

businesses that cease operations would not necessarily cancel their registrations.

(Response) Because a registration cancellation is essentially an update of registration information, FDA believes the time period for canceling a registration should be 60 days, the same as that for updates. Regarding purging its database of obsolete registrations, FDA will cancel a registration if it independently verifies that the registrant has gone out of business or if someone has registered a facility that does not exist. If FDA cancels a facility's registration that has gone out of business, FDA will mail a confirmation of the cancellation to the facility.

(Comment 141) One commenter believes that the amount of information FDA proposes to require in the cancellation notice is excessive. The commenter requests that FDA require only the facility's registration number, the name and contact information for the person submitting the cancellation, and the certification statement for a cancellation.

(Response) The only elements the cancellation form includes in addition to those listed in the commenter's request is the facility's PIN number, whether the facility is domestic or foreign, and the facility's name and address. FDA believes the information in the cancellation form is necessary for FDA to verify that it is canceling the correct registration, because canceling the wrong facility's registration could have unintended consequences.

(Comment 142) Several commenters request that FDA clarify the penalty for failure to update a registration within the required timeframe. The commenters indicate that absent a coercive element, the value of this tool is subject to failure.

(Response) The Bioterrorism Act requires owners, operators, and agents in charge of facilities to register with FDA and also requires FDA to keep its registration database current. Accordingly, § 1.241 states that failure to submit a timely update to required registration elements is a prohibited act, because obsolete information may hinder FDA's efforts in responding to a threatened or actual bioterrorist act or other food-related emergency. The FD&C Act provides for civil and criminal sanctions for those who commit a prohibited act.

(Comment 143) Several commenters urge FDA to not require facilities to update optional information previously submitted (such as the type of activities conducted at the facility, as well as the optional food categories or type of storage). One commenter requests that

FDA state in the interim final rule that the failure to update optional information will not subject the registrant to penalties under the act or FDA's implementing regulations. The commenter states that the requirement to update previously submitted information in optional fields "could have a chilling effect on the willingness of companies to provide the optional information in the first place."

(Response) FDA has considered these comments and has revised § 1.241(a) to delete the reference to optional information. The Bioterrorism Act requires that a registrant notify the Secretary in a timely manner of changes to information submitted in a registration (21 U.S.C. 350d(a)(2)). FDA believes that it is clear that the failure to update required information is a prohibited act (21 U.S.C. 331(dd)). The agency is concerned, however, that extending the prohibited act to failure to update optional information will create a disincentive to registrants to provide the optional information contrary to the interests of the agency and registered facilities. Accordingly, FDA has revised § 1.234(a) to provide that only required information must be updated and § 1.241(a) to provide that failure to update required information is a prohibited act.

Although the interim final rule will not make the failure to update optional information a prohibited act, FDA emphasizes that updates of registration information are very important, because obsolete information may hinder FDA's efforts in responding to a bioterrorist act or other food-related emergency. Accordingly, the agency strongly encourages the owner, operator, or agent in charge of each registered facility that provides FDA with optional information in a registration to promptly update such information when it changes. In addition, FDA encourages the owners, operators, and agents in charge of registered facilities to update their registrations to delete optional information that is obsolete.

(Comment 144) One commenter asks FDA to clarify whether FDA will keep updated information on file as well as the reason for the change. The commenter states that "[i]n order to track activities of all sides, if that is what the intended purpose is, a 'tracking and activity mechanism' would have to be in place. This would require, however, that the agency has trained personnel that are able to spot unreasonable irregularities and not go on a 'witch hunt.'"

(Response) FDA intends to keep updated information on file. FDA inspectors will compare a facility's

registration information with the information they obtain during the inspection of a registered facility. The failure of an owner, operator, or agent in charge to register a facility is a prohibited act, as is both the failure to update outdated required registration elements within 60 days of the change, and the failure to cancel a registration within 60 days if changes at the facility warrant cancellation.

(Comment 145) One commenter requests that FDA's electronic registration system be designed to permit a facility to use the original information screen as the starting point for updating or canceling the registration.

(Response) FDA advises that when a registrant accesses the electronic system to update the registration for a particular facility, the system is designed to provide the existing registration. Therefore, the registrant will only need to edit the sections of the registration that need to be updated.

(Comment 146) One commenter asks FDA to send an automatic e-mail reminder to registrants on a yearly basis to remind them to update their registrations.

(Response) As resources allow, FDA will send periodic notices to registrants, reminding them to update, as necessary, information in their registration.

In addition to the changes noted previously, on its own initiative FDA has made several editorial changes to this section for the purpose of clarity. FDA has also added section § 1.235 "How and when do you cancel your facility's registration information?" This new section contains information that was previously in section § 1.234, "How and when do you update your registration information?" FDA has added this section for the purpose of clarity.

*K. Comments on "What Other Registration Requirements Apply?" (Proposed § 1.240)*

(Comment 147) Many commenters state that they have already registered with other U.S. Government agencies, as well as foreign governments and States. The commenters state that requiring these facilities to be registered with FDA as well is a burden. The commenters also argue that FDA should coordinate with other agencies and governments to avoid duplication.

(Response) The interim final rule maintains the registration requirement as proposed, for several reasons. For all facilities that FDA determines are subject to section 305 of the Bioterrorism Act, we believe that the