

Food and Drug Administration, HHS

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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

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is obtained for export and the article is immediately exported from the port of arrival under CBP supervision, it must be held within the port of entry for the article unless directed by CBP or FDA.

(ii) *Inaccurate prior notice.* If prior notice has been submitted and confirmed by FDA for review, but upon review of the notice or examination of the article of food, the notice is determined to be inaccurate, the food is subject to refusal of admission under section 801(m)(1) of the act (21 U.S.C. 381(m)(1)). If the article of food is refused due to inaccurate prior notice, unless CBP concurrence is obtained for export and the article is immediately exported from the port of arrival under CBP supervision, it must be held within the port of entry for the article unless directed by CBP or FDA.

(iii) *Untimely prior notice.* If prior notice has been submitted and confirmed by FDA for review, but the full time that applies under § 1.279 of this subpart for prior notice has not elapsed when the article of food arrives, the food is subject to refusal of admission under section 801(m)(1) of the act (21 U.S.C. 381(m)(1)), unless FDA has already reviewed the prior notice, determined its response to the prior notice, and advised CBP of that response. If the article of food is refused due to untimely prior notice, unless CBP concurrence is obtained for export and the article is immediately exported from the port of arrival under CBP supervision, it must be held within the port of entry for the article unless directed by CBP or FDA.

(2) *Status and movement of refused food.* (i) An article of food that has been refused under section 801(m)(1) of the act and paragraph (a) of this section shall be considered general order merchandise as described in section 490 of the Tariff Act of 1930, as amended, 19 U.S.C. 1490.

(ii) Refused food must be moved under appropriate custodial bond. FDA must be notified of the location where the food has been or will be moved, within 24 hours of refusal. The refused food shall not be entered and shall not be delivered to any importer, owner, or ultimate consignee. The food must be taken directly to the designated location.

(3) *Segregation of refused foods.* If an article of food that is refused is part of a shipment that contains articles of food that have not been placed under hold, the refused article of food may be segregated from the rest of the shipment. This segregation must take place where the article is held. FDA or CBP may supervise segregation. If FDA or CBP determines that supervision is necessary, segregation must not take place without supervision.

(4) *Costs.* Neither FDA nor CBP are liable for transportation, storage, or other expenses resulting from refusal.

(5) *Export after refusal.* An article of food that has been refused under § 1.283(a) may be exported with CBP concurrence and under CBP supervision unless it is seized or administratively detained by FDA or CBP under other authority. If an article of food that has been refused admission under § 1.283(a) is exported, the prior notice should be cancelled within 5 business days of exportation.

(6) *No post-refusal submission or request for review.* If an article of food is refused under section 801(m)(1) and no prior notice is submitted or resubmitted, no request for FDA review is submitted in a timely fashion, or export has not occurred in accordance with paragraph (a)(5) of this section, the article of food shall be dealt with as set forth in CBP regulations relating to general order merchandise (19 CFR part 127), except that the article may only be sold for export or destroyed as agreed to by CBP and FDA.

(b) *Food carried by or otherwise accompanying an individual.* If food carried by or otherwise accompanying an individual arriving in the United States is not for personal use and does not have adequate prior notice or the individual cannot provide FDA or CBP with a copy of the PN confirmation, the food is subject to refusal of admission under section 801(m)(1) of the act. If before leaving the port, the individual does not arrange to have the food held at the port or exported, the article of food may be destroyed.

(c) *Post-Refusal Prior Notice Submissions.* (1) If an article of food is refused under § 1.283(a)(1)(i) (no prior notice)

and the food is not exported, prior notice must be submitted in accordance with §§ 1.280 and 1.281(c) of this subpart.

(2) If an article of food is refused under § 1.283(a)(1)(ii) (inaccurate prior notice) and the food is not exported, you should cancel the prior notice in accordance with § 1.282 and must resubmit prior notice in accordance with §§ 1.280 and 1.281(c).

(3) Once the prior notice has been submitted or resubmitted and confirmed by FDA for review, FDA will endeavor to review and respond to the prior notice submission within the timeframes set out in § 1.279.

(d) *FDA Review After Refusal.* (1) If an article of food has been refused admission under section 801(m)(1) of the act, a request may be submitted asking FDA to review whether the article is subject to the requirements of this subpart under § 1.276(b)(5) or § 1.277, or whether the information submitted in a prior notice is accurate. A request for review may not be used to submit prior notice or to resubmit an inaccurate prior notice.

(2) A request may be submitted only by the submitter, importer, owner, or ultimate consignee. A request must identify which one the requester is.

(3) A request must be submitted in writing to FDA and delivered by mail, express courier, fax, or e-mail. The location for receipt of a request is listed at <http://www.fda.gov>—see Prior Notice. A request must include all factual and legal information necessary for FDA to conduct its review. Only one request for review may be submitted for each refused article.

(4) The request must be submitted within 5 calendar days of the refusal. FDA will review and respond within 5 calendar days of receiving the request.

(5) If FDA determines that the article is not subject to the requirements of this subpart under § 1.276(b)(5) or § 1.277 or that the prior notice submission is accurate, it will notify the requester, the transmitter, and CBP that the food is no longer subject to refusal under section 801(m)(1) of the act.

(e) *International Mail.* If an article of food arrives by international mail with inadequate prior notice or the PN confirmation number is not affixed as required, the parcel will be held by CBP

for 72 hours for FDA inspection and disposition. If FDA refuses the article under section 801(m)(1) of the act and there is a return address, the parcel may be returned to sender stamped “No Prior Notice—FDA Refused.” If the article is refused and there is no return address or FDA determines that the article of food in the parcel appears to present a hazard, FDA may dispose of or destroy the parcel at its expense. If FDA does not respond within 72 hours of the CBP hold, CBP may return the parcel to the sender or, if there is no return address, destroy the parcel, at FDA expense.

(f) *Prohibitions on delivery and transfer.* (1) Notwithstanding section 801(b) of the act, an article of food refused under section 801(m)(1) of the act may not be delivered to the importer, owner, or ultimate consignee until prior notice is submitted to FDA in accordance with this subpart, FDA has examined the prior notice, FDA has determined that the prior notice is adequate, and FDA has notified CBP and the transmitter that the article of food is no longer refused admission under section 801(m)(1).

(2) During the time an article of food that has been refused under section 801(m)(1) of the act is held, the article may not be transferred by any person from the port or the secure facility until prior notice is submitted to FDA in accordance with this subpart, FDA has examined the prior notice, FDA has determined that the prior notice is adequate, and FDA has notified CBP and the transmitter that the article of food no longer is refused admission under section 801(m)(1). After this notification by FDA to CBP and transmitter, entry may be made in accordance with law and regulation.

(g) *Relationship to other admissibility decisions.* A determination that an article of food is no longer refused under section 801(m)(1) of the act is different than, and may come before, determinations of admissibility under other provisions of the act or other U.S. laws. A determination that an article of food is no longer refused under section 801(m)(1) does not mean that it will be

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granted admission under other provisions of the act or other U.S. laws.

[68 FR 59070, Oct. 10, 2003; 69 FR 4851, 4852, Feb. 2, 2004]

§ 1.284 What are the other consequences of failing to submit adequate prior notice or otherwise failing to comply with this subpart?

(a) The importing or offering for import into the United States of an article of food in violation of the requirements of section 801(m), including the requirements of this subpart, is a prohibited act under section 301(ee) of the act (21 U.S.C. 331(ee)).

(b) Section 301 of the act (21 U.S.C. 331) prohibits the doing of certain acts or causing such acts to be done.

(1) Under section 302 of the act (21 U.S.C. 332), the United States can bring a civil action in Federal court to enjoin persons who commit a prohibited act.

(2) Under section 303 of the act (21 U.S.C. 333), the United States can bring a criminal action in Federal court to prosecute persons who are responsible for the commission of a prohibited act.

(c) Under section 306 of the act (21 U.S.C. 335a), FDA can seek debarment of any person who has been convicted of a felony relating to importation of food into the United States or any person who has engaged in a pattern of importing or offering adulterated food that presents a threat of serious adverse health consequences or death to humans or animals.

[68 FR 59070, Oct. 10, 2003; 69 FR 4852, Feb. 2, 2004]

§ 1.285 What happens to food that is imported or offered for import from unregistered facilities that are required to register under 21 CFR part 1, subpart H?

(a) If an article of food from a foreign manufacturer that is not registered as required under section 415 of the act (21 U.S.C. 350d) and subpart H is imported or offered for import into the United States, the food is subject to refusal of admission under section 801(m)(1) of the act and § 1.283 for failure to provide adequate prior notice. The failure to provide the correct registration number of the foreign manufacturer, if registration is required under section 415

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of the act and 21 CFR part 1, subpart H, renders the identity of that facility incomplete for purposes of prior notice.

(b) Unless CBP concurrence is obtained for export and the article is immediately exported from the port of arrival, if an article of food is imported or offered for import from a foreign facility that is not registered as required under section 415 of the act and is placed under hold under section 801(l) of the act, it must be held within the port of entry for the article unless directed by CBP or FDA.

(c) *Status and movement of held food.*

(1) An article of food that has been placed under hold under section 801(l) of the act shall be considered general order merchandise as described in section 490 of the Tariff Act of 1930, as amended (19 U.S.C. 1490).

(2) Food under hold under section 801(l) must be moved under appropriate custodial bond. FDA must be notified of the location where the food has been or will be moved, within 24 hours of the hold. The food subject to hold shall not be entered and shall not be delivered to any importer, owner, or ultimate consignee. The food must be taken directly to the designated facility.

(d) *Segregation of held foods.* If an article of food that has been placed under hold under section 801(l) of the act is part of a shipment that contains articles that have not been placed under hold, the food under hold may be segregated from the rest of the shipment. This segregation must take place where the article is held, if different. FDA or CBP may supervise segregation. If FDA or CBP determine that supervision is necessary, segregation must not take place without supervision.

(e) *Costs.* Neither FDA nor CBP will be liable for transportation, storage, or other expenses resulting from any hold.

(f) *Export after hold.* An article of food that has been placed under hold under section 801(l) of the act may be exported with CBP concurrence and under CBP supervision unless it is seized or administratively detained by FDA or CBP under other authority.

(g) *No Registration or Request for Review.* If an article of food is placed under hold under section 801(l) of the act and no registration or request for