

registration and a permanent registration number. You will be considered registered once FDA electronically transmits your confirmation and registration number unless notified otherwise.

(b) Registration by mail: (1) If you do not have reasonable access to the Internet through any of the methods provided under paragraph (a) of this section, you must register by obtaining a copy of the registration form (Office name or mail code), the Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, or by phone at [toll-free number that will be provided in the final rule].

(2) When you receive the form in the mail, you must fill it out completely and legibly and mail it to the address in paragraph (b) of this section.

(3) If any required information on the form is incomplete or illegible when FDA receives it, FDA will send the form back to you for completion, provided that your mailing address is legible and valid.

(4) FDA will enter completed registration submissions into the system as soon as practicable, in the order received.

(5) FDA will then mail to the mailing address shown on the registration form a copy of the registration as entered, confirmation of registration, and your registration number.

(6) If any information you previously submitted is incorrect as entered into the system, you must update your registration as specified in § 1.234.

(7) You will be considered registered once FDA enters your registration data into the registration system and the system generates a registration number.

(c) No registration fee is required.

(d) You must submit all registration information in the English language.

§ 1.232 What information is required in the registration?

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

(a) The name, full address, phone number, fax number, and e-mail address of the facility;

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

(c) Emergency contact information, including an individual's name, title, office phone, home phone, cell phone (if available), and e-mail address (if available);

(d) All trade names the facility uses;

(e) Product categories as identified in § 170.3 of this chapter;

(f) For a foreign facility, the name, address, phone number, fax number (if

available), and e-mail address (if available) of its U.S. agent; and

(g) A statement certifying that the information submitted is true and accurate, and that the person submitting the registration is authorized by the facility to register on its behalf. The statement requires the name of the person registering the facility. This statement also requires the phone number, e-mail address (if available), and fax number (if available) of the person submitting the registration.

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

FDA encourages, but does not require, you to submit the following optional items in your 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) Preferred mailing address, if different from that of the facility;

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

(c) Food categories not included under § 170.3 of this chapter, but which are helpful to FDA for responding to an incident (e.g., infant formula, dietary supplements, and food for animal consumption);

(d) Type of storage, if the facility is solely a holding facility;

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

(f) Approximate dates of operation, if the facility's business is seasonal.

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

(a) The owner, operator, or agent in charge must submit an update to the registration within 30 calendar days of any change to any of the information previously submitted, including, but not limited to, the name of the owner, operator, or agent in charge of a facility.

(b) A facility canceling its registration must do so on the cancellation of registration form.

(c) 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 in which the individual submitting the cancellation will certify that the information submitted is true and accurate and the submitter is authorized by the facility to cancel its registration.

Additional Provisions

§ 1.240 What other registration requirements apply?

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

§ 1.241 What happens if you fail to register?

(a) Failure of a domestic or foreign facility to register in accordance with this regulation is a prohibited act under section 301 of the act (21 U.S.C. 331).

(b) Any person who imports or offers for import an article of food without complying with the requirements of section 801(l) of the act (21 U.S.C. 381(l)) as set out in this subpart, or otherwise violates any requirement under section 801(l) of the act, or any person who causes such an act, commits a prohibited act within the meaning of section 301(dd) of the act.

(c) Under section 302 of the act (21 U.S.C. 332), the United States can bring a civil action in Federal court to enjoin persons who commit prohibited acts. Under section 303 of the act (21 U.S.C. 333), the United States can bring a criminal action in Federal court to prosecute persons who commit prohibited acts. 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.

(d) If an article of food is imported or offered for import and a foreign facility that manufactured/processed, packed, or held that food has not registered in accordance with this subpart, the food must be held at the port of entry unless FDA directs its removal to a secure facility in accordance with paragraph (e) of this section.

(e) Under paragraph (d) of this section, if FDA determines that removal to a secure facility is appropriate (e.g., due to a concern with the security of the article of food or due to space limitations in the port of entry), FDA may direct that the article of food be removed to a bonded warehouse, container freight station, centralized examination station, or another appropriate secure facility approved by FDA.