

§ 1.232

21 CFR Ch. I (4–1–20 Edition)

that the person identified as the U.S. agent for your foreign facility has agreed to serve as your U.S. agent. FDA will not provide you with a confirmation of your registration renewal until that person confirms that the person agreed to serve as your U.S. agent.

(8) FDA will mail or fax you 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).

(9) 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.

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

(d) *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.

[81 FR 45950, July 14, 2016]

§ 1.232 What information is required in the registration?

(a) For a domestic and foreign facility, the following information is required:

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

(2) Beginning October 1, 2020, the facility's UFI recognized as acceptable by FDA;

(3) The preferred mailing address, if different from that of the facility;

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

(5) All trade names the facility uses;

(6) The name, full address, and phone number of the owner, operator, or agent in charge of the facility. In addition,

the email address of the owner, operator, or agent in charge is required, unless FDA has granted you a waiver under § 1.245;

(7) The applicable food product categories of any food manufactured/processed, packed, or held at the facility as identified on Form FDA 3537;

(8) The type of activity conducted at the facility for each food product category identified. You may select more than one activity type for each food product category identified. The activity type options are as follows:

(i) Ambient human food storage warehouse/holding facility;

(ii) Refrigerated human food warehouse/holding facility;

(iii) Frozen human food warehouse/holding facility;

(iv) Interstate conveyance caterer/catering point;

(v) Contract sterilizer;

(vi) Labeler/relabeler;

(vii) Manufacturer/processor;

(viii) Acidified food processor;

(ix) Low-acid food processor;

(x) Farm mixed-type facility;

(xi) Packer/repacker;

(xii) Salvage operator (reconditioner);

(xiii) Animal food warehouse/holding facility;

(xiv) Other activity.

(9) A statement in which the owner, operator, or agent in charge provides an assurance that FDA will be permitted to inspect the facility at the times and in the manner permitted by the Federal Food, Drug, and Cosmetic Act;

(10) 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. In addition, the registration must identify the individual who authorized submission of the registration by email address, unless FDA

has granted a waiver under § 1.245. Each registration must include the name of the individual submitting the registration, and the individual's signature (for the paper option).

(b) For a domestic facility, the following additional information is required:

(1) The email address for the contact person of the facility;

(2) An emergency contact phone number and email address if different from the email address for the contact person in paragraph (b)(1) of this section.

(c) For a foreign facility, the following additional information is required:

(1) The name, full address, phone number, and email address of the foreign facility's U.S. agent;

(2) An emergency contact phone number and email address.

[81 FR 45951, July 14, 2016]

§ 1.233 Are there optional items included in the registration form?

Yes. FDA encourages, but does not require, you to submit items that are indicated as optional on the Form FDA 3537 that you submit.

[81 FR 45952, July 14, 2016]

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

(a) *Update requirements.* You must update 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. You may authorize an individual to update a facility's registration on your behalf. For updates not submitted by the owner, operator, or agent in charge of the facility, the update must provide the email address of the individual who authorized submission of the update, unless FDA has granted a waiver under § 1.245.

(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 submit a new registration for 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) After you submit your electronic update, FDA will provide you with an electronic confirmation of your update. When updating UFI information, FDA will verify the accuracy of your facility's UFI and will also verify that the facility-specific address associated with the UFI is the same address associated with your registration. FDA will not provide you with an electronic confirmation of your registration update until FDA verifies the accuracy of your facility's UFI and verifies that the facility-specific address associated with the UFI is the same address associated with your registration. For foreign facilities, when updating information about your U.S. agent, FDA will verify that the person identified as the U.S. agent for your foreign facility has agreed to serve as your U.S. agent. FDA will not provide you with an electronic confirmation of your registration update until that person confirms that the person agreed to serve as your U.S. agent.

(3) For electronic updates not submitted by the owner, operator, or agent in charge of the facility, after submission of the electronic update, FDA will verify that the individual identified as having authorized submission of the update in fact authorized the submission on behalf of the facility. FDA will not confirm the update to the registration until that individual confirms that he or she authorized the submission.

(4) Your registration will be considered updated once FDA sends you your update confirmation, unless notified otherwise.

(d) *Update by mail or fax.* Beginning January 4, 2020, you must submit your update electronically, unless FDA has granted you a waiver under § 1.245. If FDA has granted you a waiver under § 1.245, you may update your facility's registration by mail or by fax.

(1) You must update your registration using Form FDA 3537. You may