

the information changes after FDA has confirmed the prior notice for review.

In sum, FDA has removed from the interim final rule all proposed sections related to product identity amendments and arrival updates (proposed §§ 1.289 through 1.294) because of the following situations:

- The timeframes are shortened substantially;
- The timeframes provide us with very little leeway in the time we have to “receive, review and respond” to the prior notice submissions. Thus, we can no longer permit changes to prior notice without restarting the clock. FDA believes that the information required by the interim final rule for prior notice should be sufficiently fixed to be submitted within these new, shorter timeframes;
- FDA has revised the required information in the interim final rule, including the requirement to provide the estimated quantity;
- If the estimated quantity, the anticipated arrival information, or the planned shipment information change, the interim final rule does not require that the prior notice be resubmitted; and
- Under the interim final rule, prior notice can be submitted through ABI/ACS. The proposed provisions for amendments and updates to a submission through ABI/ACS are not feasible after the submissions have been electronically transmitted to OASIS and confirmed by FDA for review.

(Summary of the interim final rule) FDA has removed from the interim final rule all proposed sections related to product identity amendments and arrival updates (proposed §§ 1.289 through 1.294).

*J. “What Happens to Food That Is Imported or Offered for Import Without Adequate Prior Notice?” (Section 1.283) and “What are the Other Consequences of Failing to Submit Adequate Prior Notice or Otherwise Failing to Comply With This Subpart?” (§ 1.284 Proposed as § 1.278)*

**1. Inadequate Prior Notice (No Prior Notice, Inaccurate Prior Notice, or Untimely Prior Notice) (§ 1.283(a) Proposed as § 1.278(a))**

FDA proposed in § 1.278(a) that if an article of food is imported or offered for import with no prior notice or inadequate prior notice, the food shall be refused admission, as set out in under section 801(m)(1) of the FD&C Act. Proposed examples of inadequacy were untimely, inaccurate, or incomplete prior notice.

(Comments) Comments ask for clarification on what would cause a

prior notice to be incomplete or inadequate. Some comments express concern that clerical errors or failure to provide minor information or optional information could result in a refusal. Some comments suggest that inadequate prior notice should be confined to material omissions or major errors that would seriously impede the agency’s ability to review and appropriately respond to the notice. Comments ask whether they would be notified about such deficiencies and given a chance to correct them. Some comments object to not receiving feedback, before reaching the port, when the prior notice is inadequate.

(Response) A prior notice is not complete if the required information, as set forth in § 1.281, has not been provided. However, FDA agrees that feedback during the transmission process to reduce mistakes and omissions that could result in unnecessary holdups or refusals is a good idea. As explained earlier, both systems will review and validate required information to minimize the likelihood that clerical or typographical errors will result in an incomplete or inaccurate prior notice. The systems will tell transmitters which required information is still lacking or is recognized by the initial validation as facially incorrect, to allow transmitters to make corrections quickly. Moreover, the systems will not provide a confirmation until required information is complete and facially valid. Thus, if the initial incorrect information is not corrected and submitted, the transmitter will not receive a prior notice confirmation. FDA believes that this initial review/validation process will help ensure that transmitters will not make inadvertent errors that could result in a refusal. We advise, however, that this initial review/validation process will not be capable of identifying all possible errors. Thus, submitters and transmitters should understand that confirmation does not mean that FDA has determined that the prior notice is accurate in all respects.

If FDA determines that the prior notice is inaccurate after the systems provide a confirmation, the article of food is subject to refusal under § 1.283(a)(1)(ii). FDA has the option of issuing the refusal notice to the transmitter under § 1.283(a)(1)(ii) before arrival, assuming that FDA determines that the prior notice is inaccurate before arrival and before the time period for the prior notice has expired. If this happens, the transmitter must resubmit an accurate prior notice in accordance with § 1.282. This will remove the refusal, although it will “restart the

clock” in terms of when prior notice must be submitted to FDA. Until we have had some experience with prior notice review, we do not know how often we will be able to determine prior notice inaccuracy before food arrives. However, in certain situations, inaccuracy of prior notice cannot be determined until the article of food is examined upon arrival.

(Comments) Comments suggest the regulation provide a waiver or other mechanism to release foods that are safe, although the electronic paperwork is not complete. Comments also suggest that the regulation provide that, unless FDA has credible evidence or information that an article of food presents a threat of serious adverse health consequences or death to humans or animals, that FDA would not refuse the article if the prior notice is incomplete or inadequate.

(Response) FDA does not agree that the regulation should provide a waiver for refusal when some, but not all required, information has been submitted. Given that the purpose of prior notice is to provide FDA with better information sooner about food imports, including such a waiver in the rule would seem to be antithetical to the provision. The reference to the credible evidence standard in section 801(m) of the FD&C Act, which appears in the part of section 801(m) that deals with FDA review of prior notice after refusal, does not suggest otherwise. Section 801(m)(2)(B)(ii) of the FD&C Act states that, when FDA reviews a prior notice that has been submitted for a refused article of food, FDA “shall determine whether there is in the possession of [FDA] any credible evidence or information indicating that such article presents a threat of serious adverse health consequences or death to humans or animals.” FDA does not agree that this provision means that FDA should not refuse food with an inadequate prior notice under section 801(m)(1) of the FD&C Act when FDA has no such credible evidence or information. If that is what Congress intended, it would not have provided for refusal of an article of food without adequate prior notice, as it did in section 801(m)(1) of the FD&C Act.

(Comments) Comments note that the proposed rule did not set out procedures for notifications regarding refusals and holds. Comments ask who would be notified of refusal and when. Comments state that FDA should notify importers, purchasers, or manufacturers that an article is being held. One comment notes that carriers would have no way of determining if prior notice had been satisfied until they arrived at