

threatened or actual food-related emergency. To assist registrants who do not speak English, FDA has given a foreign facility the option of authorizing an individual (including its U.S. agent if an individual) to register on its behalf.

(Comment 109) Some commenters question whether there will be a contingency plan if the electronic registration system is not as efficient as expected or if more facilities register than anticipated. Some of these commenters question whether the paper system will be able to handle the 8-week registration period.

(Response) The electronic system is designed to handle anticipated peak loads. The paper-based system is being designed to handle the 8-week registration period; however, depending on the number of paper registrations received, and depending on when FDA receives the registrations within this 8-week period, FDA may be unable to process all paper registrations, confirm the registration, and provide a registration number to each registrant within the 8-week period. For this reason, FDA strongly encourages all facilities to register electronically to ensure they are registered on time.

(Comment 110) Some commenters ask whether trade associations, commodity groups, or parent companies can register on behalf of facilities represented by their organizations.

(Response) As stated in the response to comment 96, we have revised § 1.232(i) and the certification statement on Form 3537 to permit an authorized individual to submit the registration. Thus, a trade association or commodity group cannot submit a registration because these entities are not individuals. However, the owner, operator, or agent in charge can authorize an individual from such a group to submit the registration. We note that the definition of U.S. agent provides that a U.S. agent may be a "person" as defined in section 201(e) of the FD&C Act. Therefore, a foreign facility could designate a trade association or commodity group as the facility's U.S. agent. However, if the U.S. trade association or commodity group agrees to serve as the U.S. agent and the facility authorizes the U.S. agent as the foreign facility's agent in charge for registration, an authorized individual from that association or group must submit the registration. In addition, the interim final rule allows a parent corporation to register on behalf of one or more of its facilities.

(Comment 111) One commenter asks whether FDA can build on the Operational and Administrative System for Import Support (OASIS) that FDA

currently has to accept registrations. The commenter states that some prospective registrants already provide information regarding "shipper" and "manufacturer" to FDA via OASIS, and that building a new registration system would cause redundancy for these registrants.

(Response) Although FDA intends to use OASIS for cross-checking registration information, both the required data elements and the universe of facilities required to register are markedly different from those entered into OASIS. Moreover, OASIS does not have the capacity to accept all the registration information from all the facilities required to register with FDA. Thus, FDA has developed a new system for registration that will interface with OASIS.

(Comment 112) One commenter asks whether FDA will accept photocopied versions of the mailed registration form.

(Response) FDA will accept a photocopy of a mailed registration form or the certification statement submitted with a CD-ROM submission, as long as the signature on each individual form is an original signature. We recognize that for multiple facility registrations, photocopying data elements that are common to each facility will reduce the burden on the registrants in completing the forms. While those common data elements may appear as photocopies, the forms must include an original signature.

(Comment 113) One commenter asks how the electronic registration form will allow registrants to proceed through the registration process. For example, if each a registrant must answer each section to proceed to the next section, how will the system address optional information?

(Response) FDA has designed both its electronic and paper registrations to specify which sections are mandatory. The electronic registration system has been designed to highlight or mark a required field that a registrant has left blank so that the submitter must fill it in before proceeding further with the electronic registration process.

(Comment 114) One commenter expresses concern that a registration may get lost in "cyberspace," even though it has been correctly filled out and the facility has received a registration number.

(Response) The system saves all submitted information before issuing a registration number. A submitter would only receive a registration number upon a successful registration; if the registration failed, a facility would not receive a registration number. The Web system is a real time system with tape

backups of the data entered. Additionally, the system has battery backups in the unlikely event of a power loss.

In addition to the changes noted previously, on its own initiative FDA has made several editorial changes to this section for clarity.

H. Comments on "What Information Is Required in the Registration?" (Proposed § 1.232)

1. General Comments

(Comment 115) Several commenters believe FDA should make the registration process as simple as possible, limiting required information to name, address, and trade names. These commenters state that the scope, exemptions, definitions, and required information in the proposed rule erode simplicity to the point that exemptions are voided, and would require registrations from a vast array of small facilities.

(Response) The Bioterrorism Act requires that a registration contain each facility's name, address, and all trade names under which the registrant does business (21 U.S.C. 350d(a)(2)). That statute provides no exemption from registration for small-size facilities. FDA believes that the information required for registration is necessary to assist FDA in notifying facilities of a threatened or actual bioterrorist attack or other food-related emergency. Together with the other regulations FDA is developing to implement the Bioterrorism Act, the information in the registration will assist FDA in determining the source and cause of such an event.

Regarding the comment that the scope, definitions, exemptions, and required information are unduly complicated, no comments FDA received in response to the proposed rule argue that the interim final rule should not include any definitions, exemptions, or specify the information to be included in a registration. FDA has made every effort to define clearly which facilities are required to register to ensure that potential registrants will know whether they are subject to the rule. FDA also has provided definitions for each exemption provided in the Bioterrorism Act. Moreover, FDA believes that the registration process itself is as uncomplicated and user-friendly as possible. A facility registering electronically should be able to complete the registration and receive its registration number expeditiously once it has gathered all the requisite information.