

persons responsible for submitting the prior notice must reside or maintain a place of business in the United States, the FDA Prior Notice System will be in English. This will also allow for the information to be placed in standard data elements that can then be maintained in a database, screened against standard criteria, and used for communication among field offices.

In proposed § 1.287(b), FDA is proposing that if its Prior Notice System is unable to receive prior notice electronically, the prior notice, amendments, and updates must be submitted using a printed version of the Prior Notice Screen delivered in person, by fax, or by e-mail to the FDA field office with responsibility over the geographical area in which the anticipated port of entry is located. If the submitter does not receive electronic acknowledgement from the FDA Prior Notice System then it should check to see if its system is working. If it is, then the submitter should assume that the FDA system might be down and attempt to contact the appropriate FDA field office to confirm.

The Prior Notice System will not provide a response to the submitter of the agency's decision regarding the adequacy or timeliness of the prior notice as this assessment will turn on information that will not be available until the food arrives in the United States. FDA anticipates the system will date and time stamp an electronic confirmation of the system's receipt of each prior notice, amendment, and update, which the system will send to the submitter automatically.

FDA believes that the prior notice process under section 801(m) precedes the review process under section 801(a). Thus, FDA's response to the prior notice will not constitute entry review. The section 801(a) review process will be separate from, and subsequent to, the prior notice process. Therefore, the FDA Prior Notice System's electronic confirmation of a prior notice submission is not an 801(a) admissibility decision and should never be construed as an FDA "release" or "may proceed."

If a person wishing to submit prior notice to the FDA is unable to do so because his or her own system is not operating, FDA expects the submitter to use an alternative Internet system for submission (e.g., a local library or copy-center with Internet access). FDA is developing a web-based system to reduce the likelihood that intermittent system outages will impact prior notice submissions.

Although the system may be developed in a way that will allow for

establishment of a personal account, users will not have to be licensed or otherwise pre-approved or have specialized software. FDA also plans to develop and provide guidance and training to potential submitters and their agents that will further describe the data elements and the submission process before December 12, 2003, which is when the requirement to provide prior notice begins. The Prior Notice Screen of FDA's Prior Notice System also identifies the information that must be submitted.

4. What Information Must be Submitted in a Prior Notice? (Proposed § 1.288)

Proposed § 1.288 lists the information or data elements that must be included in each prior notice. Much of this list is taken directly from section 801(m)(1) of the act. The remainder of the list, although not explicitly listed in section 801(m), is information that FDA believes is necessary for the efficient enforcement of section 801(m) of the act and is thus authorized under section 701(b) of the act. We explain below why each of these items is necessary for the efficient enforcement of section 801(m). Accordingly, as set out in proposed § 1.278(a), FDA is proposing that a prior notice that does not contain all of the information listed in proposed § 1.288 will be considered inadequate. FDA solicits comments on this approach.

Most of this information is already supplied by the filer to FDA through ACS as part of the U.S. Customs entry process, including the entry type; the entry number (both ACS line number and FDA line identifier); the FDA product code; a written description of the product in common business terms; brand name; the quantity; lot numbers; the manufacturer; country of origin; shipper; importer; ultimate consignee; and the carrier (the mode of transportation and the carrier code).

Before discussing each data element in the context of prior notice, we want to emphasize that the prior notice requirement does not apply to a whole shipment; for the purpose of section 801(m) of the act, it applies to "each article of food." FDA believes that in section 801(m) "each article of food" means each article of food produced by each manufacturer. Thus, any food product identified by a specific FDA product code and quantity description produced by a single manufacturer (or grower, if fresh) associated with a single entry line number (U.S. Customs entry number plus ACS line number plus OASIS/FDA line number) must be covered by a prior notice. Therefore, each article of food that is represented

by an FDA line must be covered by a prior notice.

Thus, if a shipment consists of four different kinds of food products, e.g., 1,000 cases of 48/6 oz. cans each of Brand X tuna, 240 cases of 24/15.25 oz. cans each of yellow corn, 300 cases of 24/12 oz cans each of Brand X tuna, and 1,500 cases of 48/6 oz. cans each of Brand P tuna, four prior notices are required. These four prior notices may be contained in one submission. If the shipment consists of only one product, e.g., 2,400 cases of 24/15.25 oz. cans each of yellow corn, one prior notice is required. If this corn came from two different manufacturers, however, two prior notices would be needed. In its Prior Notice System FDA will give the submitter the option of completing additional prior notices for other articles after each notice is completed. We are working with the developers of the Prior Notice System to accept "header" information that will permit repeated information to be automatically entered. This "header" would contain information consistent across several articles of food within the same submission, i.e., U.S. Customs entry. This will reduce the amount of data entry and potentially reduce typing and transcription errors. FDA plans to develop its Prior Notice System to allow submitters to automatically repeat information already entered in the submission where appropriate (e.g., all information is the same except for the identity of the article or the manufacturer).

FDA is proposing to require the following information in the prior notice identifying the following details for each article of food:

2. *The submitter.* FDA is proposing to require the identity of the submitter and the associated submitting firm. This information is needed so that FDA may communicate the adequacy or non-adequacy of the prior notice to the responsible party and to follow up when audits, inspections, or enforcement are necessary.

Generally, for all firms that the proposed rule requires to be identified in a prior notice (submitter, importer, owner, consignee, manufacturer, growers (if known), shipper), FDA is proposing that the prior notice include the firm's name, address, phone number, fax number, and e-mail address, and if the firm is required to register a facility associated with the article of food, the facility's registration number. The registration requirement is contained in a separate provision of the Bioterrorism Act (section 305). FDA believes that it needs identifying information in addition to the