

prepare for, and respond to bioterrorism and other public health emergencies.” (Pub. L. 107–188 (emphasis added)). Title III of the Bioterrorism Act is titled, “Protecting the Safety and Security of the Food and Drug Supply.” (Pub. L. 107–188 (emphasis added)). Indeed, when reviewing prior notices that have been submitted after a food has already been refused for lack of adequate prior notice, Congress explicitly directs FDA to determine if it has in its possession any “credible evidence or information indicating that such article present a threat of serious adverse health consequences or death to humans or animal,” (section 801(m)(2)(B)(ii) of the FD&C Act). This standard is a health-based standard and is not limited to intentional acts of contamination.

For clarity, the interim final rule also has segregated the information requirements for food imported or offered for import by international mail as new § 1.281(b) and the information requirements for food refused under section 801(m) of the FD&C Act as new § 1.281(c).

1. Registration Numbers

(Comments) Comments note that the submitter may not know the necessary registration numbers and recommend that FDA confirm the registration numbers within its system. A comment reasons that, because FDA will have access to the contact information in its facility registration database, FDA should only require the registration number rather than the name, address, telephone number, fax number, and e-mail address to reduce the burden on submitters. Another comment states that it would be impossible to provide the FDA registration numbers of all operators that have handled the imported food and questions FDA’s need for the registration numbers because the “one up, one down” recordkeeping provision added to the FD&C Act by section 306 of the Bioterrorism Act is sufficient to help FDA take appropriate steps. Other comments express concern about the confidentiality of registration numbers, *i.e.*, they may be denied access to the registration number or be unable to verify it. Other comments state that an importer who imports returned U.S. goods has no direct relationship with the U.S. manufacturer and therefore assert that these importers cannot obtain the registration number.

(Response) Registration of facilities that manufacture/process, pack, or hold food for consumption in the United States is required by new section 415 of the FD&C Act, which was added by section 305 of the Bioterrorism Act.

FDA does not believe that the statute gives FDA authority to waive the registration requirement for facilities that manufacture/process, pack or hold food for consumption in the United States. The one instance when not providing a registration number may be appropriate is when the manufacturer is out of business or registration no longer is appropriate because the manufacturer has ceased making food products under FDA’s jurisdiction.

If such a food is refused because of inadequate prior notice for failure to provide a registration number, or if the food is held under § 1.285(b), you may request an FDA review under § 1.285(j). As part of your request, you should provide FDA information to show that the facility associated with the food is out of business or inactive.

Registration is designed to work in concert with prior notice at the border, as reflected in new section 801(l) of the FD&C Act, which provides that food from facilities that must register may not be admitted into distribution for consumption in the United States unless the relevant facilities have been registered. To enforce section 801(l) of the FD&C Act as intended by Congress, FDA has determined that it must review registration status of manufacturers and shippers as part of prior notice. The information provided by registration will allow FDA to check prior notice submissions against registration data to confirm the identity. Moreover, the information provided by prior notice submissions can serve as a crosscheck as to whether these firms are registered as required and have provided the necessary updates. FDA thus believes that prior notice and registration will work in tandem to provide FDA with information about the article of food and a facility involved in its production and distribution that will inform and improve our risk-based border inspection decisions, as well as our later admissibility determinations.

FDA does not agree that it should confirm registration without requiring that the number be submitted. Each registered facility will be assigned a unique registration number by FDA. Thus, the registration number will help identify the manufacturer. Without a registration number, it may be difficult to determine exactly which registered facility to associate with the article: Different firms may have the same or similar names and more than one firm may operate from a particular location. In addition, requiring the registration number as part of manufacturer identity makes it clear to foreign exporters and U.S. importers from the outset when

registration is required for imported food.

FDA does not agree that the registration number, when one is required, is sufficient by itself to “identify” a person in a prior notice submission. The additional information is needed to verify that the registration number is accurate. For example, without additional information, there is a significant possibility of typographical errors, leading to misidentification of facilities, which could lead to foods being stopped at the border for inadequate prior notice and registration. FDA is requiring identifying information in addition to the registration number (if one is required) to reduce the number of clerical or typographical errors in registration information that could result in refusals. The FDA PN System Interface will require the firm name and at least the city and country as “confirmatory information,” in addition to the registration number to allow for validation. (If registration is not required for the facilities associated with a particular article of food, a registration number may still be provided, along with the name of the facility and the city and country. If a registration number is not required and the submitter chooses not to provide the number voluntarily, the name and full address of the facility must be provided to ensure that FDA can fully identify the correct party.)

Finally, the systems will not automatically fill in the registration number on any documents or electronic screens that are provided to, or appear, to the submitter or transmitter.

To minimize the burden, the interim final rule only requires registration numbers for shippers (if the shipper is a facility required to register for that article of food) and the manufacturer. The interim final rule also states when a registration number is not required in a prior notice for these persons. Under section 415 of the FD&C Act, registration is only required for food for consumption in the United States. Thus, the interim final rule does not require that a prior notice include registration numbers of facilities associated with articles of food that are imported or offered for import for transshipment, storage and export, or further manipulation and export. The interim final rule does not require a registration number for the manufacturer if the article of food is sent by an individual as a personal gift (*i.e.*, for non-business reasons) to an individual in the United States.