

prior notice has been submitted and has addressed this in § 1.287(a), which specifies when changes require resubmission to FDA. Most of this information is currently submitted to FDA by customs brokers or self-filers through ABI/ACS. The planned shipment information is necessary to ensure the effective enforcement of section 801(m) of the FD&C Act. FDA and CBP have determined that the planned shipment information includes submission of HTS code information. The HTS code is particularly critical for communication between FDA and CBP for shipments that are entered for transportation in-bond without appraisement under 19 U.S.C. 1552 or 1553, and identification of the HTS will assist CBP in the efficient processing of prior notice through ACS. CBP uses the HTS number in ACS to ensure that the required FDA information accompanies the entry or entry summary transmitted through ABI/ACS to OASIS. For prior notices submitted through the FDA PN System Interface, the HTS numbers are needed to ensure that the data collected from the Customs entry when it is transmitted through ABI/ACS can be matched to prior notice.

(Interim final rule) Section 1.281(a)(17) requires submission of the following planned shipment information, as applicable, based on the mode of transportation:

- Airway bill number(s) or bill of lading number(s) (not applicable to food carried by or otherwise accompanying an individual);
- For food arriving by ocean vessel, vessel name and voyage number;
- For food arriving by air carrier, flight number;
- For food arriving by truck, bus, or rail, trip number;
- For food arriving as containerized cargo by water, air, or land, container number(s);
- For food arriving by rail, car number (not applicable to food carried by or otherwise accompanying an individual);
- For food arriving by privately owned vehicle, the license plate number and state or province; and
- The 6-digit HTS code that is applicable to the article of food.

The interim final rule does not require that prior notice be cancelled and resubmitted if this information changes after FDA has confirmed the prior notice for review. A prior notice will not be inadequate if any of the planned shipment information changes between the confirmation of prior notice and the time of arrival.

20. International Mail (§ 1.281(b))

FDA did not propose separate information requirements for prior notice for food imported or offered for import by international mail.

(Comments) No comments were received on information requirements for food imported or offered for import by international mail.

(Response) For clarity and ease of reference, the interim final rule segregates the information required in prior notice submissions for food arriving by international mail. In addition, FDA has clarified the information required in three instances. FDA has replaced anticipated arrival information with planned date of mailing. FDA has determined that identification of the recipient of an article of food arriving by mail is necessary instead of the importer, owner, or consignee. Thus, the interim final rule requires the identification of the recipient by name and address for food arriving by international mail. Finally, we also have not included information identifying the mode of transportation, carrier, planned shipment information, and hold information, as this information is not relevant to mail imports.

(Interim final rule) See table 1A in section II.J of this document for the information requirements for food imported or offered for import by international mail.

21. Refused Food (§ 1.281(c))

FDA did not propose separate information requirements for prior notice for food refused because of inadequate prior notice. However, proposed § 1.288(d) required identification of the location where the food is being held after the food had been refused for inadequate prior notice. This information is necessary to ensure FDA can locate the food for inspection and to ensure compliance with the hold requirement.

(Comments) No comments were received on separate information requirements for food refused because of inadequate prior notice. However, comments ask for clarification that the hold location information is only necessary if the prior notice was absent or inadequate, e.g., the article of food has been refused under section 801(m) of the FD&C Act.

(Response) FDA agrees. For clarity and ease of reference, the interim final rule segregates the information required in prior notice submissions for food refused because of inadequate prior notice. Submission of the hold location information is not necessary for prior

notice submissions covering an article of food arriving by international mail.

(Interim final rule) See table 1A in section II.J of this document for the information requirements for food refused under section 801(m) of the FD&C Act.

(Summary of the interim final rule) Table 1A in section II.J of this document shows a summary of all information required by § 1.281(a), (b), and (c). For clarity, the table also identifies under what circumstances certain information is not required, e.g., registration numbers.

I. "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 through 1.294)

1. "What Changes Are Allowed to a Prior Notice After It Has Been Submitted to FDA?" (Proposed § 1.289)

FDA proposed to allow changes to certain information in the prior notice after a prior notice was submitted. FDA proposed to allow amendments to the product identity information when complete product identity did not exist by the deadline for the submission of a prior notice and updates to arrival information. The proposed rule also required that, if the identity of the grower was not known at the time of initial submission of the prior notice, but was known at the time of submission of amended or updated information, the identity of all known growers must be submitted. The proposed rule required that, in the event that other information in the prior notice changed, no amendment or update was permitted, and the prior notice must be cancelled and resubmitted.

(Comments) Comments ask FDA to be more flexible in allowing changes to prior notices. Some comments state that the time periods for prior notice and amendments and updates are not workable and should be made flexible. Comments note that requiring notice by noon of the day before the anticipated importation would cause an increased amount of amendments and updates.

Some comments note that the high degree of detail required in the prior notice will increase the need for amendments and that the likelihood of amendments will be more than FDA estimated. Some comments state that if the timeframe for submitting prior notice was changed, i.e., shortened to 4 hours for land and air and 8 hours for water, then amendments and updates would not be necessary.