

§ 1.235

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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 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 registra-

tion system and the system generates an update confirmation.

§ 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 301-210-0247.

(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 re-submit 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 re-submit 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.

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