

reduced the timeframes for submitting prior notice in the interim final rule to the minimum amount of time that we need to meet our statutory responsibility to receive, review, and respond to prior notice submissions, the interim final rule does not provide for amendments or updates to the prior notice. However, as discussed in more detail in section D, FDA and CBP will be actively exploring ways to reduce prior notice timeframes, while fulfilling the Bioterrorism Act mandates.

*E. How Must You Submit Prior Notice? (Section 1.280 Proposed as § 1.287)*

FDA proposed that prior notice, amendments, and updates be submitted electronically to FDA through the FDA PN System. The interim final rule provides that prior notice must be submitted electronically, in English (except an individual's name, the name of a company, or the name of a street), through either CBP's ABI/ACS or the FDA PN System Interface. All information must be submitted using the Latin (Roman) alphabet. The interim final rule eliminates submission of duplicative information to FDA by those who can file import entry information through ABI/ACS. FDA and CBP are upgrading and interfacing their respective electronic systems so that information required for prior notice can be submitted through ABI/ACS. Information required by the interim final rule also can be submitted through the FDA PN System Interface. The interim final rule also provides that if a customs broker's or self-filer's system is not working or if ABI/ACS is not working, prior notice must be submitted through the FDA PN System Interface. If the FDA PN System Interface or OASIS is not operating, prior notice information must be submitted by e-mail, or by fax to the FDA, but not in person.

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

The interim final rule requires the following information to be submitted in the prior notice:

- Submitter (name of individual, individual's telephone, fax, e-mail, name/address of submitting firm);
- Transmitter, if different than submitter (name of individual, individual's telephone, fax, e-mail, name/address of transmitting firm);
- Entry type;
- CBP entry identifier, such as the CBP entry number or in-bond number;
- The identity of the article of food as follows: The complete FDA product code; the common or usual name or

market name; the estimated quantity described from largest container to the smallest package size; and the lot or code numbers or other identifier of the food if required by the FD&C Act or FDA regulations;

- Manufacturer, for food no longer in its natural state (name, address, registration number, except that the requirement to provide registration number does not apply to an article of food that is imported for transshipment or other export;
- Grower, if known, for an article of food that is in its natural state (name and growing location);
- Consolidator may voluntarily be provided by the submitter, at the submitter's option, if the grower is not known (name and address);
- FDA Country of Production;
- Shipper (name, address, registration number; except that the requirement to provide registration number does not apply to an article of food that is imported for transshipment or other export;
- The country from which the article is shipped;
- Anticipated arrival information (port of arrival and crossing location within that port, date, and time) or, if the food is imported by international mail, the anticipated date of mailing;
- The name and address of the importer, owner, and ultimate consignee, unless the shipment is imported or offered for import for transshipment through the United States under a T&E entry, or, if the food is imported by international mail, the U.S. recipient (name and address);
- Mode of transportation;
- Carrier (SCAC/Standard Carrier Abbreviated Code or IATA/International Air Transportation Association code or, if codes are not applicable, the name and country of the carrier) (except for food imported by international mail);
- Planned shipment information as applicable (except for food imported by international mail), including 6-digit HTS code; and
- If the article of food is under hold for failure to submit prior notice or submit an adequate prior notice, the location where it is being held, the date the article has arrived or will arrive at the location, and the name of a contact individual at the location.

FDA eliminated from the interim final rule telephone and fax numbers and e-mail addresses for most firms, entry line numbers, trade or brand name, and consumption entry information (port of entry/anticipated date of entry for Customs purposes). FDA revised information requirements regarding the quantity, lot/code identifier,

manufacturer, grower, and carrier in the interim final rule. FDA added mode of transportation and planned shipment information to the interim final rule. In the interim final rule, registration numbers are required only for manufacturer and shipper, if the shipper is a facility that is required to be registered under section 415 of the FD&C Act (21 U.S.C. 350d) and 21 CFR part 1, subpart H, for that article of food. For clarity, the interim final rule segregates the information required for food arriving by international mail (§ 1.281(b)) and also segregates the information required for food refused under section 801(m) of the FD&C Act (§ 1.281(c)).

Table 1A, which appears later in this preamble, describes the information required in prior notice.

*G. "What Must You Do If Information Changes After You Have Received Confirmation of a Prior Notice From FDA?" (Section 1.282 Proposed as §§ 1.289 to 1.294)*

This provision has been revised in the interim final rule. The proposed rule allowed one product identity amendment for certain product identity information that was not known at the time of submission and for arrival updates. Product identity amendments could be submitted up to 2 hours before arrival at the border. Arrival updates were required if the port of entry changed or if the time of arrival was expected to be more than 3 hours later or 1 hour earlier than the anticipated time of arrival.

The interim final rule does not provide for product identity amendments or arrival updates. Because we reduced the timeframes for submitting prior notice in the interim final rule to the least amount of time that we need to meet our statutory responsibility to receive, review, and respond to prior notice submissions, the interim final rule does not provide for amendments or updates. The interim final rule requires that if required information (except estimated quantity, anticipated arrival information including the anticipated date of mailing, and planned shipment information) changes after FDA has confirmed prior notice for review, the prior notice should be cancelled and a prior notice with the correct information must be submitted.

*H. "What Happens to Food That Is Imported or Offered for Import Without Adequate Prior Notice?" (Section 1.283 Proposed as § 1.278)*

FDA revised the proposed rule to provide for more specificity, to clarify