crops (including botanicals), raising animals (including fish, which includes seafood), or both.

(8) *International mail* means foreign national mail services. International mail does not include express consignment operators or carriers or other private delivery services unless such service is operating under contract as an agent or extension of a foreign mail service.