

article of food refused under § 801(m)(1) may not be delivered to the importer, owner, or ultimate consignee or transferred by any person from the port or 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 subject to refusal of admission under § 801(m)(1) of the FD&C Act. After this notification, entry may be made in accordance with law and regulation.

6. Relationship to Admissibility (§ 1.283(g))

The proposed rule (§ 1.278(f)) differentiated between a refusal of admission under section 801(m)(1) of the FD&C Act (prior notice) and refusal of admission under section 801(a) of the FD&C Act or other U.S. laws. The proposed rule clarified that a determination that an article of food is no longer subject to refusal of admission under section 801(m)(1) of the FD&C Act does not mean that it will be admitted to the United States under other provisions of the law that apply to admissibility determinations.

(Comments) One comment asks for clarification on whether a shipment will have to remain at the port and be subject to inspection until after FDA receives and reviews the entry documentation through OASIS. The comment points out that in most cases, OASIS review occurs after the goods have at least been conditionally released. Other comments state FDA should conduct its review under section 801(a) of the FD&C Act at the same time it is doing its prior notice review. Another comment asks what would happen if a prior notice was determined to be inadequate as part of FDA's review under section 801(a) of the FD&C Act.

(Response) Section 1.283(g) provides that FDA's determination that an article of food is no longer refused under section 801(m)(1) of the FD&C Act is different than, and may come before, determinations of admissibility under other provisions of the FD&C Act or other U.S. laws. As a general matter, FDA intends to use prior notice information to determine what products should be inspected upon arrival; we do not intend to make admissibility decisions under section 801(a) of the FD&C Act until entry has been made. The refusal under section 801(m)(1) of the FD&C Act will be removed after prior notice has been received, reviewed, and responded to by FDA, and there will be no further requirement to hold at the port for purposes of

section 801(m). As a general matter, at that point, the procedures under section 801(a) and (b) of the FD&C Act would apply. If FDA discovers that prior notice was inadequate after an article leaves the port of arrival but before it makes a decision to "may proceed" or release an article of food under section 801(a) of the FD&C Act, FDA may refuse the article under section 801(m)(1) and ask CBP to issue a notice of redelivery.

Interim Final Rule (§ 1.283)

FDA revised the proposed rule to provide for more specificity, clarify the status of refused food, and provide a mechanism for FDA review after refusal. In the interim final rule, FDA identifies the consequences and procedures for the following situations:

a. *Inadequate Prior Notice (No, inaccurate, or untimely prior notice) (§ 1.283(a)(1))*. The article is subject to refusal under section 801(m) and, if refused, unless immediately exported with CBP concurrence, must be held.

b. *Status and movement of refused food (§ 1.283(a)(2))*. A refused article of food shall not be delivered to the importer, owner, or ultimate consignee until FDA has examined the prior notice, determined the adequacy of the prior notice and notified the transmitter and CBP that the article of food covered by the prior notice is no longer refused. A refused food is considered general order merchandise under section 490 of the Tariff Act of 1939, as amended. The 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 food must be taken directly to the designated location, shall not be entered, and shall not be delivered to any importer, owner, or ultimate consignee.

c. *Segregation (§ 1.283(a)(3))*. If a refused food is part of a shipment that contains other articles, the refused food may be segregated from the rest of the shipment within the port of arrival or where it is held, if different. FDA or CBP may supervise the segregation.

d. *Costs (§ 1.283(a)(4))*. Neither FDA nor CBP will be liable for transportation, storage, or other expenses resulting from refusal.

e. *Post-refusal submissions and resubmissions (§ 1.283(c))*. If an article of food is refused for no or inaccurate prior notice, the prior notice must be submitted to and confirmed by FDA for review.

f. *Export after refusal (§ 1.283(a)(5))*. A refused food may be exported with CBP concurrence and supervision. If a refused food is exported, the prior

notice should be cancelled within 5 days of exportation.

g. *No post refusal submission or request for review (§ 1.283(a)(6))*. If no prior notice, correction, or request for FDA review is submitted in a timely fashion after an article of food is refused, the food will be dealt with as set forth in CBP regulations relating to general order merchandise. It may only be sold for export or destroyed as agreed to by CBP and FDA.

h. *International mail (§ 1.283(e))*. In the case of food arriving by international mail, if prior notice is inadequate, the article will be held by CBP for 72 hours for FDA inspection and disposition. If the article of food is refused and there is a return address, the parcel may be returned to sender. If there is no return address or the article of food in the parcel appears to present a hazard, FDA may dispose of or destroy it at FDA's expense. If FDA does not respond within 72 hours of the CBP hold, CBP will return the parcel back to the sender or, if there is no return address, may destroy the parcel at FDA's expense.

i. *Food carried by or otherwise accompanying an individual (§ 1.283(b))*. The individual must have a copy of the confirmation when entering the United States. If there is inadequate prior notice, the article will be refused entry and may be held at the port or exported. If arrangements for holding or export cannot be made, the food may be destroyed.

j. *FDA review after refusal (§ 1.283(d))*. After refusal, the submitter, importer, owner, or ultimate consignee may submit a written request asking FDA to review whether the article is subject to the requirements of this subpart under §§ 1.276(b)(5) and 1.277, or whether the prior notice submission is accurate. The interim final rule also sets out procedures and timeframes for this review process.

k. *Prohibition on delivery outside of the port (§ 1.283(f))*. A refused article of food may not be delivered to the importer, owner, or ultimate consignee until FDA has examined the prior notice, determined the adequacy of the prior notice and notified the transmitter and CBP that the article of food covered by the prior notice is no longer refused. When food that has been refused under section 801(m)(1) of the FD&C Act is held at the port or secure facility, it may not be transferred by any person from the port or 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