

timeframes for issuing this interim final rule do not provide FDA adequate time to reconcile the different information required or to work with the other agencies to have them amend their existing requirements to capture all the information FDA needs. Merely obtaining existing information about the food from other agencies would not guarantee that FDA has the information required by section 801(m) of the FD&C Act's prior notice requirements because there is wide variation in the purposes and information required by other government programs. We would also need to work with other agencies to ensure the confidentiality of nonpublic prior notice information under relevant information disclosure laws, *e.g.*, 21 CFR 20.85 (Federal), 20.88 (State), and 20.89 (foreign). Because a purpose of providing prior notice to FDA is to assist FDA in responding to bioterrorism incidents or other food-related emergencies, FDA must have the required information readily accessible. If FDA has to coordinate with other agencies or governments to obtain from them the information necessary to respond to such an emergency, FDA may be prevented from responding to the emergency in a timely manner.

FDA notes that it is dedicated to increasing information-sharing capabilities with other agencies even after this interim rule is in effect, and we will continue to work with other government agencies to further streamline the prior notice process, consistent with our statutory obligations.

(Comments) Several comments suggest that exclusion for baggage in the proposed rule should be broadened in the final rule to include all food in baggage, even food that is not for the traveler's personal use. For example, one comment reasons that samples carried in the baggage of company representatives (or sent unaccompanied) generally do not enter commercial trade.

(Response) FDA disagrees. Except as already provided for, section 801(m) of the FD&C Act does not authorize an exclusion from prior notice for all food imported or offered for import into the United States in baggage. In the preamble to the proposed rule, we explained that the information that section 801(m)(1) of the FD&C Act requires in a prior notice, in conjunction with the purpose of the provision, demonstrates that Congress did not intend prior notice to apply to food that travelers bring into the United States in their personal baggage for personal use (*i.e.*, consumption by themselves, family or friends, not for sale or other distribution). We reasoned that when

travelers bring food back from their travels in their personal baggage for their own use, we do not believe that Congress intended for us to characterize such travelers as "shippers" for purposes of section 801(m) of the FD&C Act.

When food is not being carried by or otherwise accompanying an individual for his or her personal use, there is a "shipper"—the person or entity on whose behalf the traveler is bringing in the food. Thus, by its terms, section 801(m) of the FD&C Act requires that food carried by or otherwise accompanying an individual arriving in the United States that is not for personal use be subject to prior notice. In addition, were we to adopt such an exemption, it would create a potentially significant loophole, which could defeat the purpose of prior notice. For example, travelers coming from Latin America sometimes carry local soft cheeses for sale in the United States (Ref. 16). In fact, these travelers often are not staying in the United States for any period of time, but are merely transporting cheese to sell in the United States in their luggage or baggage. These cheeses have been tested by FDA and found positive for listeria, salmonella, and other pathogens associated with raw milk and insanitary conditions. Consumption of such contaminated cheese has been associated with illnesses and deaths. Another example is travelers arriving by automobile who carry cases of shellfish from unapproved foreign growing locations. These shellfish may be contaminated with a variety of illness-causing pathogens including vibrio cholerae or Norwalk virus. These shellfish are often not destined for personal consumption but for sale directly to the public or for consumption by the public at restaurants. Finally, trade samples are imported or offered for import to generate sales, which is a commercial, not personal, use. Thus, there is a "shipper" when these samples are brought to the United States.

FDA notes that it is changing the proposed rule by removing the term "baggage" and referring instead to food carried by or otherwise accompanying an individual. This change clarifies that the exclusion applies to food that might not be regarded as "baggage" but, nonetheless, accompanies the traveler. For example, food in the trunk of a car is not in baggage, but it accompanies the driver and any passengers.

(Comments) Comments ask that any food imported for personal use which arrives in the country by common carrier (*e.g.*, express carrier, truck, plane) should be treated the same as

food imported for personal use and carried with a traveler.

(Response) FDA disagrees. Section 801(m) of the FD&C Act does not authorize a broad exclusion from prior notice for all food imported or offered for import for personal use. In the preamble to the proposed rule, we explained that the information that section 801(m)(1) of the FD&C Act requires in a prior notice, in conjunction with the purpose of the provision, demonstrates that Congress did not intend prior notice to apply to food that travelers bring into the United States in their personal baggage for personal use (*i.e.*, consumption by themselves, family or friends, not for sale or other distribution). We reasoned that when travelers bring food back from their travels in their personal baggage for their own use, we do not believe that Congress intended to characterize such travelers as "shippers" for purposes of section 801(m) of the FD&C Act. However, when food is shipped by an individual or business in another country to a consumer in the United States for his or her personal use (or otherwise), there is a "shipper" as that term is used in section 801(m)(1) of the FD&C Act and defined in § 1.276(b)(10). Accordingly, there is no basis in section 801(m) of the FD&C Act for concluding that Congress did not intend prior notice to apply to articles sent (as opposed to carried) to the United States for the recipients' personal use.

(Comments) One comment asked that FDA address the issue of noncommercial family food shipments and to add these to the list of exemptions from prior notice. Another comment stated that a food shipment consisting of one noncommercial shipper sending food to another noncommercial recipient (*e.g.*, a friend abroad shipping cookies to a friend in the United States) should be outside the scope of the prior notice requirement.

(Response) FDA agrees in part and we have added a provision that excludes personal gifts of homemade food from prior notice. Although we believe that this food is imported into the United States, the information that § 801(m)(1) of the FD&C Act requires in a prior notice, in conjunction with the purpose of the provision, demonstrates that Congress did not intend prior notice to apply to homemade food sent as a personal gift by the maker to a recipient in the United States. In particular, under § 801(m)(1) of the FD&C Act, a prior notice must contain the identity of the manufacturer of the food. When an individual makes a food in their home as a gift for a relative or friend, we do not believe that Congress intended for