

are an owner, operator, or agent in charge of a domestic facility * * *, you must register the facility * * *."

FDA believes no revisions are needed to § 1.226, because it is clear in this section that the exemptions apply to facilities, not the owner, operator, or agent-in-charge of the facilities.

In § 1.230, FDA has made the following change indicated by the italicized language: "[t]he owner, operator, or agent in charge of a facility that manufactures/processes, packs, or holds food for consumption in the United States must *register the facility* no later than December 12, 2003."

In § 1.233, in the first paragraph, FDA has made the following change indicated by the italicized language: "FDA encourages, but does not require, you to submit the following items in your *facility's* registration."

(Comment 98) Several commenters submitted comments regarding when to register. Some of these commenters request general information about when they will be able to register with FDA. Others acknowledge the proposed timeframe in which FDA expects to publish the final rule; these commenters question why they cannot register, either electronically or by mail, before publication of the interim final rule. Some commenters ask that FDA publish a final rule and implement its electronic registration system before October 12, 2003. Some commenters suggest that, to alleviate the burden on FDA's electronic system, FDA should either accept staggered registrations based on such identifiers as last name of the facility, or that FDA should only require registration 15 days before a facility's intended date of a food shipment to the United States. One commenter requests that FDA ensure that the final regulation and electronic system are in place by October 12, 2003.

(Response) FDA understands that many commenters may view the proposed 8-week timeframe for facilities to register as too brief. However, this timeframe is limited due in large part to the restrictions imposed by the Bioterrorism Act, which requires FDA to develop both proposed and final regulations detailing the process by which facilities must register by December 12, 2003. Within this timeframe, FDA has also had to develop an electronic system that can implement the requirements of this regulation. FDA has expedited the process for developing and completing the proposed and interim final regulations, as well as the electronic registration system. It is not possible for FDA to complete a final rule in less than 16 months from enactment of the

Bioterrorism Act, or before October, 2003. Moreover, because this interim final rule articulates the final requirements for registration, which FDA must incorporate into its electronic registration system, FDA could not allow registration in advance of publication of the interim final rule, either electronically or by mail. FDA also believes the time period for registration is reasonable. Because both the proposed rule and this interim final rule have alerted facilities to the general requirements of registration, facilities have had ample time to prepare for registration pending the issuance of the interim final rule.

(Comment 99) Some commenters argue that FDA should provide a 3 to 6-month grace period after December 12, 2003, in which it will accept late registrations without penalizing the facilities that submit these late registrations. These commenters state that they are concerned that FDA will not be able to accommodate the large number of electronic registrations that must be submitted within this 8-week timeframe, and that this breakdown could cause large monetary losses to industry.

(Response) The Bioterrorism Act provides that the effective date for registration is December 12, 2003. The statute further specifies that, after this date, food imported or offered for import from unregistered facilities must be held at the port until the facility is registered (21 U.S.C. 381(l)). FDA has designed its electronic system to be robust enough to handle the large volume of registrations anticipated during this 8-week period. However, the planned capacity will not be sufficient to process all of the registrations in 1 day; thus, if all registrants wait until the last day to register (*i.e.*, December 12, 2003), the system's capacity could be exceeded. Therefore, FDA encourages facilities to register early.

(Comment 100) Some commenters indicate that the 8-week timeframe does not allow paper registrations as a real alternative to electronic registrations, because FDA states in the proposed rule that registration by mail could take several weeks to several months. This timeframe could render a facility out of compliance with the effective date for registration, because even if a facility were to mail its registration to FDA soon after October 10, FDA might not return the registration number to the facility until after December 12.

(Response) The paper processing facility will be able to electronically process over 1,800 Form 3537 submissions each business day during the regulatory peak processing period of

October 16, 2003, through December 12, 2003 (41 business day period). This will result in a total of 73,800 submissions processed in a 41 business day period. All Form 3537 submissions will be processed in the order they are received and will be turned around within a 24-hour period, if the registration form is error free. Submitters should expect to receive their registration number within 5 to 7 days after processing depending on postal mailing delays if the number of submissions does not exceed the processing capacity.

If the registration submissions should exceed the daily 1,800 Form 3537 processing capacity, a backlog will develop. FDA expects that if backlogs occur, they are most likely near the end of the initial 41 business day registration period. If our estimates are correct, FDA would expect a backlog of 2 to 3 weeks. However, if the number of submissions and rejections being resubmitted exceed our estimates, the backlogs will be longer. So including the mailing time, the backlog, and processing times, the delay toward the end of the initial registration period could be 3 to 6 weeks or longer if the number of submissions exceeds our estimates.

If a submission has been rejected due to error the submitter made or failed mandatory validation, the submission will be returned to the submitter via postal mail. Depending on mailing delays, the submitter should expect to receive the rejected submission with a letter explaining the rejection within 5 to 7 days plus the time the submission spent in the processing backlog (0 to 3 weeks). After the submitter corrects their registration and resubmits it to FDA via postal mail, the corrected registration will be processed in the order received along with all other submissions and is subject to all of the delays identified previously.

For the CD-ROM option, submitters are allowed to store a fill-in PDF Form 3537 for each facility onto a CD as a separate file. FDA will process the CD-ROM submission, presumably containing multiple registrations, electronically as part of the paper process. This means the PDFs on the CD-ROM will not be printed out and then keyed in because they are already in the format that the paper process system needs. The PDF files will be fed into the paper process queue in their order of arrival as though they were a normal paper form. Each file on the CD will go through the same validation checks as if it were a normal paper submission. If the registration file on the CD-ROM is processed successfully, the registration will be returned by postal