obtain a copy of this form by writing to the U.S. Food and Drug Administration, Center for Food Safety and Applied Nutrition, 5001 Campus Dr. (HFS–681), College Park, MD 20740 or by requesting the form by phone at 1–800–216–7331 or 301–575–0156.

(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.

(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 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). After you submit your update by mail or fax, 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 a 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 a confirmation of your registration update until that person confirms that the person agreed to serve as your U.S. agent.

(6) For registration updates not submitted by the owner, operator, or agent in charge of the facility, after submission of the registration update by mail or fax, 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 registration update until that individual confirms that he or she authorized the update.

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

(8) 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.

[81 FR 45952, July 14, 2016]

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

(a) *Notification of registration cancellation*. You must cancel a registration within 60 calendar days of the reason for cancellation (e.g., your facility ceases operations, ceases providing food for consumption in the United States, or 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 email address (if available) of the individual submitting the cancellation;

(5) For registration cancellations not submitted by the owner, operator, or agent in charge of the facility, the email address of the individual who authorized submission of the registration cancellation, unless FDA has granted a waiver under §1.245; and

(6) 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 provide you with an electronic confirmation of your cancellation.

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

(4) Your registration will be considered cancelled once FDA sends you your cancellation confirmation.

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

(1) You must cancel your registration using Form FDA 3537a. You may obtain a copy of this form by writing to the U.S. Food and Drug Administration, Center for Food Safety and Applied Nutrition, 5001 Campus Dr. (HFS–681), College Park, MD 20740 or by requesting the form by phone at 1–800–216–7331 or 301–575–0156.

(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.

(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 as soon as practicable, in the order FDA receives them.

(5) FDA will 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) For registration cancellations not submitted by the owner, operator, or agent in charge of the facility, after submission of the registration cancellation by mail or fax, FDA will verify that the individual identified as having authorized submission of the cancellation in fact authorized the submission on behalf of the facility. FDA will not confirm the registration cancellation until that individual confirms that he or she authorized the registration cancellation.

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

[81 FR 45952, July 14, 2016]

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, renew, or cancel your registration?

(a) Section 301 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331) prohibits the doing of certain acts or causing such acts to be done. Under section 302 of the Federal Food, Drug, and Cosmetic 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 Federal Food, Drug, and Cosmetic 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 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 335a), FDA can seek debarment of any person who has been