

(Response) FDA agrees with the comments that state that if the deadline for submission of prior notice were reduced, amendments and updates would not be necessary. FDA has chosen timeframes that provide it with very little leeway in the time it has to "receive, review and respond" to the prior notice submissions. Thus, we concluded that we could no longer permit changes to prior notice without restarting the clock. In addition, the use of ABI/ACS precludes amendments and updates: changes to ABO/ACS submissions that have been electronically transmitted to FDA's OASIS and confirmed by FDA for review are not feasible because CBP also needs finality so it can complete its own screening of the entry. Therefore, the interim final rule does not allow for changes to a prior notice after the transmitter has been notified that FDA has confirmed the prior notice for review.

(Comments) One comment asks that FDA clearly define the circumstances under which updates and amendments to submissions of prior notice must be made. One comment asks FDA to clarify that a change in the anticipated arrival information is not the same as a product identity amendment and, therefore, is not subject to the same mandates as the procedure for changes in the product identity.

(Response) Because the interim final rule does not provide for amendments and updates, there is no need to address these comments asking for clarification.

(Comments) Some comments suggest that FDA allow amendments to all information in the prior notice. Some comments state that it is likely that companies filing numerous prior notices will inadvertently make clerical errors, such as telephone or fax numbers, Customs ACS entry line numbers, or Customs entry type. Others ask for clarification of any penalties associated with cancellation of a prior notice and resubmission of a correct notice.

(Response) FDA believes that the reduction of the deadline for submission of prior notice and the revisions to the information required have eliminated much of the need for amendments. FDA notes that transmitters should try to avoid clerical errors that could result in unnecessary rejections or refusals. To assist, FDA has designed the FDA PN System Interface to review presentation of some information before confirmation. The FDA PN System Interface will reject certain information if it is in the wrong format or does not match FDA's databases and the transmitter will be given an opportunity to make corrections during the

submission process, before notice of confirmation from FDA that the prior notice has been submitted for review. The interim final rule provides for no penalty if a prior notice is cancelled. If prior notice has been submitted and confirmed and the food is no longer imported or offered for import, the prior notice should be cancelled. However, if the article of food is still imported or offered for import into the United States, submission of a corrected and timely prior notice is necessary.

(Interim final rule) Section 1.282 of the interim final rule requires that if the information except estimated quantity, anticipated arrival information, and planned shipment information changes after the transmitter receives notice that FDA has confirmed the prior notice for review, the prior notice should be canceled. If the article of food is still intended for import or will be offered for import, the prior notice must be resubmitted in accordance with this subpart. If you submitted the prior notice via the FDA PN System Interface, you should cancel the prior notice via the FDA PN System Interface. If you submitted the prior notice via ACS, you should cancel the prior notice by requesting that CBP delete the line or entry. The "clock" restarts after the confirmation of the submission containing the corrected information.

2. "Under What Circumstances Must You Submit a Product Identity Amendment to Your Prior Notice After You Have Submitted It to FDA?" (Proposed § 1.290)

FDA proposed that product identity information required by proposed § 1.288(e)(1) may be amended if all of the information about the identity of the food did not exist by 12 noon of the calendar day before the day of arrival. The proposed rule also provided that the common or usual or trade name, brand name, lot or code or identification numbers, and quantity may be amended. FDA also clarified that a prior notice may not be amended to change completely the identity of the article, e.g., a prior notice identifying the food as lettuce may not be amended to identify the food as pears. The proposed rule provided that prior notice may be amended only once.

(Comments) Some comments suggest that FDA allow unlimited amendments to any information requirement at any time. Several comments express concern about the limitation of only one amendment. They explain if the process has to start over again because the information changes after submitting one amendment, there would be an additional 2-day delay before the

product is allowed to cross the border. Some comments indicate that more than one amendment might be needed to provide accurate information. Some comments indicate specific additional information for which amendments should be allowed, such as the carrier and consignee.

(Response) FDA has chosen timeframes that provide it with very little leeway in the time it has to "receive, review, and respond" to prior notice submissions. Thus, we concluded that we could no longer permit changes to prior notice without restarting the clock. However, the significant shortening in timeframes should address many of the concerns. In addition, the submission systems will allow for correction of errors revealed by the systems' initial validation. The interim final rule has thus eliminated the requirement for amendments.

(Comments) One comment asks FDA to create an exemption from quantity amendments for bulk shipments for which the actual quantity is within 10 percent of the proposed actual quantity. (Response) The interim final rule requires submission of the estimated quantity. This revision nullifies the need for amendment to the quantity description by allowing the submitter to estimate the amount of food that is expected to arrive. The interim final rule provides for no penalty if the quantity of an article of food imported or offered for import differs from the quantity estimated in a prior notice.

a. *Intention to amend.* The proposed rule required that the submitter must indicate his or her intention to amend the product identity information at the time the prior notice is submitted.

(Comments) One comment contends that, if certain elements are amendable, FDA should not need additional advance notice of that fact. Other comments ask FDA to eliminate the requirement for the submitter to anticipate the need for an amendment. Other comments ask for clarification on whether the intent to amend or update must be evident on the initial prior notice or if a product identity amendment or arrival update can be made anytime within the minimum 2-hour requirement.

(Response) The interim final rule eliminates the requirement for amendments and updates. Thus, comments on the proposed limitation are moot.

b. *Topping off.* FDA recognized that the limitation on amendments might affect the practice of "topping off a container" by filling unused space in the shipping container or truck bed with last-minute shipments of other food