

Food and Drug Administration, HHS

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(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 specifications, 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 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:

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(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/furl>s.

(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.