§ 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 convicted of a felony relating to importation of food into the United States. Failure of an owner, operator, or agent in charge of a domestic or foreign facility to register its facility, renew the registration of its facility, update required elements of its facility's registration, or cancel its registration in accordance with the requirements of this subpart is a prohibited act under section 301(dd) of the Federal Food, Drug, and Cosmetic Act.

(b) FDA will consider a registration for a food facility to be expired if the registration is not renewed, as required by § 1.230(b). Thus, if you previously submitted a registration to FDA, but do not submit a registration renewal to FDA during the period beginning on October 1 and ending on December 31 of each even-numbered year, FDA will consider the registration for the facility to be expired. FDA will consider a food facility with an expired registration to have failed to register in accordance with section 415 of the Federal Food, Drug, and Cosmetic Act.

(c) FDA will cancel a registration if FDA independently verifies that the facility is no longer in business or has changed owners, and the owner, operator, or agent in charge of the facility fails to cancel the registration, or if FDA determines that the registration is for a facility that does not exist, is not required to register, or where the information about the facility's address was not updated in a timely manner in accordance with § 1.234(a) or the registration was submitted by a person not authorized to submit the registration under § 1.225. Also, FDA will cancel a registration if the facility's registration has expired because the facility has failed to renew its registration in accordance with § 1.230(b). If FDA cancels a facility's registration, FDA will send a confirmation of the cancellation using contact information submitted by the facility in the registration database.

(d) If an article of food is imported or offered for import into the United States and a foreign facility that manufactured/processed, packed, or held that article of food has not registered in accordance with this subpart, the disposition of the article of food shall be governed by the procedures set out in subpart I of this part.

[81 FR 45953, July 14, 2016]

§ 1.242 What does assignment of a registration number mean?

Assignment of a registration number to a facility means that the facility is registered with FDA. Assignment of a registration number does not in any way convey FDA's approval or endorsement of a facility or its products.

§ 1.243 Is food registration information available to the public?

(a) The list of registered facilities and registration documents submitted under this subpart are not subject to disclosure under 5 U.S.C. 552 (the Freedom of Information Act). In addition, any information derived from such list or registration documents that would disclose the identity or location of a specific registered person, is not subject to disclosure under 5 U.S.C. 552 (the Freedom of Information Act).

(b) Paragraph (a) of this section does not apply to any information obtained by other means or that has previously been disclosed to the public as defined in § 20.81 of this chapter.

§ 1.245 Waiver request.

Under §§ 1.231(a)(2) and (b), 1.234(d), and 1.235(d), beginning January 4, 2020, you must submit your registration, registration renewal, updates, and cancellations to FDA electronically unless FDA has granted a waiver from such