

to get a hard copy printout of the prior notice submission and a confirmation for verification upon arrival of the article of food, if needed.

If the prior notice was submitted through the FDA PN System Interface, this confirmation number must accompany the article of food when it arrives at the port of arrival. For food arriving by international mail, the PN Confirmation Number received from the FDA PN System Interface must be entered on the "Customs Declaration—CN22 and CN23" supplied when the article is mailed. When food subject to this subpart is carried by or otherwise accompanies an individual, the individual must have the PN Confirmation Number, as well. The number will provide CBP and FDA personnel at the border with the means to connect to the results of the FDA review of the prior notice information.

Receipt of a PN Confirmation Number is evidence only that a prior notice has been received for FDA review. Should the FDA review process determine that an article of food should be inspected, personnel at the border will examine the food.

Prior Notice covering a refused food (no prior notice or inaccurate prior notice) must be submitted through the FDA PN System Interface. In addition to prior notice information, the FDA PN System Interface will be used to inform FDA of the port or secure storage location where refused food is or will be held.

## 12. FDA Review

The FDA prior notice review process will operate 7 days a week, 24 hours a day to review prior notice submissions transmitted through both ABI/ACS and the FDA PN System Interface. This process begins with an automated screening process. If additional evaluation of the prior notice information is necessary, FDA headquarters staff, operating 24 hours a day, 7 days a week, will review the information and may initiate an examination by FDA or CBP of the article of food at the port of arrival, or in the case of rail shipments, within the confines of the closest appropriate examination site. The review process is and manual review by FDA staff. It will be designed to identify food products that may pose serious risks to public health so that appropriate action can be taken upon arrival in the United States. The review process is not impacted by the method of electronic submission. The results of this process will be transmitted to CBP.

The existing OASIS screening and FDA staff review and examination

processes will determine admissibility under section 801(a) of the FD&C Act. Thus, food that has not been refused after review and/or examination of the prior notice information may be subject to further inspection and sampling at an inland destination for determination of admissibility under section 801(a) of the FD&C Act.

## 13. Summary of the Interim Final Rule

The interim final rule requires that prior notice be submitted electronically to FDA. All prior notice information must be submitted in the English language except an individual's name, the name of a company, and the name of a street may be submitted in a foreign language. All information, including these items, must be submitted using the Latin (Roman) alphabet. The prior notice may be submitted through ABI/ACS or the FDA PN System Interface at <http://www.access.fda.gov>. Prior notice must be submitted via the FDA PN System Interface for articles of food imported or offered for import by international mail or other transaction types that cannot be made through ABI/ACS and articles of food that have been refused under section 801(m)(1) of the FD&C Act.

The interim final rule, in § 1.279(b) through (d), also sets out how we will handle prior notice in four "down-time" situations: The customs broker's or self-filer's access to ABI/ACS is not working; the ABI/ACS interface is not working; the FDA PN System Interface is not working; and OASIS is not working. In all these situations, an alternative form of prior notice information is required. If access to ABI/ACS is not available or if the ABI/ACS interface is not working, prior notice must be submitted via the FDA PN System Interface. If FDA determines that FDA PN System Interface is not working, prior notice may be submitted manually by those who do not use ABI/ACS. If FDA determines that OASIS is not working, all prior notices must be submitted manually. FDA will issue notification through notices on the FDA Web site at <http://www.fda.gov>, at <http://www.access.fda.gov> and through messages in ABI/ACS. Once FDA issues this notification, prior notice information must be submitted to FDA by e-mail or by fax. Hand delivery of hard copy to FDA is not allowed. The location for receipt of submission by e-mail or fax is listed at <http://www.fda.gov>—see "prior notice."

*H. "What Information Must Be in a Prior Notice?" (§ 1.281 Proposed as § 1.288)*

Proposed § 1.288 listed the information that was to be included in

each prior notice. Part of the information was taken directly from section 801(m)(1) of the FD&C Act. The remainder of the list consisted of information that FDA and CBP have determined is necessary to ensure that we can enforce section 801(m) of the FD&C Act's prior notice requirements as intended by Congress. This additional information is thus authorized under section 701(b) of the FD&C Act (21 U.S.C. 371(b)). In the proposed rule, we explained why each of these items was necessary for the efficient enforcement of section 801(m) of the FD&C Act.

(Comments) Generally, comments assert that the proposed rule required too many data elements. Some comments state that the required information is more than that necessary to facilitate inspection; is burdensome on industry; and is more information than that authorized by the Bioterrorism Act, particularly with regard to product identity, port of entry, and identification of parties involved in prior notice. One comment argues that the prior notice was intended by Congress only to aid FDA in its efforts to ensure the security of the food supply, not to enhance compliance of imported food with all applicable FD&C Act requirements.

(Response) FDA agrees with many of these comments. Accordingly, the interim final rule will not require submission of the following information:

- Telephone and fax numbers and e-mail addresses for most firms;
- Registration numbers, except for the manufacturer and shipper, if otherwise required by section 801(l) of the FD&C Act;
- Entry line numbers;
- Brand or trade name;
- CBP port of entry;
- Anticipated date of entry for CBP purposes; and

- The identities of multiple carriers.

FDA has also revised the following information requirements to make them less burdensome:

- Quantity;
- Lot/code identifier;
- Manufacturer; and
- Grower.

Finally, FDA has added the following information requirements due to the changes in timeframe, the need to coordinate with CBP, and in response to comments:

- The mode of transportation; and
- Planned shipping information, including the 6-digit HTS code.

FDA does not agree that section 801(m) of the FD&C Act is limited to "food security." The purpose of the Bioterrorism Act is "[t]o improve the ability of the United States to prevent,