

(1) The CBP Automated Broker Interface of the Automated Commercial System (ABI/ACS); or

(2) The FDA PN System Interface at <http://www.access.fda.gov>. You must submit prior notice through the FDA PN System Interface for articles of food imported or offered for import by international mail, 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 act and this subpart.

(b) If a custom broker's or self-filer's system is not working or if the ABI/ACS interface is not working, prior notice must be submitted through the FDA PN System Interface.

(c) If FDA determines that FDA PN System Interface is not working, FDA will issue notification at <http://www.access.fda.gov> or <http://www.cfsan.fda.gov/~furls/fisstat.html>, whichever FDA determines is available. Once FDA issues this notification, if you intended to use the FDA PN System Interface to submit a prior notice, you must submit prior notice information by e-mail or by fax to FDA. The location for receipt of submission by e-mail or fax will be listed at <http://www.access.fda.gov> or <http://www.cfsan.fda.gov/~furls/fisstat.html>, whichever FDA determines is available.

(d) If FDA determines that the Operational and Administration System for Import Support (OASIS) is not working, FDA will issue notification at <http://www.cfsan.fda.gov/~fulrs/fisstat.html>, on the FDA Web site at <http://www.fda.gov>, and through messages in ABI/ACS. Once FDA issues this notification, all prior notices must be submitted to FDA by e-mail or by fax. The location for receipt of submission by e-mail or fax will be listed at <http://www.access.fda.gov> or <http://www.cfsan.fda.gov/~furls/fisstat.html>, whichever FDA determines is available.

(e) Prior notice information will only be accepted at the listed e-mail or fax locations if FDA determines that the FDA PN System Interface or OASIS is not working.

[68 FR 59070, Oct. 10, 2003; 69 FR 4851, Feb. 2, 2003; 69 FR 8330, Feb. 24, 2004]

#### § 1.281 What information must be in a prior notice?

(a) *General.* For each article of food that is imported or offered for import into the United States, except by international mail, you must submit the information for the article that is required in this paragraph.

(1) The name of the individual submitting the prior notice and his/her business address, and phone number, fax number, and e-mail address, and the name and address of the submitting firm, if applicable. If a registration number is provided, city and country may be provided instead of the full address;

(2) If different from the submitter, the name of the individual and firm, if applicable, transmitting the prior notice on behalf of the submitter and his/her business address, and phone number, fax number, and e-mail address. If a registration number is provided, city and country may be provided instead of the full address;

(3) The entry type;

(4) The CBP entry identifier (*e.g.*, CBP entry number or in-bond number), if available;

(5) The identity of the article of food being imported or offered for import, as follows:

(i) The complete FDA product code;

(ii) The common or usual name or market name;

(iii) The estimated quantity of food that will be shipped, described from largest container to smallest package size; and

(iv) The lot or code numbers or other identifier of the food if required by the act or FDA regulations, *e.g.*, low acid canned foods, by 21 CFR 113.60(c); acidified foods, by 21 CFR 114.80(b); and infant formula, by 21 CFR 106.90;

(6) For an article of food that is no longer in its natural state, the name and address of the manufacturer and the registration number assigned to the facility that is associated with the article of food. A registration number is not required for a facility associated with an article of food if the article is imported or offered for import for transshipment, storage and export, or further manipulation and export. If the article of food is sent by an individual as a personal gift (*i.e.*, for nonbusiness

**§ 1.281**

**21 CFR Ch. I (4-1-04 Edition)**

reasons) to an individual in the United States, you may provide the name and address of the firm that appears on the label under 21 CFR 101.5 instead of the name, address, and registration number of the manufacturer. If a registration number is provided, city and country may be provided instead of the full address;

(7) For an article of food that is in its natural state, the name and growing location address of the grower, if known. If the submitter does not know the identity of the grower or, if the article has been consolidated and the submitter does not know the identity of any of the growers, you may provide the name and address of the firm that has consolidated the articles of food from different growers or different growing locations;

(8) The FDA Country of Production;

(9) The name and address of the shipper and, if the shipper is required to register under 21 CFR part 1, subpart H, the registration number assigned to the shipper's facility that is associated with the article of food. A registration number is not required for a facility associated with an article of food if the article is imported or offered for import for transshipment, storage and export, or further manipulation and export. If a registration number is provided, city and country may be provided instead of the full address;

(10) The country from which the article is shipped;

(11) Anticipated arrival information about the article of food being imported or offered for import, as follows:

(i) The anticipated port of arrival and, if the anticipated port of arrival has more than one border crossing, the specific anticipated border crossing where the food will be brought into the United States;

(ii) The anticipated date on which the article of food will arrive at the anticipated port of arrival; and

(iii) The anticipated time of that arrival;

(12) The name and address of the importer. If a registration number is provided, city and country may be provided instead of the full address. The identity of the importer is not required for an article of food that is imported or offered for import for transshipment

through the United States under a Transportation and Exportation entry;

(13) The name and address of the owner if different from the importer or ultimate consignee. If a registration number is provided, city and country may be provided instead of the full address. The identity of the owner is not required for an article of food that is imported or offered for import for transshipment through the United States under a Transportation and Exportation entry;

(14) The name and address of the ultimate consignee. If a registration number is provided, city and country may be provided instead of the full address. The identity of the ultimate consignee is not required for an article of food that is imported or offered for import for transshipment through the United States under a Transportation and Exportation entry;

(15) The mode of transportation;

(16) The Standard Carrier Abbreviation Code (SCAC) or International Air Transportation Association (IATA) code of the carrier which is, or will be, carrying the article of food from the country from which the article is shipped to the United States, or if codes are not applicable, then the name and country of the carrier;

(17) Planned shipment information, as applicable:

(i) The Airway Bill number(s) or Bill of Lading number(s). This information is not required for an article of food when carried by or otherwise accompanying an individual when entering the United States;

(ii) For food arriving by ocean vessel, the vessel name and voyage number;

(iii) For food arriving by air carrier, the flight number;

(iv) For food arriving by truck, bus, or rail, the trip number;

(v) For food arriving as containerized cargo by water, air, or land, the container number(s). This information is not required for an article of food when carried by or otherwise accompanying an individual when entering the United States;

(vi) For food arriving by rail, the car number. This information is not required for an article of food when carried by or otherwise accompanying an individual;

(vii) For food arriving by privately owned vehicle, the license plate number and State or province; and

(viii) The 6-digit Harmonized Tariff Schedule (HTS) code.

(b) *Articles arriving by international mail.* For each article of food that is imported or offered for import into the United States by international mail, you must submit the information for the article that is required in this paragraph.

(1) The name of the individual submitting the prior notice and his/her business address, and phone number, fax number, and e-mail address, and the name and address of the submitting firm, if applicable. If a registration number is provided, city and country may be provided instead of the full address;

(2) If different from the submitter, the name of the individual and firm, if applicable, transmitting the prior notice on behalf of the submitter and his/her business address and phone number, fax number, and e-mail address. If a registration number is provided, city and country may be provided instead of the full address;

(3) The entry type (which will be a mail entry);

(4) The identity of the article of food being imported or offered for import, as follows:

(i) The complete FDA product code;

(ii) The common or usual name or market name;

(iii) The estimated quantity of food that will be shipped, described from largest container to smallest package size; and

(iv) The lot or code numbers or other identifier of the food if required by the act or FDA regulations, *e.g.*, low acid canned foods, by 21 CFR 113.60(c); acidified foods, by 21 CFR 114.80(b); and infant formula, 21 CFR 106.90;

(5) For an article of food that is no longer in its natural state, the name and address of the manufacturer and the registration number assigned to the facility that is associated with the article of food. A registration number is not required for a facility associated with an article of food if the article is imported or offered for import for transshipment, storage and export, or further manipulation and export. 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, you may provide the name and address of the firm that appears on the label under 21 CFR 101.5 instead of the name, address, and registration number of the manufacturer. If a registration number is provided, city and country may be provided instead of the full address;

(6) For an article of food that is in its natural state, the name and growing location address of the grower, if known. If the submitter does not know the identity of the grower or, if the article has been consolidated and the submitter does not know the identity of any of the growers, you may provide the name and address of the firm that has consolidated the articles of food from different growers or different growing locations;

(7) The FDA Country of Production;

(8) The name and address of the shipper and, if the shipper is required to register under 21 CFR part 1, subpart H, the registration number assigned to the shipper's facility that is associated with the article of food. A registration number is not required for a facility associated with an article of food if the article is imported or offered for import for transshipment, storage and export, or further manipulation and export. If a registration number is provided, city and country may be provided instead of the full address;

(9) The country from which the article is shipped (*i.e.*, mailed);

(10) The anticipated date of mailing; and

(11) The name and address of the U.S. recipient.

(c) *Refused articles.* If the article of food has been refused under section 801(m)(1) of the act and this subpart, you must submit the information for the article that is required in this paragraph. However, if the refusal is based on § 1.283(a)(1)(iii) (Untimely Prior Notice), you do not have to re-submit any information previously submitted unless it has changed or the article has been exported and the original prior notice was submitted through ABI/ACS. If the refusal is based on § 1.283(a)(1)(ii), you should cancel the

## § 1.281

## 21 CFR Ch. I (4-1-04 Edition)

previous submission per § 1.282(b) and (c).

(1) The name of the individual submitting the prior notice and his/her business address, and phone number, fax number, and e-mail address, and the name and address of the submitting firm, if applicable. If a registration number is provided, city and country may be provided instead of the full address;

(2) If different from the submitter, the name of the individual and firm, if applicable, transmitting the prior notice on behalf of the submitter and his/her business address, and phone number, fax number, and e-mail address. If the registration number is provided, city and country may be provided instead of the full address;

(3) The entry type;

(4) The CBP entry identifier (*e.g.*, CBP entry number or in-bond number), if available;

(5) The identity of the article of food being imported or offered for import, as follows:

(i) The complete FDA product code;

(ii) The common or usual name or market name;

(iii) The quantity of food that was shipped, described from largest container to smallest package size; and

(iv) The lot or code numbers or other identifier of the food if required by the act or FDA regulations, *e.g.*, low acid canned foods, by 21 CFR 113.60(c); acidified foods, by 21 CFR 114.80(b); and infant formula, by 21 CFR 106.90;

(6) For an article of food that is no longer in its natural state, the name and address of the manufacturer and the registration number assigned to the facility that is associated with the article of food. A registration number is not required for a facility associated with an article of food if the article is imported or offered for import for transshipment, storage and export, or further manipulation and export. 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, you may provide the name and address of the firm that appears on the label under 21 CFR 101.5 instead of the name, address, and registration number of the manufacturer. If a registration number is provided, city and coun-

try may be provided instead of the full address;

(7) For an article of food that is in its natural state, the name and growing location address of the grower, if known. If the submitter does not know the identity of the grower or, if the article has been consolidated and the submitter does not know any of the growers, you may provide the name and address of the firm that has consolidated the articles of food from different growers or different growing locations;

(8) The FDA Country of Production;

(9) The name and address of the shipper and, if the shipper is required to register under 21 CFR part 1, subpart H, the registration number assigned to the shipper's facility that is associated with the article of food. A registration number is not required for a facility associated with an article of food if the article is imported or offered for import for transshipment, storage and export, or further manipulation and export. If a registration number is provided, city and country may be provided instead of the full address;

(10) The country from which the article is shipped;

(11) The port of arrival;

(12) The name and address of the importer. If a registration number is provided, city and country may be provided instead of the full address. The identity of the importer is not required for an article of food that is imported or offered for import for transshipment through the United States under a Transportation and Exportation entry;

(13) The name and address of the owner, if different from the importer or ultimate consignee. If a registration number is provided, city and country may be provided instead of the full address. The identity of the importer is not required for an article of food that is imported or offered for import for transshipment through the United States under a Transportation and Exportation entry;

(14) The name and address of the ultimate consignee. If a registration number is provided, city and country may be provided instead of the full address. The identity of the ultimate consignee is not required for an article of food that is imported or offered for import

## Food and Drug Administration, HHS

## § 1.283

for transshipment through the United States under a Transportation and Exportation entry;

(15) The mode of transportation;

(16) The Standard Carrier Abbreviation Code (SCAC) or International Air Transportation Association (IATA) code of the carrier which carried the article of food from the country from which the article is shipped to the United States, or if codes are not applicable, then the name and country of the carrier;

(17) Shipment information, as applicable:

(i) The Airway Bill number(s) or Bill of Lading number(s); however, this information is not required for an article of food when carried by or otherwise accompanying an individual when entering the United States;

(ii) For food that arrived by ocean vessel, the vessel name and voyage number;

(iii) For food that arrived by air carrier, the flight number;

(iv) For food that arrived by truck, bus, or rail, the trip number;

(v) For food that arrived as containerized cargo by water, air, or land, the container number(s); however, this information is not required for an article of food when carried by or otherwise accompanying an individual when entering the United States;

(vi) For food that arrived by rail, the car number; however, this information is not required for an article of food when carried by or otherwise accompanying an individual;

(vii) For food that arrived by privately owned vehicle, the license plate number and State or province;

(viii) The 6-digit HTS code; and

(18) The location and address where the article of refused food will be or is being held, the date the article has arrived or will arrive at that location, and identification of a contact at that location.

[68 FR 59070, Oct. 10, 2003; 69 FR 4851, Feb. 2, 2004]

### § 1.282 What must you do if information changes after you have received confirmation of a prior notice from FDA?

(a)(1) If any of the information required in § 1.281(a) except the information required in:

(i) § 1.281(a)(5)(iii) (quantity),

(ii) § 1.281(a)(11) (anticipated arrival information), or

(iii) § 1.281(a)(17) (planned shipment information) changes after you receive notice that FDA has confirmed your prior notice submission for review, you must resubmit prior notice in accordance with this subpart unless the article of food will not be offered for import or imported into the United States.

(2) If any of the information required in § 1.281(b), except the information required in § 1.281(b)(10) (the anticipated date of mailing), changes after you receive notice that FDA has confirmed your prior notice submission for review, you must resubmit prior notice in accordance with this subpart, unless the article of food will not be offered for import or imported into the United States.

(b) If you submitted the prior notice via the FDA PN System Interface, you should cancel the prior notice via the FDA PN System Interface.

(c) If you submitted the prior notice via ABI/ACS, you should cancel the prior notice via ACS by requesting that CBP delete the entry.

### CONSEQUENCES

### § 1.283 What happens to food that is imported or offered for import without adequate prior notice?

(a) For each article of food that is imported or offered for import into the United States, except for food arriving by international mail or food carried by or otherwise accompanying an individual, the consequences are:

(1) *Inadequate prior notice*—(i) *No prior notice*. If an article of food arrives at the port of arrival and no prior notice has been submitted and confirmed by FDA for review, the food is subject to refusal of admission under section 801(m)(1) of the act (21 U.S.C. 381(m)(1)). If an article of food is refused for lack of prior notice, unless CBP concurrence