

§ 1.278

sent by that individual as a personal gift (*i.e.*, for non-business reasons) to an individual in the United States;

(3) Food that is imported then exported without leaving the port of arrival until export;

(4) Meat food products that at the time of importation are subject to the exclusive jurisdiction of the U.S. Department of Agriculture (USDA) under the Federal Meat Inspection Act (21 U.S.C. 601 *et seq.*);

(5) Poultry products that at the time of importation are subject to the exclusive jurisdiction of USDA under the Poultry Products Inspection Act (21 U.S.C. 451 *et seq.*); and

(6) Egg products that at the time of importation are subject to the exclusive jurisdiction of USDA under the Egg Products Inspection Act (21 U.S.C. 1031 *et seq.*).

REQUIREMENTS TO SUBMIT PRIOR NOTICE OF IMPORTED FOOD

§ 1.278 Who is authorized to submit prior notice?

A prior notice for an article of food may be submitted by any person with knowledge of the required information. This person is the submitter. The submitter also may use another person to transmit the required information on his/her behalf. The person who transmits the information is the transmitter. The submitter and transmitter may be the same person.

§ 1.279 When must prior notice be submitted to FDA?

(a) Except as provided in paragraph (c) of this section, you must submit the prior notice to FDA and the prior notice submission must be confirmed by FDA for review as follows:

(1) If the article of food is arriving by land by road, no less than 2 hours before arriving at the port of arrival;

(2) If the article of food is arriving by land by rail, no less than 4 hours before arriving at the port of arrival;

(3) If the article of food is arriving by air, no less than 4 hours before arriving at the port of arrival; or

(4) If the article of food is arriving by water, no less than 8 hours before arriving at the port of arrival.

(b) Except in the case of an article of food imported or offered for import by

21 CFR Ch. I (4–1–04 Edition)

international mail, you may not submit prior notice more than 5 calendar days before the anticipated date of arrival of the food at the anticipated port of arrival.

(c) Notwithstanding paragraphs (a) and (b) of this section, if the article of food is arriving by international mail, you must submit the prior notice before the article of food is sent to the United States.

(d) FDA will notify you that your prior notice has been confirmed for review with a reply message that contains a Prior Notice (PN) Confirmation Number. Your prior notice will be considered submitted and the prior notice time will start when FDA has confirmed your prior notice for review.

(e) The PN Confirmation Number must accompany any article of food arriving by international mail. The PN Confirmation Number must appear on the Customs Declaration that accompanies the package.

(f) A copy of the confirmation, including the PN Confirmation Number, must accompany any article of food that is subject to this subpart when it is carried by or otherwise accompanies an individual when arriving in the United States. The copy of the confirmation must be provided to CBP or FDA upon arrival.

(g) The PN Confirmation Number must accompany any article of food for which the prior notice was submitted through the FDA Prior Notice System Interface (FDA PN System Interface) when the article arrives in the United States and must be provided to CBP or FDA upon arrival.

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

§ 1.280 How must you submit prior notice?

(a) You must submit the prior notice electronically to FDA. You must submit all prior notice information in the English language, except that 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. Unless paragraphs (c) and (d) of this section apply, you must submit prior notice through:

(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