

mail with a registration number. If the registration fails validation checks or contains errors, the registration will be returned with a letter explaining why registration was not successful and will need to be resubmitted in order to complete registration.

The only way for a registrant to ensure a fast response to a registration is to register the facility electronically on the Internet.

(Comment 101) One commenter states that FDA does not mention the registration requirements for facilities that form after December 12, 2003.

(Response) Section 1.230 of the interim final rule states “\* \* \* a facility that begins to manufacture/process, pack, or hold food for consumption in the United States on or after December 12, 2003, must be registered before the facility begins such activities.”

FDA has made a small editorial change to this section for clarity.

*G. Comments on “How and Where Do You Register?” (Proposed § 1.231)*

(Comment 102) Several commenters ask FDA to explain how they should register their facilities with FDA.

(Response) As stated in § 1.231, those wishing to register a facility electronically must access <http://www.fda/furls> and follow the directions on that Web site for registering. This Web site will be available starting on October 16, 2003, at 6:00 p.m. eastern daylight time. Registrants needing technical assistance with the paper or electronic registration forms can call 1-800-216-7331 or 301-575-0156, or can fax their questions to 301-210-0247 or e-mail them to [furls@fda.gov](mailto:furls@fda.gov). Starting on October 16, 2003, these phone numbers will be staffed on business days from 7 a.m. until 11 p.m. eastern standard time.

FDA had anticipated having the electronic and paper systems operational on the date of this interim final rule's publication. However, given the fluid and dynamic nature of developing the electronic system in parallel with finalizing the regulation that determines the requirements for the system and given the short deadline imposed by the statute, much of the development and testing effort of the system had to occur in the last 2 months. Accordingly, for much of these 2 months, work on the system has been taking place 7 days a week. Moreover, hurricane Isabel caused significant delays in the work for the week of Thursday, September 18. Due to these delays, FDA determined that if it postponed the launching of the system until Thursday, October 16, there would be a much higher level of assurance that

those persons registering food facilities electronically would be able to do so effectively and efficiently without user frustration or confusion. FDA believes that the slight delay of the system will not affect stakeholders substantially, as potential registrants will need several days to become familiar with the rule and its requirements.

Therefore, beginning on October 16, 2003, the Web site will be available 24 hours a day, 7 days a week, from wherever the Internet is accessible, including libraries, copy centers, schools, and Internet cafes. In addition, as noted previously, the owner, operator, or agent of a foreign facility may authorize an individual to register the facility; the owner, operator, or agent in charge may choose to authorize an individual who has access to the Internet. In addition, the Bioterrorism Act requires a foreign facility to designate a U.S. agent. That agent (if an individual) could be authorized by the owner, operator, or agent in charge of a foreign facility to register that facility. If the U.S. agent does not have Internet access onsite, the U.S. agent may register the facility electronically from a local library or other public facility that offers Internet access either free of charge or for a relatively small fee. Thus, all foreign facilities will be able to receive an electronic confirmation of registration and the facility's registration number, as will domestic facilities that register electronically.

FDA strongly encourages electronic registration for the benefit of both FDA and the registrant. FDA will be able to accept electronic registrations from anywhere in the world where the Internet is available 24 hours a day, 7 days a week. Electronic registration also will enable a facility to be registered more quickly than if registering by mail, because obtaining confirmation of registration and the facility's registration number online should be instantaneous once a facility fills in all required fields on the electronic registration form.

As stated in § 1.231(b), a registrant may also register by fax or mail (for example, if none of the means of electronic access mentioned previously are reasonably available). Processing of fax or mail (including CD-ROM) registrations will also begin on October 16, 2003. In registering by mail or fax, a registrant also may fill out one or more forms on behalf of one or more facilities. A registrant registering by mail must call FDA at 1-877-FDA-3882 (1-877-332-3882) to request a copy of the form, or send FDA a written request for the form at U.S. Food and Drug Administration (HFS-681), 5600 Fishers Lane, Rockville, MD 20857. Once the

registrant receives the mailed or faxed copy of the form, the form must be filled out completely and legibly, and either mailed back to FDA at the same address, or faxed back to FDA at 301-210-0247. FDA will process the registration forms in the order received. An agency employee will check to make sure all mandatory fields are filled out completely and legibly. If the form is not complete or is illegible, it will be returned to the registrant for completion, provided that the registrant's mailing address is legible and valid. If the form is complete and legible, FDA will manually enter the data on the form into the system as soon as practicable, which will depend on the number of other registration forms awaiting manual entry into the system. FDA will then mail or fax to the registrant a copy of the registration as entered, confirmation of the registration, and the facility's registration number. When responding to a registration submission, FDA will use the means by which the form was received by the agency (i.e., by mail or by fax). If the copy of the registration form mailed or faxed back to the registrant contains incorrect information, the registrant must update the incorrect information under § 1.234. Registration by CD-ROM, which is also permitted by the interim final rule, is discussed in the response to comment 103.

(Comment 103) Several commenters request that FDA accept batched multiple facility registrations via CD or XML format instead of registering one facility at a time through the online system.

(Response) Due to the stringent timeframe that FDA had to develop proposed and interim final regulations and in which to finalize the electronic registration system, FDA is unable to accept multiple registrations in XML format because it would take substantial additional time and money for FDA to develop the compatibility necessary to accept registrations in this format. However, FDA will accept multiple submissions in CD-ROM format ISO 9660 (CD-R or CD-RW) Data format. These registrations must be submitted on FDA's fill-in Portable Document Format (PDF) rendition of the appropriate form (Form 3537) accompanied by one signed copy of the certification statement on the registration form. Each submission on the CD-ROM must use the same preferred mailing address in the appropriate block on Form 3537. The CD-ROM can contain as many submissions as needed up to its capacity (650-700 megabytes (MB) or about 1,300 submissions per CD-ROM). Importantly,