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Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002; Draft Compliance Policy Guide; “Sec. 110.310 Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002;” Availability; Final Rule and Notice

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1

[Docket No. FDA-2002-N-0233] (formerly Docket No. 2002N-0278)

RIN 0910-AC41

Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final regulation that requires the submission to FDA of prior notice of food, including animal feed, that is imported or offered for import into the United States. The final rule implements the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act), which required prior notification of imported food to begin on December 12, 2003. The final rule requires that the prior notice be submitted to FDA electronically via either the U.S. Customs and Border Protection (CBP or Customs) Automated Broker Interface (ABI) of the Automated Commercial System (ACS) or the FDA Prior Notice System Interface (FDA PNSI). The information must be submitted and confirmed electronically as facially complete by FDA for review no less than 8 hours (for food arriving by water), 4 hours (for food arriving by air or land/rail), and 2 hours (for food arriving by land/road) before the food arrives at the port of arrival. Food imported or offered for import without adequate prior notice is subject to refusal and, if refused, must be held. Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of a draft compliance policy guide (CPG) entitled "Sec. 110.310 Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002."

DATES: This rule is effective May 6, 2009.

FOR FURTHER INFORMATION CONTACT: Laura Draski, Office of Regulatory Affairs (HFC-100), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 866-521-2297.

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I. Background and Legal Authority

Section 307 of the Bioterrorism Act, which was enacted on June 12, 2002, amended the Federal Food, Drug, and Cosmetic Act (the act) (section 307 of the Bioterrorism Act added section 801(m) to the act (21 U.S.C. 381(m)) and amended section 301 of the act (21 U.S.C. 331)) by changing when FDA will receive certain information about imported foods by requiring the Secretary of Health and Human Services (the Secretary), after consultation with the Secretary of the Treasury,¹ to issue an implementing regulation by December 12, 2003, to require prior notification to FDA of food that is imported or offered for import into the United States. Beginning on December 12, 2003, food importers were required to provide FDA with advance notice of human and animal food shipments imported or offered for import.

FDA and CBP jointly published the proposed prior notice regulation in the **Federal Register** of February 3, 2003 (68 FR 5428), for comment (proposed rule). On October 10, 2003, FDA and CBP issued the prior notice interim final rule (IFR) (prior notice IFR) (68 FR 58974) (corrected by a technical amendment on February 2, 2004; 69 FR 4851). The IFR implemented section 307 of the Bioterrorism Act, and required that the prior notice be submitted to FDA electronically via either the CBP ABI/ACS or the FDA PNSI. The information must be submitted and confirmed electronically as facially complete by FDA for review no less than 8 hours (for food arriving by water), 4 hours (for food arriving by air or land via rail), and 2 hours (for food arriving by land via road) before the food arrives at the port of arrival. Food imported or offered for import without adequate prior notice is subject to refusal and, if refused, must be held. The IFR responded to comments from the public on the proposed rule, and established a 75-day comment period. In order to ensure that those commenting on the IFR had the benefit of FDA's outreach and educational efforts and had experience with the systems, timeframes, and data elements of the prior notice system, FDA reopened the comment period for

¹ Under the Homeland Security Act of 2002 (Public Law 107-296), the Secretary of the Treasury has delegated all relevant Customs revenue authorities to the Secretary of Homeland Security who has, in turn, delegated them to the Commissioner of the Bureau of Customs and Border Protection (CBP or Customs). Thus, the Secretary is issuing this final rule jointly with the Secretary of Homeland Security.

30 days on April 14, 2004 (69 FR 19763), and for an additional 60 days on May 18, 2004 (69 FR 28060), for a total of 165 days.

II. Summary of Significant Changes Made to the IFR

The highlights of how this final rule compares to the IFR and the rationale for certain changes are described briefly in the following paragraphs and are discussed in more detail later in the preamble.

A. What Definitions Apply to This Subpart? (§ 1.276)

We retain the following terms without change from the IFR:

- "The act;"
- "Calendar day;"
- "Country from which the article originates;"
- "FDA Country of Production;"
- "Grower;"
- "Port of entry;" and
- "United States."

FDA made the following changes in the final rule:

- We revised the term, "Country from which the article is shipped," to read, "* * * or, in the case of food sent by international mail, the country from which the article is mailed."
- We revised the term, "food," to add the phrase, "except as provided in paragraph (b)(5)(i) of this section," in the first sentence; and reworded § 1.276(b)(5)(i) to read, "For purposes of this subpart, food does not include".
- We added the term, "full address," to the final rule. *Full address* means the facility's street name and number; suite/unit number, as appropriate; city; Province or State as appropriate; mail code as appropriate; and country.
- We revised the term, "international mail," to make the sentence easier to read, and to add the phrase, "unless such service is operating under contract as an agent or extension of a foreign mail service," at the end of the definition.

• We added the term, "manufacturer," to the final rule. *Manufacturer* means the last facility, as that word is defined in § 1.227(b)(2), that manufactured/processed the food. A facility is considered the last facility even if the food undergoes further manufacturing/processing that consists of adding labeling or any similar activity of a *de minimis* nature. If the food undergoes further manufacturing/processing that exceeds an activity of a *de minimis* nature, then the subsequent facility that performed the additional manufacturing/processing is considered the manufacturer.

- We revised the term, "no longer in its natural state," by deleting "waxed"

from the list of actions that render an article of food still in its natural state for purposes of this subpart.

- We revised the term, “port of arrival” to read “* * * the water, air, or land port at which the article of food is imported or offered for import into the United States. For an article of food arriving by water or air, this is the port of unloading. For an article of food arriving by land, this is the port where the article of food first crosses the border into the United States. The port of arrival may be different than the port where consumption or warehouse entry or foreign trade zone admission documentation is presented to the U.S. Customs and Border Protection (CBP).”

- We revised the term, “registration number,” by changing the phrase, “refers to,” to “means,” and by adding the phrase, “to a facility,” after the word, “assigned,” to clarify that FDA assigns registration numbers by facility.

- We revised the term, “shipper,” by adding the phrase, “or express consignment operators or carriers or other private delivery service,” after “international mail” to clarify that a shipper is involved with various types of transactions, and not just international mail shipments.

- We revised the term, “you,” to simplify the last phrase of the definition to “i.e., the submitter or the transmitter, if any.”

B. What is the Scope of This Subpart? (§ 1.277)

We revised this provision and added “Articles of food subject to Art. 27(3) of The Vienna Convention on Diplomatic Relations (1961), i.e., shipped as baggage or cargo constituting the diplomatic bag” to the list of food that does not require prior notice.

C. Who is Authorized to Submit Prior Notice? (§ 1.278)

We retain this provision without change.

D. When Must Prior Notice Be Submitted to FDA? (§ 1.279)

FDA revised this provision. Section 1.279(b) of the IFR states that, except for international mail, prior notice may not be submitted more than 5 calendar days before the anticipated date of arrival at the anticipated port of arrival. We revised this section to permit prior notice submissions to be submitted no more than 15 calendar days before the anticipated date of arrival for submissions made through the PNSI and no more than 30 calendar days before the anticipated date of arrival for submission made through the ABI/ACS.

E. How Must You Submit Prior Notice? (§ 1.280)

FDA revised this provision. Under 21 CFR 1.280(a)(2) (§ 1.280(a)(2)) of the IFR, prior notice must be submitted via PNSI for articles of food that have been refused under section 801(m)(1) of the act. Under the final rule, prior notice for articles that have been refused under section 801(m) of the act must be submitted through PNSI until such time as ACS or its successor system can accommodate such transactions.

FDA also simplified the IFR provisions pertaining to system outages at § 1.280(b) through (e) by providing the outage notification at one Web address (<http://www.fda.gov>) and stating that FDA will accept prior notice submissions in the format it deems appropriate during the system(s) outage.

F. What Information Must Be in a Prior Notice? (§ 1.281)

FDA revised the following information requirements:

- **Submitter:** The IFR states that “if a registration number is provided, city and country may be provided instead of the full address.” For clarity, in the final rule, FDA has revised this phrase to state that “if the business address of the individual submitting the prior notice is a registered facility, then the facility’s registration number, city, and country may be provided instead of the facility’s full address.” FDA also deleted the requirement for providing the submitter’s fax number.

- **Transmitter:** The IFR states that “if a registration number is provided, city and country may be provided instead of the full address.” For clarity, in the final rule, FDA has revised this phrase to state that “if the business address of the individual submitting the prior notice is a registered facility, then the facility’s registration number, city, and country may be provided instead of the facility’s full address.” FDA also deleted the requirement for providing the transmitter’s fax number.

- **Manufacturer,** for food no longer in its natural state:

Under the IFR, the name, address, and registration number of the manufacturer must be submitted; if a registration number is provided, city and country may be provided instead of the full address. The final rule requires the name of the manufacturer and either: (1) The registration number, city and country of the manufacturer or (2) both the full address of the manufacturer and the reason the registration number is not provided. Publishing elsewhere in this issue of the **Federal Register**, the Prior Notice Final Rule Draft CPG lists the

reasons to use when the registration number is not provided.

In the IFR, a registration number is not required for a facility associated with an article of food if the article is imported or offered for import for transshipment, storage, and export, or further manipulation and export. We have removed this from the final rule and are requiring the registration number of the manufacturer (or the full address of the manufacturer and a reason) in all circumstances.

In the final rule, we have removed the option provided in the IFR that allows the label information in § 101.5 (21 CFR 101.5) to be submitted instead of the name, address, and registration number of the manufacturer for food sent by an individual as a personal gift (i.e., for nonbusiness reasons) to an individual in the United States. FDA notes, however, that under the enforcement policy proposed in the Prior Notice Final Rule Draft CPG, FDA and CBP should typically consider not taking any regulatory action when no prior notice is submitted for food imported or offered for import for noncommercial purposes with a noncommercial shipper, irrespective of the type of carrier.

- **Shipper:** The IFR required the name and address of the shipper and, if the shipper is required to register, the registration number assigned to the shipper’s facility; if a registration number is provided, city and country may be provided instead of the full address. The final rule requires the name and full address of the shipper, if the shipper is different from the manufacturer in order to eliminate duplicative requirements. If the address of the shipper is a registered facility, the submitter may submit the registration number of the shipper’s registered facility.

In the IFR, the shipper’s registration number was not required for a facility associated with an article of food if the article is imported or offered for import for transshipment, storage, and export, or further manipulation and export. We have removed this from the final rule because the shipper’s registration number is now optional.

- **Anticipated arrival information:** Under the final rule, we removed the requirement for the identity of the anticipated border crossing within the port of arrival because FDA and CBP have determined that it is no longer necessary for purposes of communication. For post-refusal submissions, actual date the article arrived is now a required data element so that FDA knows how long it has been since the refused food shipment arrived

in the United States and how to connect the refused prior notice to the post-refusal prior notice submission for shipments where a previously refused prior notice was filed.

The final rule also includes a new provision for food arriving by express consignment operator or carrier since certain information may not be available to persons who ship food using an express consignment operator or courier. If the article of food is arriving by express consignment operator or carrier, and neither the submitter nor transmitter is the express consignment operator or carrier, and the prior notice is submitted via PNSI, the express consignment operator or carrier tracking number may be submitted in lieu of the anticipated arrival information.

- The name and address of the importer, owner, and ultimate consignee: The IFR required the name and address of the importer, owner, and ultimate consignee, unless the shipment is imported or offered for import for transshipment through the United States under a Transportation and Exportation (T&E) entry. In the final rule, FDA is inserting the word “full” in front of “address” to make clear that the complete address is required.

Consequently, FDA is revising the subsequent text to state that if the business address of the importer, owner, or ultimate consignee is a registered facility, then the facility’s registration number also may be provided in addition to the facility’s full address.

- Planned shipment information: FDA revised this provision by clarifying that the required planned shipment information is applicable by mode of transportation and when it exists.

Moreover, FDA added a new provision in the final rule for the Airway Bill number/Bill of Lading number and flight number since this information is generally not available to individual submitters. The final rule provides that for food arriving by express consignment operator or carrier when neither the submitter nor transmitter is the express consignment operator or carrier, the tracking number can be submitted in lieu of the Bill of Lading or Airway Bill number and the flight number for prior notices submitted via PNSI.

FDA also revised the IFR by deleting the requirement to provide the Harmonized Tariff Schedule (HTS) code since FDA and CBP have determined that the HTS code is no longer critical for communication with CBP.

In the final rule, we deleted the requirement for the license plate number (and State or Province that issued the license) for food arriving by

privately owned vehicle from the planned shipment information and added this data element to the section identifying the carrier of the article of food (§ 1.281(a)(16) and (c)(16)).

Table 2, which appears later in this preamble, summarizes the information required in a prior notice.

G. What Must You Do If Information Changes After You Have Received Confirmation of a Prior Notice From FDA? (§ 1.282)

The IFR required that for prior notices submitted via ABI/ACS, the submitter should cancel the prior notice via ACS by requesting that CBP “delete” the entry. FDA has revised the final rule to state that the submitter should request that CBP “cancel” the entry. Moreover, we changed references to “PN System Interface” to “PNSI.”

H. What Happens to Food That Is Imported or Offered for Import Without Adequate Prior Notice? (§ 1.283)

The IFR stated that refused food must be moved under appropriate custodial bond. FDA has revised this paragraph in the final rule to state that the refused food must be moved under appropriate custodial bond unless immediately exported under CBP supervision. The final rule clarifies that the refused food may be held at the port or at a secure facility outside the port. FDA also changed the timeframe for notifying FDA of the hold location from within 24 hours of refusal to before the food is moved to the hold location. For clarity and consistency throughout the final rule, we are changing the phrase, “designated location,” to “designated secure facility.”

Under the section describing FDA review after refusal, FDA revised the final rule by including the carrier as one of the entities who can submit a request for FDA review. FDA also revised the final rule to delete acceptance of requests for review by mail and express courier. We are limiting delivery to fax and e-mail.

I. What Are the Other Consequences of Failing to Submit Adequate Prior Notice or Otherwise Failing to Comply With This Subpart? (§ 1.284)

We corrected the word “federal” in the IFR to read “Federal.” We also corrected the citation to “section 303 of the act” in the IFR to read “sections 301 and 303 of the act.”

J. What Happens to Food That Is Imported or Offered for Import From Unregistered Facilities That Are Required to Register Under Subpart H of This Part? (§ 1.285)

The final rule removes the provision in § 1.285(a) that if food is from a foreign manufacturer that is not registered as required and is imported or offered for import, it is subject to refusal of admission for failure to provide adequate prior notice. It also deletes the text in that provision that states that failure to provide the manufacturer’s registration number renders the identity of the facility incomplete for purposes of prior notice. The final rule retains, with revisions, the provision that states that if food is from a foreign facility that is not registered and is imported or offered for import, it is subject to being placed under hold under section 801(l) of the act.

III. Comments on the IFR

FDA received 320 timely submissions in response to the IFR. To make it easier to identify comments and FDA’s responses to the comments, the word “Comment” will appear in parentheses before the description of the comment, and the word “Response” will appear in parentheses before FDA’s response. A summary follows which includes a description of the appropriate section in the final rule.

A. General Comments

(Comments) Most comments generally support the intent of the Bioterrorism Act and FDA’s efforts to implement its provisions with the IFR. Some comments commend FDA for revising certain proposed requirements to address the needs of international trade by shortening timeframes, reducing the amount of information required to be submitted, and adding a reasonable amount of flexibility for the submission of prior notice based on the mode of transportation in the IFR. However, several comments assert that the agency has misinterpreted the Bioterrorism Act and some comments suggest that the final rule should be more consistent with the existing trade practices established in accordance with CBP.

(Response) FDA drafted the IFR in response to the comments to the proposed rule, the needs of international trade, and the continued threat of international terrorism and other significant risks to public health posed by imported food. We also drafted the final rule accordingly.

(Comments) Several comments support the graduated enforcement policy the agency used to implement the

IFR, noting that this policy facilitated the transition into compliance with the prior notice requirements. Comments ask that FDA provide a similar transition period after publication of the final rule during which time submitters may become familiar with new requirements, understand the new procedures and adjust business processes and practices.

(Response) After publication of the IFR, FDA published guidance that included a transition period during which we emphasized education to achieve compliance (the December 2003 Prior Notice Interim Final Rule CPG) (68 FR 69708, December 15, 2003). FDA agrees that implementing a graduated enforcement policy using enforcement discretion has assisted submitters to become accustomed to the new requirements. The new requirements of the final rule will not take effect until 180 days after publication. Since the final rule retains most of the requirements found in the IFR, and with the 180-day delay in effective date, we are not implementing a graduated enforcement policy for implementing the final rule.

FDA and CBP have issued elsewhere in this issue of the **Federal Register** a new CPG (hereinafter the Prior Notice Final Rule Draft CPG) that explains our proposed policies for enforcing violations of this final rule. The draft CPG describes the circumstances under which FDA and CBP should typically consider not taking any regulatory action, the types of violations FDA and CBP intend to focus on, and other enforcement policies.

(Comments) Several comments thank FDA for providing an opportunity to provide comments on the provisions of the IFR after a period of active FDA/CBP enforcement.

(Response) FDA agrees that providing several comment periods following publication of the IFR has permitted affected stakeholders an additional opportunity to offer specific and informed comments on the new requirements.

(Comments) One comment requests that FDA clarify that prior notices submitted to FDA will not be subject to public disclosure under the Freedom of Information Act (5 U.S.C. 552, *et seq.*) (FOIA) because information contained in a prior notice is confidential business information. Alternatively, the comment requests that FDA develop policies to protect confidential business information contained in prior notices from public disclosure.

(Response) FDA does not believe this is necessary. FDA already has relatively detailed regulations, in 21 CFR part 20,

governing the disclosure of information under FOIA, including the disclosure of confidential business information. Likewise, the agency's general policies, procedures, and practices relating to the protection of confidential information received from third parties apply to information received under prior notice. We do not believe rules, policies, or procedures specific to prior notice are needed.

(Comments) One comment states that during the period of enforcement discretion, various ports of arrival took different approaches to enforcement and suggests that FDA ensure that all ports and all officials act in a similar fashion to achieve a consistent enforcement posture. The comment also suggests that FDA and CBP conduct "cross-training" of their officials staffing FDA or CBP help desks.

(Response) All prior notice field operations and procedures are directed by the FDA Prior Notice Center (PNC). The PNC works to ensure a consistent implementation and enforcement program. Since the initial implementation of the prior notice rule, FDA staff has received additional training and guidance on prior notice requirements.

(Comments) Several comments acknowledge the efforts of CBP and FDA to work together to achieve the common goal of securing the imported food supply. In particular, comments congratulate FDA for coordinating with CBP to allow transmission of FDA-required information through the ABI to CBP's ACS. In addition, comments support the integration and cooperation of both agencies in utilizing CBP's targeting system to efficiently and rapidly spot anomalies in freight crossing our borders; reducing the FDA proposed timeframes for submission of prior notice in the advance electronic information requirements; and the commissioning of CBP staff to conduct examinations and investigations. One comment requests that CBP and FDA ensure that there are adequate resources at ports of arrival to mitigate anticipated delays at border crossings when the rule is enforced. Several comments anticipated that trade would collapse on December 12, 2003, when the new regulations took effect.

(Response) FDA and CBP are continuously coordinating efforts to receive, review, and respond to prior notice submissions. We further note that trade continued without significant interruption on December 12, 2003, or anytime after that implementation date. Rather, the implementation of the prior notice requirements was relatively smooth.

(Comments) Several comments acknowledge the importance and value of FDA's educational outreach efforts to the trade industry through scheduled outreach and education sessions, port-specific flyers, foreign government training and Web site communications, especially those that summarize certain compliance data. The comments also applaud the unprecedented efforts the FDA has made in this regard.

(Response) FDA and CBP will continue outreach and education efforts as resources permit. See section III.M entitled "Outreach and Enforcement" later in this document for further discussion on this subject.

(Comments) Several comments commend FDA for its efforts in developing the prior notice regulation in an efficient and effective manner, reaching out to affected stakeholders for input and comment, and acknowledge the tremendous effort put forth by the agency in the development of the regulation. Other comments state that the rule lacked real world international business input and will have both business and government unable to function because of the amount of paperwork generated, which will not stop a terrorist attack. In particular, one comment notes that tracing a grower of a particular shipment is impossible in many instances.

(Response) FDA and CBP systems have been able to manage the millions of prior notice submissions received, reviewed, and responded to since December 12, 2003. The agencies strove to implement the requirements in the Bioterrorism Act in a manner that required only that information deemed necessary and appropriate to ensure FDA could meet its statutory obligation to receive, review and respond to prior notices and target those shipments needing inspection upon arrival in the United States. Based on FDA's and CBP's experience since December 2003, the agencies have revised some of the requirements in the IFR and eliminated some of the information we no longer deem necessary (e.g., HTS codes). FDA notes that the grower of a food in its natural state is required only when known.

(Comments) One comment suggests that the prior notice IFR is "functionally redundant" because prior notice has long been a part of FDA protocol long before the Bioterrorism Act.

(Response) While FDA agrees that most of the information required by the IFR has been submitted to FDA via CBP processes for decades, the information has not been required prior to arrival of the food, making prior notice a new, unique, and valuable process.

(Comments) One comment suggests that the IFR was unduly costly, ill-considered and generally more harmful than useful. An additional comment believes that the prior notice requirements would restrict trade more than necessary and hopes that the United States will implement the Bioterrorism Act in the least trade-restrictive manner. Another comment states that despite efforts to comply with the new requirements, massive problems seem to constantly occur. Another comment complains about accessibility to the Web site, cost and time of the submission procedures, language barriers, and complexity of the information requested.

(Response) FDA disagrees. The prior notice process, which allows submission of the required information via either ABI/ACS or PNSI, has been relatively smooth. Although there were some technical problems encountered during the early implementation phase, FDA believes that the graduated enforcement process coupled with the vigorous education and outreach efforts by both the government and the industry have supported a relatively smooth transition to the new procedures and have improved compliance with the new requirements. FDA also has considered its international trade obligations under various World Trade Organization agreements, North America Free Trade Agreement, and other international agreements throughout the rulemaking development processes for both the IFR and this final rule. Both rules are consistent with our international obligations.

(Comments) Some comments believe there is a disincentive towards product diversification when exporting articles of food to the United States because the prior notice requirements put them at a competitive disadvantage compared to shipments that originate in the United States.

(Response) The requirement for prior notice was established by Congress with the passage of the Bioterrorism Act to improve the ability of the United States to prevent, prepare for, and respond to bioterrorism and other public health emergencies. Section 307 of the Bioterrorism Act requires prior notice of all food imported or offered for import into the United States. FDA is aware of the international trade obligations of the United States and has considered these obligations throughout the rulemaking process for this final rule and the IFR preceding it. Both are consistent with these international obligations. FDA and CBP have actively explored ways to reduce the burden on industry to the extent feasible while fulfilling the

Bioterrorism Act mandates.

Accordingly, we have made a number of changes in the final rule that minimize the impact of prior notice requirements on the food being imported or offered for import into the United States. We also note that the registration requirement applies to domestic facilities, as well as foreign facilities, and that the registration provisions in the Bioterrorism Act contain certain exclusions that apply only to foreign facilities. (See e.g., 21 CFR 1.226(a), which exempts from the requirement to register a foreign facility, if food from such facility undergoes further manufacturing/processing (including packaging) by another facility outside the United States; no similar exclusion applies to facilities within the United States.)

(Comments) Other comments suggest that the IFR failed to include a provision that would ensure that high risk imports arrive at ports staffed by FDA inspection personnel and notes that this could be accomplished by designating particular ports of entry for accepting high risk products or requiring importers of such products to provide longer notice to ensure adequate inspection coverage.

(Response) FDA disagrees. Section 307 of the Bioterrorism Act specifically prohibits FDA from limiting the port of entry by stating, "Nothing in this section may be construed as a limitation on the port of entry for an article of food." We also disagree that certain shipments require longer timeframes for submission of prior notice to ensure adequate inspection coverage. Under a Memorandum of Understanding (MOU) between FDA and CBP, published on January 7, 2004 (69 FR 924), FDA has commissioned thousands of CBP officers in ports and other locations to conduct, on FDA's behalf, investigations and examinations of imported foods. This helps ensure that there is adequate inspection coverage, including at ports where FDA does not currently have personnel.

B. Comments on the Legal Authority

(Comments) One comment requests that FDA delegate authority to the U.S. Department of Agriculture (USDA), as it has with CBP, to enable USDA to implement prior notice requirements on products where the USDA shares jurisdiction.

(Response) FDA disagrees. FDA has not delegated its authority under section 801(m) of the act to CBP, although FDA has commissioned CBP officers in ports and other locations to conduct, on FDA's behalf, investigations and examinations of imported foods. FDA recognizes that there are some products

over which both FDA and USDA have jurisdiction. For example, both FDA and USDA's Animal and Plant Health Inspection Service (APHIS) regulate the importation of fruits and vegetables into the United States, although the goal of APHIS' regulation is to safeguard U.S. agriculture and natural resources from the risks associated with the plant pests. Nonetheless, FDA does not believe that there is a need to have USDA implement the prior notice requirements for products for which we share jurisdiction, nor do we believe that doing so would lead to an efficient enforcement of the prior notice requirements. The Bioterrorism Act mandates that advance notice be given to FDA for any article of food that is being imported or offered for import into the United States and that the Secretary receive, review, and appropriately respond to such notifications. To accomplish this, FDA established the PNC that operates 24 hours a day, 7 days a week, to receive, review, and respond to these notices as they are submitted. The purpose of prior notice is to enable FDA to conduct inspections of imported foods at U.S. ports upon arrival and target foods that may pose a significant risk to public health, based on the information submitted.

Prior Notice is submitted electronically to FDA through either Customs' ABI/ACS or FDA's PNSI. Regardless of the mode of transmission, the prior notice information will undergo both a validation process and a screening in FDA's Operational and Administrative System for Import Support (OASIS) for food safety and security criteria. If the FDA system does not indicate that further evaluation or action on the notice or article of food is necessary for prior notice, the system will transmit a message through OASIS to the ABI/ACS interface for CBP that the article of food may be conditionally released. However, if additional evaluation of the prior notice information is necessary, personnel at the FDA's PNC will access the information provided and determine if that information suggests the potential for a significant risk to public health.

FDA personnel are able to make this determination by using their experience of imported foods, utilizing the expertise within the Center for Food Safety and Nutrition (CFSAN), the Center for Veterinary Medicine (CVM), the inspectional information obtained by the Office of Regulatory Affairs (ORA), and utilizing the expertise of CBP staff who are co-located with the PNC. If FDA determines that a potential health risk is present, FDA or CBP will

examine the food or take other appropriate action.

Evaluations of imported articles of food are made on an article-of-food by article-of-food basis. CBP and FDA are continuously working together to incorporate further intelligence gained from this process. The recent addition of USDA personnel to assist in the sharing of information affecting the safety and security of imported foods will help further this effort.

FDA does note that food items that are under the exclusive jurisdiction of the USDA are not subject to the requirements of prior notice. (See the discussion on § 1.277 (scope), discussed *infra*.)

(Comments) Another comment suggests that to be consistent with the Bioterrorism Act, FDA should permit an alternative to prior notice for administrative flexibility. The comments suggest that this could be accomplished by including in the final rule a provision which states, "Other measures as appropriate that provide an equivalent level of assurance of compliance with the requirements of this part."

(Response) FDA disagrees. Section 801(m) of the act requires the submission of prior notice for all food imported or offered for import into the United States, except as outlined in § 1.277(b). FDA is to use that information to determine whether it should inspect the food upon arrival in the United States. Compliance with prior notice, therefore, means providing the required information within the specified timeframes. No other "measures" would "provide an equivalent level of assurance of compliance" with the prior notice requirements.

C. What Definitions Apply to This Subpart? (§ 1.276)

Section 1.276 of the IFR provides definitions for the following terms: The act, calendar day, country from which the article originates, country from which the article is shipped, FDA Country of Production, food, grower, international mail, no longer in its natural state, port of arrival, port of entry, registration number, shipper, United States, and you. FDA received no comments on the definitions for the act, calendar day, country from which the article originates, FDA Country of Production, grower, and United States, and thus, the final rule retains the definitions for these terms that were in the IFR. Although no comments were received on the definitions for "country from which the article is shipped," "registration number," and "you," we

made minor revisions to these definitions. We also added a definition for the term, "full address," although we did not get any comments on this term.

1. The Act (§ 1.276(a))

The final rule defines "the act" to mean "the Federal Food, Drug, and Cosmetic Act."

2. Calendar Day (§ 1.276(b)(1))

The final rule defines "calendar day" to mean "every day shown on the calendar."

3. Country From Which the Article Originates (§ 1.276(b)(2))

The final rule defines "country from which the article originates" to mean "FDA Country of Production."

4. Country From Which the Article is Shipped (§ 1.276(b)(3))

The final rule defines "country from which the article is shipped" to mean "the country in which the article of food is loaded onto the conveyance that brings it to the United States or, in the case of food sent by international mail, the country from which the article is mailed." For clarity, we revised the last phrase of this definition to change, "the country in which the article will be mailed" to "the country from which the article is mailed."

5. FDA Country of Production (§ 1.276(b)(4))

The final rule defines "FDA Country of Production" to mean, for an article of food that is in its natural state, the country where the article of food was grown, including harvested or collected and readied for shipment to the United States. If an article of food is wild fish, including seafood that was caught or harvested outside the waters of the United States by a vessel that is not registered in the United States, the FDA Country of Production is the country in which the vessel is registered. If an article of food that is in its natural state was grown, including harvested or collected and readied for shipment, in a Territory, the FDA Country of Production is the United States. For an article of food that is no longer in its natural state, the country where the article was made; except that, if an article of food is made from wild fish, including seafood, aboard a vessel, the FDA Country of Production is the country in which the vessel is registered. If an article of food that is no longer in its natural state was made in a Territory, the FDA Country of Production is the United States.

6. Full Address (§ 1.276(b)(6))

The IFR did not have a definition for the term, "full address." However, we added this term to the final rule for clarity since this term is used throughout the rule. The final rule defines "full address" to mean "the facility's street name and number; suite/unit number, as appropriate; city; Province or State as appropriate; mail code as appropriate; and country."

7. Grower (§ 1.276(b)(7))

The final rule defines "grower" to mean "a person who engages in growing and harvesting or collecting crops (including botanicals), raising animals (including fish, which includes seafood), or both."

8. Registration Number (§ 1.276(b)(13))

The final rule defines "registration number" to mean "the registration number assigned to a facility by FDA under section 415 of the act (21 U.S.C. 350d) and subpart H of this part." FDA made a minor change in this definition in the final rule by adding the phrase "to a facility" after the word "assigned" to clarify that FDA assigns registration numbers by facility.

9. United States (§ 1.276(b)(15))

The final rule defines "United States" to mean "the Customs territory of the United States (i.e., the 50 States, the District of Columbia, and the Commonwealth of Puerto Rico), but not the Territories."

10. You (§ 1.276(b)(16))

The final rule defines "you" to mean "the person submitting the prior notice, i.e., the submitter or the transmitter, if any." We made a minor change to this definition by simplifying the last phrase of the definition to "i.e., the submitter or the transmitter, if any."

FDA received comments on the definitions for the following terms in the IFR: food, international mail, no longer in its natural state, port of arrival, and shipper. FDA also received comments that recommend that FDA include additional definitions for the following terms in the IFR: Carrier, manufacturer, trip number, and ultimate consignee. FDA responds to these comments in the following paragraphs.

11. Food (§ 1.276(b)(5))

The IFR defines "food" as having the meaning given in section 201(f) of the act, except that it does not include food contact substances as defined in section 409(h)(6) of the act (21 U.S.C. 348(h)(6)) or pesticides as defined in 7 U.S.C. 136(u). Examples of food include fruits, vegetables, fish, including seafood,

dairy products, eggs, raw agricultural commodities for use as food or as components of food, animal feed (including pet food), food and feed ingredients, food and feed additives, dietary supplements and dietary ingredients, infant formula, beverages (including alcoholic beverages and bottled water), live food animals, bakery goods, snack foods, candy, and canned foods.

(Comments) One comment asks FDA to define food contact substances, which are exempt from the requirements of prior notice, to include secondary direct food additives. The comment reasons that secondary direct food additives, many of which are food processing aids, meet the criteria for food contact substances as defined in section 409(h)(6) of the act (21 U.S.C. 348(h)(6)). The comment further reasons that secondary direct food additives meet the criteria that FDA used in the registration IFR to exclude food contact materials from the requirements of the registration IFR as they are not "food for consumption" in that "they are not intentionally eaten for their taste, aroma, or nutritive value" (68 FR 58894 at 58911).

(Response) Some secondary direct food additives meet the definition of food contact substances as given in section 409(h)(6) of the act and, therefore, would not be subject to the prior notice requirements (§ 1.276(b)(5)(i)(A)). The comment, however, asks about secondary direct food additives that are not food contact substances, for example food processing aids. The IFR concluded that food processing aids that are not food contact substances are subject to prior notice "Whether a food processing aid or 'indirect additive' is subject to prior notice depends upon whether such a substance is 'food' under this rule. As noted, for purposes of the interim final rule, 'food' excludes 'food contact substances' as defined at section 409(h)(6) of the FD&C Act. Among other things, unlike food processing aids and 'indirect additives,' 'food contact substances' are not 'intended to have any technical effect in food,' [section 409(h)(6) of the act]. In addition, 'food' excludes pesticides as defined at 7 U.S.C. 136(u). Thus, if the substance is not a pesticide and is intended to have a technical effect in the food being processed, the substance is not exempt from the definition of 'food' under § 1.276(b)(5) in the interim final rule. This is a reasonable result in that such processing aids are intentionally and directly added to 'traditional' foods." (68 FR 58974 at 58986). We continue to hold this view. Thus, if a secondary

direct food additive is not a food contact substance but is a food processing aid, then it would be subject to prior notice.

(Comments) Two comments ask the FDA to clarify the term, "reasonably expected to be directed to a food use." One comment states that seed produced by seed companies is intended to be used for planting crops, but the production process inevitably results in remnant or culled seed that is suitable for use as animal feed (and to a far lesser degree, as food for human consumption), which generally is sold by the seed company as such. The comment states that a similar issue arises with some crops, such as onions, for which bulbs sold to farmers may also be used as feed or, in limited cases, as food if they are determined to be remnant or culled. The comment believes that FDA should provide specific limitations on the definitions of "reasonably believes" and "reasonably expected" that take into consideration that the seed produced by seed companies is intended to be used for planting crops, even though it is understood that there inevitably will be some remnant seed and culls. Without such limitations, the comment believes the rule is unreasonably broad, imposes a burden on seed companies primarily marketing seeds for planting purposes that is out of proportion to the protective goals of the act, and is subject to widely varying interpretations. Another comment notes that the seed industry's research and development activities generate very small amounts of seed that may be found "unsuitable" for planting and end up in the food supply, and similarly asks for clarification of the "reasonably believes" and "reasonably expected" language.

(Response) In the preamble to the IFR, we state that "FDA will consider a product as one that will be used for food if any of the persons involved in importing or offering the product for import (e.g., submitter, transmitter, manufacturer, grower, shipper, importer, owner, or ultimate consignee) reasonably believes that the substance is reasonably expected to be directed to a food use" (68 FR 58974 at 58987). The purpose of this statement was to explain when an article of food would be subject to prior notice if it is capable of multiple uses. The comments, and our experience with the IFR, have shown that there is some confusion as to how to determine when a substance that is capable of a food use and a nonfood use is a "food" for purposes of prior notice. To clarify, we will consider such a substance to be "food" for the purpose of prior notice if it is reasonably likely

to be directed to a food use. This should make it clearer that, as explained in the preamble to the IFR, the determination is not based on the intended use of the article (68 FR 58974 at 58987).

In one of the comments, the seed will "inevitably" contain remnant seed and culls that will be diverted to human or animal feed. In this case, since at the time of import, the seed is reasonably likely to be directed to a food use, prior notice is required. FDA believes this is consistent with the purpose of the Bioterrorism Act. With respect to the other comment about seeds found "unsuitable" for planting, there is insufficient detail in the comment to determine whether these seeds would be considered food.

Nonetheless, we note that the Prior Notice Final Rule Draft CPG, announced elsewhere in this issue of the **Federal Register**, proposes an enforcement policy regarding seeds for planting. Under the draft policy, FDA and CBP would typically consider not taking any regulatory action regarding seeds that will be used for cultivation. The policy would apply when no more than a small portion of that seed is diverted from cultivation to animal feed or other food use. It would not apply, however, where the seed is used for the production of edible sprouts, such as alfalfa seeds for the production of alfalfa sprouts.

(Comments) One comment states that the Bioterrorism Act regulations do not present a means to provide FDA with certification that any of the indicated persons (i.e., submitter, transmitter, manufacturer, grower, shipper, importer, owner, or ultimate consignee) do not reasonably believe that an item is reasonably expected to be directed to a food use prior to arrival at a U.S. port. The comment further states that there is no method to avoid classifying their products as anything other than those flagged as FD4² articles requiring prior

² HTS codes are "flagged" in ACS as follows to indicate that products are or may be under FDA jurisdiction:

FD0—Indicates that FDA has determined the article, even though subject to FDA's laws and regulations, is acceptable for CBP release without further presentation of prior notice or other entry information to FDA.

FD1—Indicates that the article may be subject to FDA jurisdiction, including FDA review under 801(a) of the act. For products not subject to FDA jurisdiction, a filer can "Disclaim" product from FDA notification requirements.

FD2—Indicates that the article is under FDA jurisdiction and review of entry information by FDA under section 801(a) of the act will take place. However, the article is not "food" for which prior notice information is required.

FD3—Indicates that the article may be subject to prior notice under section 801(m) of the act and 21 CFR Part 1, subpart I, e.g., the article has both food and nonfood uses.

notice, thereby providing no means to avoid refusal of the goods upon arrival because the prior notice was not filed.

(Response) FDA disagrees. FDA is continuously reviewing the FD3 and FD4 flags associated with HTS codes. The HTS codes are flagged to indicate which products will (FD4) or may (FD3) require prior notice and which product will or may require FDA review under section 801(a) of the act for admissibility; all FDA-regulated products are covered, not just foods. If you believe that an item has been incorrectly flagged, you should contact the FDA and provide a statement that explains your rationale. The designation will be reviewed and action taken to correct the flag if deemed appropriate. With respect to the comment about providing certification about the belief of the "indicated persons," submitters may disclaim articles of food marked FD3 if the article is not reasonably likely to be directed to a food use by using an affirmation of compliance in ABI/ACS.

(Comments) Many comments address the FD flags associated with the HTS codes. Two comments state that they are currently importing a product that was flagged FD4, which requires that prior notice be submitted for that article. However, the item is not an article of food and the commenter would like the HTS code changed from a FD4 flag to a FD3 flag. An additional comment had concerns about multiple use products, where one use would require prior notice and another use would not. Another comment states that there is no clear methodology provided to disclaim an item beyond the initial FD3 designation. The comment recommends that the agency outline the elements of a due diligence protocol that would become part of the disclaimer process. One comment suggested that the data elements in the prior notice submission be amended to permit an affirmation that a substance is not directed for a food use. This would avoid the article of food from being refused if the prior notice was submitted for a category that required prior notice. Another comment wants FDA to develop a method that would allow the submitter or the transmitter to disclaim the need for prior notice at the time of the prior notice transmission.

(Response) If there is a concern regarding the FD flags associated with the HTS codes, you should contact FDA and provide a detailed description of why you believe the HTS code is flagged incorrectly. FDA and CBP are

continuously reviewing and updating the FD flags associated with the HTS codes. If you have questions regarding whether prior notice is required for a particular article of food, contact the PNC for assistance. Furthermore, we have established procedures in place to disclaim articles of food the submitter believes does not require prior notice. This can be accommodated by ABI/ACS as an affirmation of compliance.

(Comments) One comment states that the list of HTS codes flagged for prior notice (both FD3 and FD4) (as provided by Customs Admin message 03-2605 dated October 31, 2003) contains 762 tariff numbers. The comment asks if this is a definitive list at this point, especially since FDA and CBP estimated the number to be around 2,000.

(Response) This is not a definitive list. FDA and CBP are continuously reviewing and updating the FD flags associated with the HTS codes. Guidance regarding the HTS flags is posted at <http://www.cfsan.fda.gov/~dms/htsguid3.html>. The lack of an FD3 or FD4 designation does not mean that prior notice is not required. If the article of food fits the definition of food provided in § 1.276 of the final rule, then prior notice is required for that article of food.

(Final rule) Section 1.276(b)(5) of the final rule defines "food" as having the meaning given in section 201(f) of the act, except that it does not include food contact substances as defined in section 409(h)(6) of the act (21 U.S.C. 348(h)(6)) or pesticides as defined in 7 U.S.C. 136(u). Examples of food include fruits, vegetables, fish, including seafood, dairy products, eggs, raw agricultural commodities for use as food or as components of food, animal feed (including pet food), food and feed ingredients, food and feed additives, dietary supplements and dietary ingredients, infant formula, beverages (including alcoholic beverages and bottled water), live food animals, bakery goods, snack foods, candy, and canned foods.

We revised this definition for clarity in the final rule by adding the phrase, "except as provided in paragraph (b)(5)(i) of this section," in the first sentence; and reworded paragraph (b)(5)(i) to read, "For purposes of this subpart, food does not include:".

12. International Mail (§ 1.276(b)(8))

The IFR defines "international mail" to mean foreign national mail services. International mail does not include express carriers, express consignment operators, or other private delivery services."

(Comments) One comment asks FDA to define international mail to include express carriers. Another comment asks FDA to clarify whether sending an item by express delivery will be considered "international mail" or "express carrier."

(Response) FDA declines to make the requested change. The IFR defines "international mail" to mean "foreign national mail services" and expressly excluded express carriers, express consignment operators, or other private delivery services from the definition. We retain this definition in the final rule but revised the wording to make the definition easier to read, and to add the phrase, "unless such service is operating under contract as an agent or extension of a foreign mail service," at the end of the definition. This phrase was needed to clarify that a contractor working for a foreign mail service also is included in the definition of "international mail." International mail is a function of the foreign postal organizations of sovereign countries who are members of the International Postal Union. International mail shipments generally do not utilize any of the electronic data transmission systems commonly used by express consignment carriers and private delivery services.

(Final rule) Section 1.276(b)(8) of the final rule defines "international mail" to mean foreign national mail services. International mail does not include express consignment operators or carriers or other private delivery services unless such service is operating under contract as an agent or extension of a foreign mail service.

13. Manufacturer (§ 1.276(b)(9))

(Comments) Two comments request that we define the word "manufacturer." One of these suggests that we define "manufacturer" to mean the last entity to conduct a processing operation; e.g., including bottling but excluding labeling.

(Response/Final rule) As discussed in section III.H.7.a of this document, FDA agrees and has added a definition for manufacturer. Section 1.276(b)(9) of the final rule defines manufacturer as the last facility, as that word is defined in § 1.227(b)(2) (in the registration rule), that manufactured/processed the food. A facility is considered the last facility even if the food undergoes further manufacturing/processing that consists of adding labeling or any similar activity of a *de minimis* nature. If the food undergoes further manufacturing/processing that exceeds an activity of a *de minimis* nature, then the subsequent facility that performed the additional

FD4—Indicates that the article is "food" for which prior notice is required under section 801(m) of the act and 21 CFR Part 1, subpart I.

manufacturing/processing is considered the manufacturer.

14. No Longer in Its Natural State (§ 1.276(b)(10))

The IFR defines “no longer in its natural state” to mean that “an article of food has been made from one or more ingredients or synthesized, prepared, treated, modified, or manipulated. Examples of activities that render food no longer in its natural state are cutting, peeling, trimming, washing, waxing, eviscerating, rendering, cooking, baking, freezing, cooling, pasteurizing, homogenizing, mixing, formulating, bottling, milling, grinding, extracting juice, distilling, labeling, or packaging. Crops that have been cleaned (e.g., dusted, washed), trimmed, or cooled attendant to harvest or collection or treated against pests, waxed, or polished are still in their natural state for purposes of this subpart. Whole fish headed, eviscerated, or frozen attendant to harvest are still in their natural state for purposes of this subpart.”

(Comments) One comment asks FDA to clarify the term, “no longer in its natural state” by expressly stating that seed for sowing or planting that are shucked, sorted and sized remain “in their natural state” for purposes of prior notice. Another comment believes that activities such as trimming, washing, waxing, and packaging of produce are part of normal harvesting activities and seeks to clarify that produce that has been trimmed, washed, waxed, and/or packaged is still “in its natural state.”

(Response) The IFR defines “no longer in its natural state” as meaning “an article of food has been made from one or more ingredients or synthesized, prepared, treated, modified, or manipulated. Examples of activities that render food no longer in its natural state are cutting, peeling, trimming, washing, waxing, eviscerating, rendering, cooking, baking, freezing, cooling, pasteurizing, homogenizing, mixing, formulating, bottling, milling, grinding, extracting juice, distilling, labeling, or packaging. Crops that have been cleaned (e.g., dusted, washed), trimmed, or cooled attendant to harvest or collection or treated against pests, waxed, or polished are still in their natural state for purposes of this subpart. Whole fish headed, eviscerated, or frozen attendant to harvest are still in their natural state for purposes of this subpart.” In the final rule, we are deleting the word “waxed” in the list of activities that render the food still in their natural state because this was included in error.

After publishing the prior notice IFR, FDA issued guidance in the form of questions and answers to help clarify

the prior notice requirements. In the second edition of “Questions and Answers Regarding the Interim Final Rule on Prior Notice of Imported Food (Edition 2)” (the prior notice question and answer guidance document) available at <http://www.cfsan.fda.gov/~pn/pnqagui2.html>, issued May 2004, under section B, Definitions, question 4.1 of the guidance, we discuss seeds. If the seed will be used only for sowing or planting, and not directed to food use, then no prior notice is required and, therefore, there is no need to determine whether the seeds are in their natural state for the purposes of prior notice.

Regarding the other comments, the definition for “no longer in its natural state” in the final rule already states that trimmed or washed produce is still in its natural state, if those activities are attendant to harvest or collection. This same definition states that waxing and packaging are activities that render food no longer in its natural state.

(Final Rule) Section 1.276(b)(10) of the final rule defines “no longer in its natural state” to mean that “an article of food has been made from one or more ingredients or synthesized, prepared, treated, modified, or manipulated.

Examples of activities that render food no longer in its natural state are cutting, peeling, trimming, washing, waxing, eviscerating, rendering, cooking, baking, freezing, cooling, pasteurizing, homogenizing, mixing, formulating, bottling, milling, grinding, extracting juice, distilling, labeling, or packaging. Crops that have been cleaned (e.g., dusted, washed), trimmed, or cooled attendant to harvest or collection or treated against pests, or polished or packaged are still in their natural state for purposes of this subpart. Whole fish headed, eviscerated, or frozen attendant to harvest are still in their natural state for purposes of this subpart.”

15. Port of Arrival (§ 1.276(b)(11))

The IFR defines “port of arrival” to mean “the water, air, or land port at which the article of food is imported or offered for import into the United States, i.e., the port where the article of food first arrives in the United States. This port may be different than the port where consumption or warehouse entry or foreign trade zone admission documentation is presented to the U.S. Customs and Border Protection (CBP).”

(Comments) Two comments ask FDA to clarify what is meant by the term, “port of arrival.” One comment notes that notwithstanding the definition in the IFR, FDA representatives have stated that “port of arrival” means the first port where the articles of food are “off-loaded” and that if the articles remain

on the vehicle or vessel, then the port of arrival definition has not been met for these and only these articles. Another comment reports being told by FDA representatives that when a ship arrives from Europe, only goods “off loaded” in that port must be given prior notice within the timeframes required. If the ship has food destined to be “off loaded” in other ports, prior notice must be filed for each port in accordance with the timeframes required by the regulations. The comments ask FDA to clarify this definition.

(Response) FDA agrees to clarify the term, “port of arrival,” as it is a required data element in a prior notice and important for gauging the timeframes for prior notice submission. The interim final rule defined “port of arrival” as “the water, air, or land port at which the article of food is imported or offered for import into the United States, i.e., the port where the article of food first arrives in the United States.” In essence, the comments ask us to identify the point at which an article of food “first arrives” in the United States when the food is arriving by water.

The preambles to the proposed rule and IFR explained that for FDA to be able to protect U.S. consumers from terrorism or other food-related emergencies, it was important for FDA to receive prior notice before the food covered by that notice is shipped around the country and potentially lost to government oversight (68 FR 5428 at 5431 and 68 FR 58974 at 58991). The preambles concluded that prior notice must be given before the food first physically appears in the United States so that FDA can inspect the food upon arrival.

As noted in the comments, some shipments contain both food and nonfood cargo. If the carrier stops at multiple ports, the articles of food may remain on board at intermediate ports where nonfood articles are unloaded. The articles of food are then unloaded at one or more subsequent ports. When food is shipped via water and FDA has bioterrorism or other public health emergency concerns about the food, it would inspect the food at the point of unloading. This is because before the food is unloaded it would remain on the carrier either at a secured port under CBP authority or in open water, preventing intentional or unintentional diversion until unloading. The same is true for food shipped by air. When an article of food remains on board at one airport to be unloaded at a subsequent airport, FDA would not need to examine the food until the point where that food is unloaded. In contrast, when food is shipped via land, any articles of food

remaining on board would travel through the United States while outside of secured ports and, therefore, could be potentially lost to government oversight due to off-loading in noncontrolled areas.

Therefore, we believe that when an article of food is shipped via water or air, the article "first arrives" at the port where it is unloaded. When an article of food is shipped via land, the article "first arrives" at the port where it crosses the border. We are revising the definition of "port of arrival" in the final rule to clarify this distinction. We have added a statement that for an article of food arriving by water or air, the port of arrival is the port of unloading. For an article of food arriving by land, the definition now states that the port of arrival is the port where the article of food first crosses the border into the United States.

(Comments) One comment asks FDA to clarify the word "port." The comment asks whether the IFR applies to U.S. Navy ships returning to "port" or to a U.S. Naval Base from outside U.S. territorial waters. The comment notes that U.S. Navy fleet ships always have been considered U.S. territory. The comment also notes that the CPG states that food entering and then leaving the "port area" is not subject to prior notice and asks FDA to clarify the term, "port area."

(Response) FDA clarifies that the term, "port," is not defined but that "port of arrival" and "port of entry" are defined. The term, "port," as used in the rule relates to ports identified by CBP. In 19 CFR 101.1 *Definitions*, "Port and port of entry refer to any place designated by Executive Order of the President, by order of the Secretary of the Treasury, or by Act of Congress, at which a Customs officer is authorized to accept entries of merchandise to collect duties, and to enforce the various provisions of the Customs and navigation laws. The terms 'port' and 'port of entry' incorporate the geographical area under the jurisdiction of a port director." If CBP changes this definition in the future, we will evaluate whether § 1.276(b)(12) should be revised to incorporate those changes. Proposed policies in the Prior Notice Final Rule Draft CPG, would apply to most articles of food on U.S. Navy ships returning to "port" or a U.S. Naval Base from outside U.S. territorial waters. One policy states that FDA and CBP should typically consider not taking any regulatory action when an article of food is imported or offered for import for an official government purpose without prior notice, provided that a Federal Government agency is the importer of

record. Another states that FDA and CBP should typically consider not taking any regulatory action when an article of food is imported or offered for import for noncommercial purposes with a noncommercial shipper without prior notice. One of the examples of foods imported or offered for import that may be covered by this policy is food in household goods, including military transfers.

(Final rule) Section 1.276 (b)(11) of the final rule defines "port of arrival" as "the water, air, or land port at which the article of food is imported or offered for import into the United States. For an article of food arriving by water or air, this is the port of unloading. For an article of food arriving by land, this is the port where the article of food first crosses the border into the United States. The port of arrival may be different than the port where consumption or warehouse entry or foreign trade zone admission documentation is presented to the U.S. Customs and Border Protection (CBP)."

16. Shipper (§ 1.276(b)(14))

The IFR defines "shipper" to mean "the owner or exporter of the article of food who consigns and ships the article from a foreign country or the person who sends an article of food by international mail to the United States."

(Comments) Two comments request that we clarify the IFR's definition of "shipper." One comment asks whether the shipper is the person who physically loads the shipment for its final journey to the United States, the company that has the business contract to export the food to the U.S. importer, or someone in the middle who removes the shipment from temporary storage for the initial phase of its entire journey to the United States. Another comment asks for clarification as to who is the shipper when the producer's shipping platform is involved in the shipment—the transporter who takes responsibility for the whole shipment or the producer's own facility (assuming that neither would be classified as "manufacturer")?

(Response) In the IFR, we defined "shipper" based upon the description of shipper as it is discussed in CBP's proposed rule "Required Advance Electronic Presentation of Cargo Information" (July 23, 2003, 68 FR 43574 at 43577). We have decided to continue to use this definition in the final rule. In the examples cited in the comments above, the shipper is considered to be the entity that arranges or directs the shipment to be sent to the United States, irrespective of who physically transports it. In the first

example it would be the company having the business contract to export the food; in the second, assuming that the producer is sending the food to a firm in the United States, they (the producer) would be the shipper. It should also be noted that a firm may be both a shipper and a manufacturer with respect to the same product if the product is shipped from the point of manufacture to the United States. Moreover, we have added the phrase, "or express consignment operators or carriers or other private delivery service," after the term, "international mail," in the definition of "shipper" to clarify that a shipper is involved with various types of transactions, and not just international mail shipments.

(Final rule) Section 1.276(b)(14) of the final rule defines shipper to mean "the owner or exporter of the article of food who consigns and ships the article from a foreign country or the person who sends an article of food by international mail or express consignment operators or carriers or other private delivery service to the United States."

17. Comments Requesting Additional Definitions

(Comments) Several comments request that we define additional terms in the final rule, including: "trip number," "carrier," and "ultimate consignee."

(Response) FDA disagrees. FDA believes these terms are sufficiently clear based on our experience since the initial implementation of the prior notice IFR. FDA intends to interpret the "ultimate consignee" consistent with CBP's use of that term in regards to the entry of merchandise, which is contained in paragraph 6.3 of Customs Directive No. 3550-079A, June 27, 2001. As stated in that CBP Directive, "if the merchandise has not been sold or consigned to a U.S. party at the time of entry or release, then the Ultimate Consignee at the time of entry or release is defined as the proprietor of the U.S. premises to which the merchandise is to be delivered."

18. Summary of the Final Rule

Section 1.276 of the final rule defines the following terms: The act, calendar day, country from which the article originates, country from which the article is shipped, FDA Country of Production, food, full address, grower, international mail, manufacturer, no longer in its natural state, port of arrival, port of entry, registration number, shipper, United States, and you.

D. What is the Scope of this Subpart?
(§ 1.277)

Section 1.277(a) of the IFR states that the prior notice requirements apply to all food for humans and other animals that is imported or offered for import into the United States. This covers food for use, storage, or distribution in the United States, and includes food for gifts, trade and quality assurance/quality control samples, food for transshipment through the United States to another country, food for future export, and food for use in a U.S. Foreign Trade Zone (FTZ).

Section 1.277(b) of the IFR sets out the exclusions from prior notice. It excludes food for an individual's personal use when it is carried by or otherwise accompanies the individual when arriving in the United States (i.e., for consumption by themselves, family and friends, not for sale or other distribution); food that was made by an individual in his/her personal residence and sent by that individual as a personal gift (i.e., for nonbusiness reasons) to an individual in the United States; food that is imported then exported without leaving the port of arrival until export; and meat food products, poultry products, and egg products that, at the time of importation, are subject to the exclusive jurisdiction of USDA under the Federal Meat Inspection Act (21 U.S.C. 601 *et seq.*), the Poultry Products Inspection Act (21 U.S.C. 451 *et seq.*), or the Egg Products Inspection Act (21 U.S.C. 1031 *et seq.*).

FDA received many comments about § 1.277(b), which are addressed in order of the exclusions covered in the IFR: Food for an individual's personal use when carried by or otherwise accompanying an individual; homemade food; food that is imported for immediate exportation; and foods under exclusive USDA/Food Safety and Inspection Service jurisdiction. The comments concerning requests for additional exclusions from the scope of the prior notice requirements are addressed by issue, beginning with general comments/requests.

1. Food for an Individual's Personal Use When Accompanied at Arrival

Section 1.277(b)(1) of the IFR excludes food for an individual's personal use when it is carried by or otherwise accompanies the individual when arriving in the United States. The IFR explains that in this situation there was no "shipper" as that term is used in section 801(m) of the act.

(Comments) One comment requests that FDA expand the exemption for food carried in to the United States for

personal use to include all food products carried in personal baggage; or to allow declaration of entry to be made through existing general CBP entry declaration procedures.

(Response) FDA disagrees. Prior notice is not required for food that is carried by or otherwise accompanies an individual entering the United States (e.g., food that is in his or her carry-on or checked baggage) when the food is for that individual's personal use (§ 1.277(b)(1)). This means that the food is for consumption by the individual or by the individual's family and friends and is not for sale or other distribution. If the food carried by or otherwise accompanying an individual is for commercial purposes, then prior notice requirements apply.

As we explained in the IFR preamble, we do not believe that Congress intended for us to characterize travelers bringing food back from their travels in their personal baggage for their own use as "shippers" for purposes of section 801(m) of the act. When there is a commercial purpose involved, there is a "shipper," i.e., the person or entity on whose behalf the traveler is bringing in the food. Thus, by its terms, section 801(m) of the 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. Moreover, we explained that we would potentially create a loophole that would defeat the purpose of the prior notice rule if we were to exempt all food products carried in personal baggage.

(Final rule) Section 1.277(b)(1) of the final rule continues to state that the rule does not apply to food for an individual's personal use when it is carried by or otherwise accompanies the individual when arriving in the United States.

2. Homemade Food Sent as Personal Gift

Section 1.277(b)(2) of the IFR excludes food that was made by an individual in his/her personal residence and sent by that individual as a personal gift (i.e., for nonbusiness reasons) to an individual in the United States.

(Comments) No comments were received about this issue.

(Final rule) Section 1.277(b)(2) is retained without change.

3. Food Imported Then Exported Without Leaving Port of Arrival Until Export

Section 1.277(b)(3) of the IFR excludes food that is imported then exported without leaving the port of arrival until export.

(Comments) One comment states that if food moves for immediate export³ (IE) out of the same port, it is not subject to prior notice. However, if the food moves on a T&E entry, prior notice is required. The comment provides a scenario where a shipment arrives at Los Angeles Harbor and then moves to Los Angeles Airport for export. Los Angeles Harbor and Los Angeles Airport are separate ports and each has its own port code assigned by CBP. The comment states that CBP considers this an IE entry. Similarly, the comment questioned if FDA considers this an IE entry as well, or if it is considered a T&E entry that requires prior notice.

(Response) If the food arrives in and is exported from the same port, then it is not subject to prior notice. FDA considers a port to be the same as defined by CBP in 19 CFR 101.1; i.e., the term "port" incorporates the geographical area under the jurisdiction of a port director. The geographical boundaries of the port of Los Angeles-Long Beach are described in 19 CFR 101.3(b)(1). While Los Angeles Harbor and Los Angeles Airport are separate for CBP management purposes, they are considered to be within the same port. Accordingly, IE entries may be filed for movements between Los Angeles Harbor and Los Angeles Airport followed by exportation of the goods. Similarly, because such movements would not leave the port of arrival until export, prior notice would not be required.

(Comments) One comment suggests that articles of food imported and admitted into a FTZ in or adjacent to the port of arrival as "zone restricted status" merchandise, and then exported from the port of arrival under an IE entry, are sufficiently similar to an IE entry that the same restrictions as for an IE entry would apply if the food were refused admission under 801(m) of the act. The comment, therefore, recommends that these articles should be exempt from the prior notice requirements.

(Response) The fact that food is for admission into an FTZ does not, by itself, mean that the food is not subject to the requirements of the prior notice regulation (§ 1.277(a)). In the first instance described in the comments, where the article of food is imported and admitted into an FTZ located in the port of arrival and then exported from the port of arrival, prior notice is not required (§ 1.277(b)(3)). In the second instance, where the article of food is imported and admitted into an FTZ

³ Food that is brought to a U.S. port but is then directly exported from that port of arrival is entered under a CBP IE entry and subject to the limitations of an IE bond. In essence, this food may not leave the port of arrival until export.

located adjacent to the port of arrival and then exported, prior notice would be required since the food has left the port of arrival before export and may not be subject to the limitations of an IE bond. An FTZ adjacent to the port of arrival is considered to be outside the port of arrival, and therefore not sufficiently similar to those IE entries that have never left the port of arrival.

(Comments) Several comments ask that FDA exempt the airline industry's food service from the requirements of prior notice. The comments assert that there is no danger to the American public from this operation. One comment suggests that leftover unopened cans of soda, unopened small bottles of liquor (to be held in bonded storage) or other "dry-stores" items on flights inbound to the United States and intended for use on later flights should be exempt from prior notice. In addition, the comment states that it is not possible to determine at "wheels up" what will remain upon landing in the United States. One comment states that it is impossible to provide detailed information about leftover soda and liquor on incoming international aircraft. One comment proposes the addition of the following exception to § 1.277(b): "Food that is imported by a shipper operating an aircraft in international air transportation, then exported by the same shipper, [as] long as such food remains on board the aircraft at all times from import to export."

(Response) If the aircraft food is consumed on the international flight or discarded and is not entered into the United States for use, storage, or distribution or remains on board and is exported from the same port into which it arrived, it is outside the scope of the regulation and prior notice is not required. By contrast, prior notice is required for in-flight food that is moved out of the port of arrival to caterers for use on other international or domestic flights (§ 1.277).

(Comments) One comment questions whether wines manufactured in a foreign country and present on a passenger ship that may cruise or dock in the United States Territorial Sea require prior notice.

(Response) If the wine remains on the ship, it does not require prior notice (§ 1.277(b)(3)). However, if the wine is offloaded from the ship and leaves the port of arrival in the United States, prior notice would be required.

(Comments) One comment asks that if wines are loaded onto a passenger ship at a U.S. port, but such an article of food has been previously imported into the U.S. to be exported or transhipped,

does the prior notice for such an article of food require the manufacturer's registration number.

(Response) Prior notice is required for food imported or offered for import into the United States before arrival and not when the food is loaded onto a passenger ship in the United States.

(Final rule) Section 1.277(b)(3) is retained without change in the final rule and excludes food that is imported then exported without leaving the port of arrival until export.

4. Food Under the Exclusive Jurisdiction of USDA

The IFR in § 1.277(b)(4), (b)(5), and (b)(6) excludes: Meat food products that at the time of importation are subject to the exclusive jurisdiction of USDA under the Federal Meat Inspection Act (21 U.S.C. 601 *et seq.*); poultry products that at the time of importation are subject to the exclusive jurisdiction of USDA under the Poultry Products Inspection Act (21 U.S.C. 451 *et seq.*); and egg products that at the time of importation are subject to the exclusive jurisdiction of USDA under the Egg Products Inspection Act (21 U.S.C. 1031 *et seq.*). The IFR explains that these are excluded as directed in the Bioterrorism Act.

(Comments) Comments state that live animals including cattle, pig, chickens, etc. require prior notice, whereas prior notice is not required for products exclusively regulated by the Federal Meat Inspection Act. The comments recommend that animals regulated exclusively by USDA/Veterinary Services such as live cattle, pigs, and chickens be exempt from prior notice because USDA examines them upon importation. One comment further suggests that live animals requiring prior notice should be those animals regulated by FDA, such as turtles, game animals, etc. Another comment asks whether prior notice is required for livestock sent to the United States for recreational purposes, but after a number of years are expected to be slaughtered and enter the food chain as pet food. One comment asks that FDA exempt breeder livestock not imported for immediate slaughter and remove "FD3" flags from HTS codes that cover breeder livestock to avoid confusion at the ports of arrival regarding applicability of prior notice requirements.

(Response) FDA disagrees. Live animals, such as poultry and cattle, are food for purposes of prior notice (§ 1.276(b)(5)(ii)) if the article of food is reasonably likely to be directed to a food use (see discussion *supra* on the definition of food in section III.C.11).

Note that live food animals are not excluded from prior notice under section 801(m)(3)(B) of the act and § 1.277(b)(4) or (b)(5) because live food animals do not fall within the exclusive jurisdiction of USDA under the Federal Meat Inspection Act or Poultry Products Inspection Act. If the live animals are imported for a nonfood use (i.e., as a pet, for show purposes, racing) and are not reasonably likely to be directed to a food use, then prior notice is not required. USDA/Veterinary Services inspects imported live animals for animal health, not human health, purposes. An FD3 flag associated with breeder livestock means that the livestock may be subject to prior notice requirements. If the live animal is not reasonably likely to be directed to a food use, then the HTS code may be disclaimed because prior notice is not required.

(Comments) Some comments had a concern regarding USDA-regulated products. One comment noted that USDA-regulated products were excluded from the FDA prior notice rule, but that an HTS codes document released on November 20, 2003, highlights a number of products that are regulated by USDA. Another comment questions why cattle imported for slaughter are coded FD4 and all other cattle are coded FD3 when the importation of cattle is under the responsibility and jurisdiction of USDA.

(Response) Only items that are under the exclusive jurisdiction of the USDA are excluded from the requirements of prior notice. Articles of food that are jointly regulated by FDA and USDA are subject to the requirements of prior notice. Live animals raised for food, even though not in their final, edible form, are considered to be food under the act. *United States v. Tomahara Enterprises Ltd.*, Food Drug Cosm. L. Rep. (CCH) 38,217 (N.D.N.Y. 1983) (live calves intended as veal are food) and *United States v. Tuente Livestock*, 888 F. Supp. 1416 (S.D. Ohio 1995) (live hogs are food).

(Final rule) Section 1.277(b)(4), (b)(5), and (b)(6) of the final rule are retained without change and exclude meat food products that at the time of importation are subject to the exclusive jurisdiction of the USDA under the Federal Meat Inspection Act (21 U.S.C. 601 *et seq.*); poultry products that at the time of importation are subject to the exclusive jurisdiction of USDA under the Poultry Products Inspection Act (21 U.S.C. 451 *et seq.*); and egg products that at the time of importation are subject to the exclusive jurisdiction of USDA under the Egg Products Inspection Act (21 U.S.C. 1031 *et seq.*).

5. Additional Exclusions Requested—General

(Comments) One comment states that cough drops containing OTC (over-the-counter) Monograph active ingredients are regulated as an over-the-counter drug by the FDA, and therefore, are not subject to prior notice. However, CBP categorizes all cough drops, including ones regulated as drugs by the FDA, as candy subject to regulation by FDA as food. Therefore, due to this classification by CBP, cough drops would require prior notice. In addition, another comment asks if pharmaceuticals, such as over-the-counter drugs, are exempt from prior notice requirements.

(Response) CBP classification does not identify foods requiring prior notice. However, CBP and FDA have worked together to provide indicators; i.e., flags associated with HTS codes to indicate which articles being imported may require prior notice submission. The FD3 flag indicates that the products categorized by that HTS code may require prior notice submission; those products categorized in those HTS codes flagged as FD3 that do not require prior notice submission may be disclaimed by the filer upon entry. On the other hand, the FD4 flag indicates that the products categorized by that HTS code require prior notice submission. FDA has published guidance regarding these flags and has published a list of the HTS codes with FD3 and FD4 flags. The guidance is posted at <http://www.cfsan.fda.gov/~dms/htsguid3.html> and the list of codes is posted at <http://www.cfsan.fda.gov/~pn/htscodes.html>.

The comment asks about such articles containing OTC monograph active ingredients. HTS Code 3004909176 (cough and cold preparations) would apply to, among other articles, cough suppressants that contain OTC monograph active ingredients. This HTS Code is not flagged for either FD3 or FD4, meaning that prior notice would not be required. Candies, which are food, would fall under different HTS Codes and would be subject to prior notice.

(Comments) One comment recommends that FDA's food category codes for raw materials could be made more complete to cover the range of materials known to be used in products marketed as foods. The comment states that there are numerous CBP "Customs Codes" that do not contain the appropriate FD3 or FD4 codes and that this causes confusion among the industry with some groups interpreting the lack of an FDA code as meaning that

that food ingredient was exempt from prior notice, even if the ingredient is known to be used in food. Other comments assume that ingredients lacking an FD3 or FD4 code that are best known as being active ingredients in drugs, but are also used in dietary supplements, are exempt from prior notice. The comment recommends that these codes should be made as complete as possible and that FDA should indicate that ingredients without a FD3 or FD4 code may still require prior notice.

(Response) FDA and CBP continuously evaluate the HTS codes in order to attach the appropriate FD3 and FD4 designations. However, the lack of an FD3 or FD4 designation does not mean that prior notice is not required. If the article fits the definition of food provided in § 1.276 of the final rule, then prior notice is required for that article of food. If you believe that an item has been incorrectly flagged, or is not currently flagged, but should be, you should contact the FDA and provide a statement with your suggestion and basis for the flag designation.

(Comments) One comment believes that there is a conflict between the registration (21 CFR part 1, subpart H) and prior notice IFRs, where the former is based upon the intended use of food (i.e., consumption), and the latter applies to "all" food. The comment states that this has caused difficulties with the import process by: (1) Requiring foreign facilities to register in order to meet the prior notice requirements and (2) requiring drug and device establishments to register as food facilities in order to facilitate importation of intra-company articles. The comment believes this places an undue burden on drug and device establishments and hampers the importation process for articles not intended for use in food, as well as for food articles not intended for consumption. The comment suggests that section § 1.277 be changed to read: "This subpart applies to all food intended for consumption by humans and other animals * * *." In addition, the comment suggests that the HTS codes be modified to allow articles designated with a FD3 or FD4 code to be disclaimed, with rationale, depending on their intended use.

(Response) FDA disagrees. FDA disagrees with changing § 1.277 to read that prior notice is only required for food that is intended for consumption. In the preamble to the IFR, FDA noted that the determination of whether a substance is "food" is not a question of intended use (See 68 FR 58974 at 58987). Moreover, we do not believe

that there is a conflict between the registration and prior notice requirements. Under the registration rule, in general, a facility engaged in the manufacturing/processing, packaging, or holding of food for consumption in the United States must be registered. Regardless of whether the facility that manufactured the food manufactured it for consumption in the United States, section 801(l) of the act prohibits food that is from an unregistered foreign facility from being delivered for distribution in the United States until the facility is registered. Thus, if the owners, operators, or agents in charge of facilities want to ensure these types of food are not subject to being held under section 801(l) of the act, they can register in accordance with section 415 of the act (21 U.S.C. 350d) (and if the food is for consumption in the United States, they must register unless the facility qualifies for an exemption). An importer can likewise ensure that food is not subject to being held under section 801(l) of the act by not importing or offering for import food that is from an unregistered foreign facility.

Throughout this preamble to the final rule, we often use the phrase "food is subject to being held" in describing our enforcement of the registration requirement through prior notice. Under section 801(l) of the act, "[i]f an article of food is being imported or offered for import into the United States, and such article is from a foreign facility for which a registration has not been submitted to the Secretary under section 415, *such article shall be held at the port of entry for the article*, and may not be delivered to the importer, owner, or consignee of the article, until the foreign facility is so registered" (emphasis added). In this situation, the article of food is being prevented from moving forward past the port of arrival because the food is from a foreign facility that has not registered. This situation is distinct from a situation where, after FDA reviews the prior notice information, the food is held upon arrival for examination because it may pose a significant risk to public health, usually referred to as a "BT Hold." In addition, we do not believe that prior notice places an undue burden on the drug and medical device industry. Items designated with a FD4 code are all believed to be used exclusively in food, and therefore, require prior notice. Articles designated by a FD3 code can have food and nonfood uses. These items do not require prior notice if the use of the article does not fit the definition of food provided in § 1.276 of

the final rule and may be disclaimed by the filer as such upon entry.

(Comments) One comment states that there is no facility registration requirement for transshippers; however, goods processed under CBP's Form CF7512 (T&Es and ITs) require a prior notice to be filed. The comment notes that this cannot be accomplished without the corresponding facility registration number. In addition, T&Es and ITs do not have a designated submitter. The comment requests that T&E and IT transactions be exempt from prior notice.

(Response) FDA disagrees that T&E or IT transactions should be exempt from the requirements of prior notice. These articles of food leave the port of arrival prior to exportation from the United States or for subsequent movement through the United States prior to entry.

Under § 1.281(a)(9) of the IFR, a shipper's (transshipper's) registration number was not required for a facility associated with an article of food if the article is imported for transshipment. Under the final rule, if the shipper's identity is provided, the shipper's registration number is optional. Therefore, the absence of a shipper's registration number should not prevent submission of a prior notice under either the IFR or final rule. Moreover, FDA disagrees with the comment's implication that a prior notice requires a designated submitter. Under § 1.278 of the IFR and final rule, a prior notice may be submitted by any person with knowledge of the required information.

(Comments) Several comments request that FDA generally exempt Canada and Mexico from submitting prior notice for food shipments. One comment requests that FDA exempt Canada, in keeping with the nature of cooperation and shared security risks between the United States and Canada, in particular the 30 point border plan. The comment reasons that Canadian origin food is easily traceable through existing Canadian registration requirements, while already meeting or exceeding United States standards in some instances. The comment further notes that the legislation acknowledges the largest threat is from offshore, yet the regulations most severely hit continental trade between the United States, Canada, and Mexico. One comment suggests that the exemption could be limited to shipments of food which are under similar security controls, especially small quantity shipments of fish imported via package delivery. Another comment asks that FDA exempt goods being imported into the United States from companies

which are inspected by the Canadian Food and Inspection Agency.

(Response) FDA disagrees. While we welcome any additional information that supports our ability to quickly review prior notice submissions and determine which food to inspect at U.S. ports of arrival, the Bioterrorism Act does not provide for blanket exclusions based on the country from which the food is shipped or the country in which the food originates. FDA currently is reviewing flexible alternative programs (e.g., CBP's Customs-Trade Partnership Against Terrorism (C-TPAT), which was adopted into law (still as a voluntary system) by Subtitle B of Title II of the SAFE Port Act of 2006 (Public Law 109-347), and Free and Secure Trade (FAST) (a voluntary program authorized under 19 U.S.C. 1411)) to determine their potential for streamlining the prior notice review process, but notes that these programs do not meet or affect the requirement to submit prior notice. Moreover, FDA notes that many shipments from Canada and Mexico into the United States in fact are transshipments from other countries, which prior notice submissions identify with the FDA Country of Production data element.

(Comments) One comment suggests that FDA create a relational database to give unique identification numbers to an importer's specific items. The comment states that this would speed submission, reduce time to enter the data, and increase compliance with the regulation. The comment reasons that most food importers will bring in the same product, in the same package, from the same country, over and over. Another comment suggests that a single weekly summary of all shipments by a company to individual consumers or a summary of orders received should be adequate for this type of commerce.

(Response) FDA disagrees. Not all importers consistently import the same types of food. The Bioterrorism Act requires submission of prior notice before an article of food is imported or offered for import into the United States. A weekly summary as suggested by the comment would not meet this requirement, as such a summary would not provide prior (advance) notice before the article of food is imported or offered for import. FDA notes, however, that a number of the software programs that customs brokers use to file prior notice and entry submissions with ABI/ACS do allow for repetitive information to be saved on the filer's computer and used for future shipments, as appropriate. Similarly, FDA's PNSI has been designed to accommodate repetitive information, such that the

basic prior notice information that will repeat on each prior notice can be created and saved for use on subsequent prior notices. A separate prior notice confirmation number is generated for each article of food or recipient.

(Comments) One comment requests that FDA exempt highly perishable food products. The comment states that highly perishable food products, such as ice cream, must be delivered in a timely manner. A delay in the delivery schedule due to holdups at the border could potentially ruin these products, and customers inconvenienced by the time delay may choose to stop importing them. A number of comments request that FDA exempt fresh produce. Several comments note that produce is already carefully monitored by CBP and placed on automatic quarantine for mandatory inspection at the first port of arrival by USDA/CBP. Other comments state that produce is already subject to 100 percent USDA inspection and approval prior to release. Another comment requests that produce be exempt from the requirement of prior notice because it already meets the requirements of the Bioterrorism Act. The comment reasons that the purpose of the prior notification to FDA is to provide FDA with the information necessary to make a decision (prior to arrival) for a possible physical inspection. The comment states that the CBP Agriculture Specialist performs the physical inspection (or reviews original documentation that confirms "pre-inspection"). Therefore, the comment reasons, importations of fresh produce are already meeting the requirements of the Bioterrorism Act. The comments further state that because prior notice is already given for produce, the new procedure created by this new legislation will only increase costs and cause extreme hardship for small business. An additional comment states that their shipments are subject to four levels of inspection: County, State, Federal, Customs and "Bio Terrorist" and reasons that the redundancy is wasteful.

(Response) FDA disagrees. Highly perishable foods, like all other foods that are covered by the final rule, are subject to prior notice requirements. The timeframes are sufficiently short, allowing for submission of prior notice as soon as 2, 4, or 8 hours before arrival in the United States depending on mode of transportation. While the Bioterrorism Act provides for an exclusion for certain types of food, such as meat and meat food products subject to USDA's exclusive jurisdiction, it does not exclude perishable foods generally

or foods jointly regulated by USDA and FDA.

As we explained in the IFR preamble, 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 act's prior notice requirements because there is wide variation in the purposes and information required by other government programs (68 FR 58974 at 58992). Moreover, our ability to respond to bioterrorism incidents or other food-related emergencies in a timely manner may be more difficult if the information is not easily accessible.

(Comments) One comment recommends that the rule be amended to include an exemption from prior notice for organizations that are importing FD4 materials for nonfood uses.

(Response) FDA disagrees. Items designated with an FD4 code are all believed to be used exclusively in food, and therefore, food encompassed by an HTS code that is flagged FD4 is subject to prior notice requirements. Moreover, as discussed previously, FDA provided extensively its rationale for not limiting the prior notice requirements to food for consumption in the United States. (See 68 FR 58974 at 58990 and 58991.) As FDA noted in the IFR, Congress did not explicitly limit the prior notice requirement to articles of food that are intended for consumption in the United States even though it could have done so as shown in section 415 of the act (requirement to register food facilities). If anyone believes that an HTS code has been flagged FD4 in error, they can inform FDA and, if we agree, we will change the flag accordingly.

(Comments) Two comments request that FDA exempt small businesses.

(Response) FDA disagrees. Prior notice is required for all FDA-regulated food that is imported or offered for import. The Bioterrorism Act does not provide for exclusions based upon the size or nature of the firms or facilities associated with that importation.

(Comments) One comment asks FDA to permit an exemption from prior notice, by importer number, to be recognized in ACS at the time of entry transmission, to importers who demonstrate that their products will not reasonably be expected to be directed to a food use.

(Response) FDA disagrees. Prior notice requirements are associated with food, not the person manufacturing, growing, shipping, importing, or owning the food. A product is food for purposes of prior notice if the article of food is reasonably likely to be directed to a food use. Prior notice is required for each

article of food imported or offered for import, and food imported or offered for import by or for select importers will not be excluded from prior notice requirements. If an importer does not import articles of food, then no "exemption" would be needed since prior notice would not apply to such imports. The FD flags associated with HTS codes are designed to help identify which products will require prior notice. If an import is marked FD3 but it is not food subject to prior notice, the importer can disclaim this import and prior notice would not need to be submitted.

6. Additional Exclusions Requested—Special Programs (C-TPAT/FAST) and Flexible Alternatives

In the explanation of the reduced timeframes and the relationship of special programs to those timeframes, FDA stated in the IFR that the "interim final rule provides for greatly reduced timeframes for foods based on mode of transportation. These timeframes are what FDA has determined are the minimum timeframes necessary to allow it to satisfy the statutory mandate that the timeframes give the agency the time it needs to 'receive, review, and respond' to prior notices. However, FDA is also interested in exploring flexible alternatives for submission of prior notice for foods or firms covered by programs of other agencies, such as C-TPAT, or imported by other agencies." (68 FR 58974 at 58995).

FDA and CBP reopened the comment period for the IFR in the **Federal Register** of April 14, 2004 (69 FR 19763). On page 19764 of that publication, FDA and CBP wrote "In the prior notice [interim final rule], we expressed interest in exploring flexible alternatives for submission of prior notice for foods or firms covered by programs of other agencies, such as CBP's Customs-Trade Partnership Against Terrorism (C-TPAT) and the Free and Secure Trade (FAST) program, or food imported by other government agencies (68 FR 58974 at 58995). C-TPAT is a government/business initiative to increase cargo security while improving the flow of trade. Under this program, businesses must conduct comprehensive self-assessments of their supply chain using the security guidelines developed jointly with CBP, and they must familiarize companies in their supply chain with the guidelines and the program. These businesses must provide CBP with specific and relevant information about their supply chains and security practices and procedures. As C-TPAT members, companies may

become eligible for expedited processing and reduced inspections, but are not exempt from advance electronic information requirements. (See CBP's advance electronic information rule). FAST, an acronym for Free and Secure Trade between the United States and Canada, and the United States and Mexico, is an expedited-clearance system designed to improve border security without slowing the flow of legitimate trade across the northern and southern U.S. borders. FAST processing is available to importers, carriers and foreign manufacturers (southern border) who participate in C-TPAT and who use a FAST-registered driver. The initiative builds on the same concepts that drove the rapid, post-9/11 construction and implementation of C-TPAT. FDA and CBP plan to assess the feasibility of including the FAST timeframes in FDA's prior notice final rule, as well as other flexible alternatives raised by comments.

To assist in this assessment, FDA and CBP requested comments on several questions, including three regarding special programs (69 FR 19763 at 19764):

C-TPAT/FAST Questions:

(1) Should food products subject to FDA's prior notice requirements be eligible for the full expedited processing and information transmission benefits allowed with C-TPAT and FAST? If so, how should this be accomplished?

(2) If the timeframe for submitting prior notice for food arriving by land via road is reduced to 1 hour consistent with the timeframe in the advance electronic information rule, would a shorter timeframe be needed for members of FAST?

(3) Should the security and verification processes in C-TPAT be modified in any way to handle food and animal feed shipments regulated by FDA? If so, how?

The comments received addressing these issues are discussed in the following paragraphs in order of the questions posed in the **Federal Register** notice, beginning with comments addressing general issues regarding C-TPAT and FAST.

a. *General comments.* (Comments) Numerous comments address special trade programs, such as C-TPAT and FAST. These comments recommend that FDA and CBP modify these CBP programs to reflect the criteria required by FDA and to develop integrated data elements for low risk FAST/C-TPAT shipments, which would meet both agencies' requirements. The comments believe it is necessary to have harmonization between FDA and CBP for "low-risk" shippers.

Many comments contend that the IFR does not take into account the Canada-United States Smart Border Plan (SBP). A key element of the SBP is the FAST bilateral arrangements. Under the C-TPAT and the Canadian Partnerships in Protection (PIP) programs, companies approved by both countries have invested in specific counter-terrorism and supply-chain integrity measures, and are therefore, accorded more expedited treatment at the Canada-U.S. border in recognition of the lower risk they present.

The comments recommend that FDA recognize foods imported under these programs as low risk and to afford them benefits, such as reduced information requirements for each shipment; reduced timeframes for providing prior notice; reduced clearance time at the border; and reduced number of verifications of information. The comments further urge FDA and CBP to permit importers who are participants in C-TPAT and FAST to comply with their prior notice obligations in a manner that does not undermine the benefits of participation in these programs. The comments contend that C-TPAT and FAST improve U.S. security on a number of levels, including reducing the risk of bioterrorism, and help to focus limited border resources on higher risk cargo. The comments suggest that FDA and CBP therefore should be careful not to remove incentives for participation in these programs by making importation of food items more cumbersome than other types of entries. Otherwise, the comments contend prior notice will dilute a key advantage offered to FAST/C-TPAT participants, thereby weakening the incentive to join the program. The companies participating in these programs have made a substantial commitment to improving security by putting in place appropriate security systems, and submitting to periodic review of those systems by CBP.

The comments believe that these programs strengthen FDA's ability to meet the objectives of the prior notice rule. They contend that this is achieved in two ways: (1) Through the rigorous security screening that participants must comply with in order to obtain a low-risk status; and (2) by removing low-risk shipments from the queue, FAST/C-TPAT work to shrink the number of shipments that must be screened, thereby "freeing up" FDA officials to focus limited resources on higher risk shipments.

One comment states that a firm having to manage its systems to track C-TPAT products and non-C-TPAT

products will incur increased complexity, increased cost, and will be subject to making errors. This comment suggests that firms who routinely send products across the border could provide prior notice on a quarterly basis. The facility would track the number of shipments each quarter and update FDA with any changes to the anticipated amounts. These shipments would be permitted to cross the border without waiting, but still could be subjected to FDA or CBP inspection.

Another comment questions the cost, benefits, etc. of these programs for small companies. In addition, a few comments address the creation of similar programs and/or the expansion of the current programs. One comment requests that FDA permit the use of Line Release (i.e., an automated system designed to release and track repetitive shipments) for food shipments arriving by rail. The comment states that their member railroads participate in C-TPAT and it would be discriminatory to permit the use of an expedited clearance system for motor carriers, but not rail transportation.

One comment urges FDA to begin working with all interested parties to identify criteria for qualification and participation in a program like C-TPAT, FAST, and others as it applies to prior notice. The comment suggests that participation might hinge on the submission and verification of documentation evidencing the implementation of, and continued adherence to, validated supply chain risk management techniques. The comment believes that there would be mutual benefits of such a program. FDA could reallocate its resources to closer review and examination of shipments from those importers that do not participate in the program and, thus, have not demonstrated the same level of commitment to food safety and shipment security as participating importers do. Program participants would benefit from the agency's recognition of their commitment to safety and security, which presumably would be reflected in more efficient and timely processing of their entries at the border. In that regard, the comment suggests that the agency consider extending to participating low risk importers the option of submitting a single prior notice for all entries in a mixed load container or truck. FDA product codes for all line entries would continue to be available to FDA through FDA's existing OASIS system.

Another comment hopes that the multiple U.S. agencies (FDA, Department of Homeland Security, and USDA) could collectively address this

issue and develop a protocol for food products that are currently ineligible for any FAST benefits.

A few comments request that C-TPAT should be open to all foreign operators willing to participate and that companies participating in C-TPAT should be exempt from the procedures under the Bioterrorism Act. These comments encourage partnerships between the U.S. and E.U. similar to C-TPAT, which would facilitate trade in food and feed between the E.U. and U.S. and avoid delays at the U.S. border, especially with respect to perishable products. In addition, one comment suggests that food transporters should be allowed eligibility in C-TPAT and FAST to ensure that all transporters operate on a level playing field.

One comment notes that C-TPAT is not currently offered to Canadian manufacturers unless they are an Importer of Record for U.S. Customs' purposes.

Finally, one comment expresses concern that any motor carrier who is not Pre-Arrival Processing System (PAPS)-certified may be required to present the prior notice confirmation number upon arrival at the border, even if prior notice was submitted through ACS. The comment states that truck drivers are generally unable to obtain the prior notice confirmation number prior to arrival given the short distance between Canada and the United States and the fact that prior notice is not generally submitted until after the trucker has left with the load. The comment states that requiring PAPS authorization as a way to avoid delays is to mandate that truck companies become C-TPAT certified or otherwise comply with the designation requirements. The comment notes that this is not possible, sometimes for cost reasons alone. The comment also has similar concerns regarding the PAPS-program at the Southern border.

(Response) While FDA welcomes the additional information provided by C-TPAT and FAST, these programs would require relatively significant changes to be useful in helping us carry out the prior notice program. The purpose of prior notice is to help identify food that potentially poses a significant health risk to the American public and to deploy resources to the port of arrival so that inspections can be conducted before the shipment enters the United States. Information about the manufacturing facility is used in conducting this risk assessment. The C-TPAT assessment, however, does not always include the food manufacturing/processing operations. Even when it does, C-TPAT focuses on security risks

whereas the prior notice program considers all health and safety risks to the food, such as unintentional contamination. Moreover, unlike PNC reviewers, the CBP Supply Chain Specialists who conduct the validation assessments for C-TPAT are not necessarily trained in assessing the potential risks associated to food products and neither FDA nor CBP has the resources to fund the extensive training that would be required to do so. Because knowing that a firm participates in C-TPAT does not assist FDA in conducting its food safety review, we have decided not to provide special treatment in terms of reduced prior notice information requirements or reduced timeframes based on C-TPAT participation.

It is important to note that participation in C-TPAT does not affect the information requirements of CBP's advance electronic information rules; the same information is required regardless of C-TPAT participation. However, successful participation in C-TPAT does affect the frequency of CBP cargo and trade examination. FDA likewise uses a risk-based approach in selecting foods for examination at the border for security and food safety reasons. FDA, thus, is continuing to explore with CBP and industry use of these programs in making decisions regarding which products to inspect for the purposes of admissibility (801(a) decisions).

Comments addressing which foreign operators are eligible for participation in FAST and C-TPAT are outside the scope of this rule. CBP stated in a document entitled "Frequently Asked Questions Regarding Minimum Security Criteria for Importers," dated March 25, 2005, (CBP's March 25, 2005, Frequently Asked Questions (FAQ) document) (available at http://www.cbp.gov/xp/cgov/trade/cargo_security/ctpat/security_criteria/criteria_importers/questions.xml) (FDA has verified the Web site address, but FDA is not responsible for any subsequent changes to the Web site after this document publishes in the **Federal Register**)), that "C-TPAT remains a voluntary, incentive based partnership. However, once a company commits to the C-TPAT program, there are specific program requirements that must be adhered to by the company to qualify for C-TPAT benefits, which are significant. C-TPAT importers are six times less likely to undergo a security related cargo examination, and four times less likely to be subject to a trade related examination, than non-C-TPAT members. These significantly fewer cargo examinations help save importers

time and money, while leading to a more predictable supply chain. CBP continues to explore additional benefits, which can be afforded members who meet or exceed the minimum-security criteria."

The document also states that "CBP employs a risk management approach in screening and targeting, and such shipments, as well as those from unknown or less established entities, receive higher scrutiny from CBP. The agency does not disclose ATS targeting rules."

(Comments) Several comments suggest that FDA should not establish a duplicative program, but should incorporate additional factors or criteria necessary for prior notice into existing programs.

(Response) FDA agrees that it is generally preferable not to establish duplicative programs. Thus, while we have determined not to provide C-TPAT members with special treatment in terms of reduced prior notice information requirements or reduced timeframes, we will continue exploring use of these programs in making decisions regarding which products to inspect for the purposes of admissibility (801(a) decisions).

b. *Special programs.*

i. *Should food products subject to FDA's prior notice requirements be eligible for the full expedited processing and information transmission benefits allowed with C-TPAT and FAST? If so, how should this be accomplished?*

(Comments) Numerous comments assert that businesses that participate in the C-TPAT and FAST programs should be eligible for processing/transmission benefits. These comments contend that importers, carriers and drivers who have been approved for C-TPAT and FAST already have been deemed to be "low risk" by CBP. Importers and carriers have had to demonstrate supply chain security controls, and drivers have been subjected to rigorous background screening. Companies have made the security investments and have bolstered their operations to provide the requisite security and integrity of their trade transactions. The federal governments of the United States and Canada have encouraged FAST participation on the grounds that it will mean expedited border crossings and reduced information requirements. By allowing food to move through the FAST "stream" in the same manner as other products, FDA would demonstrate the commitment to harmonization that industry has long encouraged and would provide an incentive for additional participation in the C-TPAT and FAST programs. In addition, the

comments noted that if the primary benefits of the C-TPAT program were removed, FDA would create a disincentive for C-TPAT participation that would ultimately reduce the security of the articles covered by the Bioterrorism Act. Finally, the comments note that these benefits are necessary to avoid duplication and inconsistent application of prior notice requirements for shipments that meet the stringent FAST criteria.

(Response) FDA continues to use a risk-based approach for determining which foods to inspect for the purposes of admissibility. FDA will continue to work with CBP and acknowledges that the additional information provided by C-TPAT participation could be helpful in this risk-based assessment. In CBP's March 25, 2005, FAQ document cited previously, CBP states that "[u]nsolicited shipments will understandably lie outside the capability of the importer to ensure security. CBP employs a risk management approach in screening and targeting, and such shipments, as well as those from unknown or less established entities, receive higher scrutiny from CBP." FDA agrees with this statement.

(Comments) Numerous comments provide suggestions on how to accomplish processing/transmission benefits for C-TPAT and FAST participants. Many of the comments cite a need for better harmonization and streamlining between FDA and CBP. Suggestions from the comments include:

- Enhance coordination between CBP and FDA, allowing trained CBP/FDA officers to process food shipments through the FAST lane, and allowing FAST importers using a FAST driver and carrier importing food and/or feed products to submit prior notice to both the CBP and FDA through the existing CBP/FDA interface.
- Allow for integrated targeting processes, including a reduction in the risk targeting factors for food shipments, as well as other product categories, which would translate into expedited processing, reduced exams and other benefits for food import shipments under the program.
- Integrate the CBP and FDA data systems to allow for one filing of the required information. The C-TPAT certification process delves into the critical aspects of a company's handling and documentation procedures, and requires a company to demonstrate it has good process controls in place throughout the supply chain.
- Modify the CBP and FDA systems for the receipt of advance notice and prior notice to "flag" importation under

C-TPAT and FAST. These notices should receive priority attention for entry and clearance purposes.

- Establish an MOU between FDA and CBP to allow the sharing of necessary information with the understanding of the program applicant.
- Implement a shorter prior notice timeframe for C-TPAT members.
- Reduce data element reporting by virtue of having successfully passed the C-TPAT validation process. Product information (HTS code, product code, manufacturer's registration numbers, etc.) should be part of the pre-filed information profiles under FAST.

Finally, one comment suggests the following:

(1) A statement of proof of acceptance (e.g., copy of acceptance letter from CBP) into the C-TPAT and/or FAST programs;

(2) A detailed statement/description of policies and procedures in place for meeting FDA prior notice requirements. This submission should follow the format of the supply chain questionnaire information submitted to CBP as part of the C-TPAT application process and should be considered as an addendum to the original submission; and

(3) FDA should notify the importer in writing of: (a) its acceptance/agreement with the importer's FDA prior notice procedures; or (b) additional questions to be answered or data to be provided to meet FDA requirements for acceptance into the FDA prior notice "C-TPAT/FAST" program.

(Response) As we discussed previously, we have determined not to provide C-TPAT members with special treatment in terms of reduced prior notice information requirements or reduced timeframes. FDA, however, is continuing to explore with CBP and industry use of these programs in making decisions regarding which products to inspect for the purposes of admissibility (801(a) decisions).

ii. *If the timeframe for submitting prior notice for food arriving by land via road is reduced to 1 hour consistent with the timeframe in the advance electronic information rule, would a shorter timeframe be needed for members of FAST?* (Comments) One comment suggests that the timeframe for submitting prior notice of one hour is fine, even for express deliveries.

Another comment believes that reducing the timeframes for submission of prior notice would not sufficiently expedite the clearance of product for participants of FAST. However, an overwhelming majority of the comments favor reducing the timeframe for FAST participants to 30 minutes. Under the

CBP Advance Electronic Information Rule, the time element for FAST participants is 30 minutes. The comments state that to have two different time standards for the same mode of transportation only serves to create confusion. The comments believe that any harmonization of FDA and CBP security programs would assist the orderly flow of trade at the border crossing points.

The comments contend that the key premise behind the FAST program is that low-risk parties should receive expedited treatment at the border, freeing up enforcement resources to concentrate on parties of higher or unknown risk, which is why the timeframes CBP adopted are shorter for FAST than for other shipments. If FDA adopted the 30 minute timeframe, it would demonstrate a commitment to harmonizing with CBP, and prevent a situation whereby FAST requirements vary depending on the type of commodity being transported. Finally, one comment believes that to ensure consistency with FAST and CBP's Automated Commercial Environment (ACE),⁴ prior notice should be required and calculated from the port of entry and not the first point of arrival, as is currently the case.

(Response) Harmonized timeframes could facilitate the orderly flow of trade traffic at the borders. Advance screening of consistent information also would aid in reducing the review time. However, as we discuss later in section II.F of this document ("When must prior notice be submitted to FDA? (§ 1.279)"), we are maintaining the timeframes that are in the IFR. These timeframes represent the minimum amount of time FDA needs to meet the statutory responsibility to receive, review, and respond to prior notice submissions. Our assessment of the timeframes and review times showed that we would not be able to reduce the timeframes to correspond to those used by CBP for land and air shipments.

iii. *Should the security and verification processes in C-TPAT be modified in any way to handle food and animal feed shipments regulated by FDA? If so, how?* (Comments) Four comments respond that the security/verification processes of C-TPAT/FAST should be modified for food. Fourteen comments respond that the process should not be modified for food. Most comments suggest that the current validation processes are sufficient and

caution that additional FDA inspection would be redundant. Many of these comments state that C-TPAT is a well-thought-out program and that with its current security profile requirements and present followup verification systems, the program is already well suited to handle human and animal food shipments. The comments suggest that FDA should rely on CBP's successful programs and avoid "recreating the wheel" or imposing new and potentially inconsistent criteria on food companies. The comments further contend that food safety and product integrity is already an integral part of the industry's own internal policies, which have always been concerned and accountable for the safety and security of their products without regard to the more recent border security program. Therefore, companies certified under C-TPAT have made the critical security investments and have bolstered their operations to provide the requisite security and integrity of their trade transactions, regardless of the commodities (food or nonfood products) that are shipped. Another comment stresses that FDA should not impose additional conditions of participation for FAST members because the requirements for FAST participation imposed by CBP provide adequate assurance that expedited clearance is appropriate.

(Response) FDA agrees with the statement in CBP's March 25, 2005, FAQ document that says "For C-TPAT to ensure its continued viability, effectiveness, and relevance, the program must continue to evolve—as the terrorist threat and the nature of global trade evolves. The impetus for strengthening the existing security guidelines is to provide more detail to the membership on the expectations of the program, and to assist CBP in defining a more consistent baseline for minimal program requirements and better-defined C-TPAT benefits." The issue of how to modify the processes is discussed in the next comments and responses.

(Comments) Numerous comments provide suggestions on how to modify the security/verification processes of C-TPAT/FAST. These include:

- FDA should investigate security plans with actual physical inspections of the facilities prior to allowing participation in the programs.

- FDA should verify that other countries' regulatory systems for food production and safety are equivalent to those of the United States. The agency should also perform on-site audits and inspection of production facilities

⁴ The ACE system will replace the current ABI/ACS, as well as combine other CBP entry functions and transactions. Prior Notice submissions will be compatible with ACE.

before a food manufacturer or carrier can be certified.

- It should be mandatory for food manufacturers to provide notice concerning any changes in the manufacturing processes or supplies, as well as those that may affect physical and personnel security. In addition, the current requirements that manufacturers periodically review the security commitment of their service providers to detect weakness or potential weaknesses in security should be altered to require that: (1) The review is conducted on an annual basis and (2) a certification that the review has been conducted.

- FDA and CBP should work together, along with the trade community, to identify potential areas where the C-TPAT security and verification processes can or should be modified. CBP and FDA should coordinate these processes to address the additional concerns of the FDA in order to allow C-TPAT/FAST members expedited processing of food and feed shipments in addition to CBP shipments.

- C-TPAT requirements should encompass any industry and food specific security measures into C-TPAT's checklist.

- These processes must be more comprehensive. There are no questions on the Supply Chain Security Profile Questionnaire to specify the type of freight being hauled. In addition, there are no opportunities in the questionnaire to indicate different locations to which a company is shipping regularly, or insurance a company has to cover those states.

(Response) FDA notes that CBP has continued to expand the C-TPAT program, which now includes minimum security criteria for importers who participate in C-TPAT. FDA also notes that as of July 10, 2006, CBP has received over 11,000 C-TPAT applications of which 6,089 have been certified and 2,973 have been validated (certified members provide a complete security profile that is screened by CBP, while validated members also undergo a complete validation of their security profile that includes an on-site visit to the company to review the submitted security profile, followed by a physical verification of security measures). There are limited resources at this time to add new significant program requirements to meet FDA's needs under the Bioterrorism Act and verify that those procedures have been incorporated. The two agencies will continue to explore the feasibility of the approaches recommended in the comments in the future.

c. *Flexible alternatives.* In the **Federal Register** document to reopen the comment period, FDA and CBP also requested comment on the following questions regarding flexible alternatives (69 FR 19763 at 19764):

- If timeframes are reduced in FDA's prior notice final rule, would other flexible alternatives for participants in FAST or for food imported by other agencies be needed?

- In considering flexible alternatives for food imported by other government agencies, what factors or criteria should FDA consider when examining alternatives? Should participation be voluntary? If so, should FDA consider inspection of companies in the supply chain from the manufacturer to those who may hold the product, including reviews of their security plans to determine what procedures are in place to prevent infiltration of their facilities as a condition of participation?

- In considering flexible alternatives for submission of prior notice, should FDA consider additional means of ensuring that all companies subject to the Registration of Food Facilities Interim Final Rule ((68 FR 58894, October 10, 2003) (21 CFR part 1, subpart H)), have an updated registration on file with FDA that has been verified?

- Are there conditions of participation that FDA should consider; e.g., inspections of companies in the supply chain from the manufacturer to those who may hold the product, or reviews of their security plans to determine what procedures are in place to prevent infiltration of their facilities?

- Should the food product category be considered as a criteria or element of expedited prior notice processing or other flexible alternatives? If so, should certain foods be excluded from expedited prior notice processing? If so, what should be the basis for determining which foods should be excluded?

- If FDA adopts reduced timeframes in the prior notice final rule, should FDA phase in the shorter timeframes as CBP phases in the advance electronic information rule?

- Should FDA offer a prior notice submission training program for submitters and transmitters, including brokers, to ensure the accuracy of the data being submitted?

This section will address the comments to each of those questions introduced in the **Federal Register** of April 14, 2004, beginning with general comments.

(Comments) One comment said that if the final rule is refined, then it is not necessary to offer additional flexible

alternatives. Several comments state that any flexible alternatives should be incorporated into existing programs because the duplication of security programs and division of limited resources are not in the best interest of our security goals and the protection of public health.

(Response) FDA believes that additional flexible alternatives should be incorporated into existing programs when appropriate and feasible. FDA will continue to work with CBP and acknowledges that the additional information provided by other programs such as C-TPAT could be helpful for purposes of admissibility decisions.

i. *If timeframes are reduced in FDA's prior notice final rule, would other flexible alternatives for participants in FAST or for food imported by other agencies be needed?* (Comments)

Several comments encourage incorporation of prior notice requirements into the C-TPAT and FAST programs. Most comments caution that additional requirements should not be added as separate programs, but that FDA should recognize participants in the existing programs for expedited review and processing of prior notice. One comment further suggests that participation in C-TPAT and FAST should also ensure expedited 801(a) admissibility processing. Another comment suggests that CBP be solely responsible for administering both the FDA and CBP requirements of C-TPAT and FAST.

(Response) As we discussed previously, we have determined not to provide C-TPAT members with special treatment in terms of reduced prior notice information requirements or reduced timeframes. FDA, however, is continuing to explore with CBP and industry use of these programs in making decisions regarding which products to inspect for the purposes of admissibility (801(a) decisions).

FDA disagrees with the comment's suggestion that CBP be solely responsible for administering both the FDA and CBP requirements for these programs, as the expertise related to food safety and possible additional participation requirements that address food safety resides in FDA. Accordingly, FDA and CBP will continue to consider how to administer FAST and C-TPAT programs so that they could apply to FDA regulated products.

ii. *In considering flexible alternatives for food imported by other government agencies, what factors or criteria should FDA consider when examining alternatives? Should participation be voluntary? If so, should FDA consider*

inspection of companies in the supply chain from the manufacturer to those who may hold the product, including reviews of their security plans to determine what procedures are in place to prevent infiltration of their facilities as a condition of participation?

(Comments/Response) There were no comments addressing flexible alternatives for food imported by other government agencies. However, FDA has considered imported shipments of foods for official U.S. federal government use and our draft policy for enforcing prior notice in these situations is contained in the Prior Notice Final Rule Draft CPG that is announced elsewhere in this issue of the **Federal Register**. Under the draft policy, FDA and CBP should typically consider not taking any regulatory action when an article of food is imported or offered for import for an official government purpose, provided that a Federal Government agency is the importer of record.

(Comments) Many comments advise that voluntary participation enhances the success of these programs.

(Response) C-TPAT is a voluntary, incentive based partnership. As we continue exploring use of the C-TPAT and FAST programs in making decisions regarding which products to inspect for the purposes of admissibility (801(a) decisions), it will be based on the assumption that participation should remain voluntary.

iii. *In considering flexible alternatives for submission of prior notice, should FDA consider additional means of ensuring that all companies subject to the Registration of Food Facilities Interim Final Rule ((68 FR 58894, October 10, 2003) (21 CFR part 1, subpart H)), have an updated registration on file with FDA that has been verified?* (Comments) Several comments reiterate that it is not necessary for FDA to provide flexible alternatives that exceed or augment CBP's existing programs, including a requirement to have an updated and verified registration on file with FDA. However, another comment believes that companies eligible to participate in low-risk programs should have an updated registration and that verification of that registration would be useful in determining low-risk status. Another comment assumes that verification of registration with FDA should have been conducted under CBP's current validation aspect of the C-TPAT program.

(Response) FDA agrees that participants designated as low risk should have an updated and verified registration of all facilities subject to 21

CFR part 1, subpart H. FDA also agrees it would be efficient to conduct the verification as part of the C-TPAT validation process, but neither FDA nor CBP has the resources to do so at this time.

iv. *Are there conditions of participation that FDA should consider; e.g., inspections of companies in the supply chain from the manufacturer to those who may hold the product, or reviews of their security plans to determine what procedures are in place to prevent infiltration of their facilities?* (Comments) Most comments suggest that other conditions, such as inspection of other companies in the supply chain would be unnecessary and a repetition of effort with little return on investment. Another comment states that to begin a process of examining the security plans and procedures of foreign food facilities would be tremendously expensive, call into question the validity of the prior notice and registration requirements already in place, and the efficacy of the targeting tools FDA employs.

(Response) We agree that adding conditions for C-TPAT participation and validating them to meet the purpose of the Bioterrorism Act would be extremely expensive and potentially only benefit a small number of those entities subject to this rule. We do not believe that this is the best use of our limited resources at this time, particularly as we have not experienced significant impacts on the flow of trade as a result of the timeframes in the rule since the IFR took effect on December 12, 2003.

v. *Should the food product category be considered as a criteria or element of expedited prior notice processing or other flexible alternatives? If so, should certain foods be excluded from expedited prior notice processing? If so, what should be the basis for determining which foods should be excluded?* (Comments) While one comment asserts that the food product category be considered an important element of expedited processing, most other comments state that no product category distinctions should be made. One comment states that to allow items imported under food product categories to qualify for expedited prior notice could easily lead to abuse of the system intended to protect us from terrorist attack. Other comments suggest that all food products be treated in the same manner and be subject to the same regulations. Most comments state that no product should be specifically included or excluded from participation, but that the criteria for participation should be focused solely on attributes of the company and a

company's ability to meet the program standards set by the particular government agency.

(Response) FDA agrees in part that no product category distinctions should be made. However, FDA acknowledges that some foods are more susceptible to terrorism and food safety problems than others, regardless of the processes within the supply chain. But if we were to make product category distinctions, such actions could be disruptive to transportation (e.g., we may need to segregate products) and may make such products targets for terrorism since such products may be eligible for special (e.g., expedited) treatment.

vi. *If FDA adopts reduced timeframes in the prior notice final rule, should FDA phase in the shorter timeframes as CBP phases in the advance electronic information rule?* (Comments/Response) Comments addressing phase-in of timeframes are found under the discussion of § 1.279 "When must prior notice be submitted to FDA."

vii. *Should FDA offer a prior notice submission training program for submitters and transmitters, including brokers, to ensure the accuracy of the data being submitted?* (Comments/Response) Most comments support additional training for submitters and transmitters. Additional discussion of training is found under section III. M (Outreach and Enforcement) of this document.

7. Additional Exclusions Requested—Samples

(Comments) Numerous comments request an exclusion from the requirements of prior notice for samples used in trade fairs, market research, market testing, and laboratory analyses (i.e., quality analysis/quality control (QA/QC) samples, scientific research, compositional analyses, research and development, standard of identity confirmation testing or quality comparison testing). The comments state that QA/QC samples are clearly not destined for consumption and will never enter the food chain or be consumed by the general public, thereby placing samples in a low-risk category. In addition, the comments note that these samples are often imported in very small quantities for a specific purpose. Samples used for organoleptic analyses will be consumed in very small quantities as part of the analytic procedures in a laboratory setting. In the case of trade samples, the comments contend that although the food will be consumed, the consumption is minor and is contained within a controlled environment, such as a test kitchen or trade booth.

In addition, the comments suggest some ways in which the burdens for submitting prior notice for samples could be less cumbersome. These recommendations include:

- Exempt all samples or some subset of samples, e.g., analytical, research, consumer complaint;
- Set a limit of the quantity of samples in each shipment and do not require prior notice for quantities below this limit;
- Exempt samples from the requirement to provide the manufacturer's registration number;
- Include a field in the prior notice in which a filer can indicate that the item(s) is a sample, and eliminate certain data elements if this field is flagged (i.e., registration number);
- Allow a single prior notice without registration numbers for commingled shipments of many small sample items falling under the same or similar FDA product codes;
- Allow shippers to provide a pre-approved list of customers who may receive samples in a particular month, on a monthly basis in lieu of filing individual prior notices;
- Specify procedures in the final rule for clearly identifying samples, such as the inclusion of a statement on the airway bill of lading that says: "Quality Evaluation and Research and Development Use Only—Resale Prohibited;" and
- Provide a limited exemption for intra-corporate (within the same company) samples.

One comment requests that FDA exempt foods for exhibit at trade shows and food samples. The comment reasons that these foods are not intended for consumption in the United States, but are imported for "show" and sampling at the trade shows, not for later general consumption. The comment further reasons that the quantity involved with each shipment is minuscule, usually no more than five hundred consumer units, which is too small a quantity to pose a potential national security threat.

Another comment states that there should be a *de minimis* provision for samples from known shippers/importers that is "cross-referenced" by shipper facility registration, manufacturer facility registration, importer facility registration, low value, and low weight.

(Response) Many samples of food, including those for test marketing, are "articles of food imported or offered for import," as stated in section 801(m) of the act. If, however, the samples are items that are in such early stages of research and development that they cannot yet be considered food under § 1.276(b)(5) of the final rule, they

would not be subject to prior notice requirements. In addition, if the sample is in a form that is not an article of food, such as a slurry of lettuce for pesticide analysis, then prior notice requirements would not apply. But where a sample is food, as defined under prior notice, the sample is not excluded from the final rule even if it is imported or offered for import for quality assurance, research or analysis purposes only, not for human or animal consumption and not for resale. However, as outlined in the Prior Notice Final Rule Draft CPG, FDA's and CBP's enforcement discretion policy would apply to these foods, under which FDA and CBP should typically consider not taking any regulatory action when there is no prior notice and the food is a sample not intended for human or animal consumption.

Samples of food are considered to be for quality assurance, research or analysis purposes, rather than human or animal consumption, when they are in small quantities (i.e., quantities consistent with the quality assurance, research, or analysis purposes) and the entire sample is used up by the analysis, destroyed after analysis, or destroyed following a reasonable retention period after analysis. The analysis may include sensory examination, such as organoleptic examination for determining tea quality or detecting the presence of histamines. Evidence that an article of food is for quality assurance, research, or analysis purposes only might include, among other evidence, markings on the food and shipping documents.

FDA disagrees with the comments that suggest that prior notice should only be required for food, including samples, that is intended for consumption. In the preamble to the IFR, FDA discussed extensively its rationale for not limiting the prior notice requirements to food for consumption in the United States. (See 68 FR 58974 at 58990 and 58991.) This rationale still holds. FDA also disagrees with the comments that state samples should be exempted from prior notice if the consumption of the samples is minor and is contained within a controlled environment, such as a test kitchen or trade booth, or the quantity involved with each shipment is minuscule, such that it "is too small a quantity to pose a potential national security threat." The purpose of the Bioterrorism Act is not limited to terrorist activity or other national security threats; its purpose is "[t]o improve the ability of the United States to prevent, prepare for, and respond to bioterrorism and other public health emergencies" [emphasis added]. (Public

Law 107–188.) Moreover, we have had incidents where small quantities of samples that had been consumed caused serious illness or death. For example, in the preamble to the IFR, FDA noted that "in the summer of 2003, FDA received a report from a poison control center in country T concerning the acute poisoning of 9 men (one died) from ingestion of an herbal fermented wine. Symptoms occurred within minutes. Reports indicated that this product may have been exported to the United States in small quantities for test marketing in restaurants. This underscores the importance of FDA receiving prior notice of all food imported or offered for import." (68 FR 58974 at 58993.)

8. Additional Exclusions Requested—Mail

(Comments) One comment sought better information regarding the sending of food products as international packages or bringing food products into the United States personally in their baggage.

(Response) Information on the sending of food through international mail can be found at: <http://www.cfsan.fda.gov/~pn/pnmail.html>. Food products for personal use brought into the United States that accompanies an individual are not subject to the requirements of prior notice (§ 1.277(b)(1)).

(Comment) One comment questions whether express couriers, such as EMS, FEDERAL EXPRESS, DHL, and TNT, are considered "international mail."

(Response) Section 1.276(b)(8) of the final rule defines international mail to mean foreign national mail services and further states that international mail does not include express consignment operators or carriers or other private delivery services unless such service is operating under contract as an agent or extension of a foreign mail service. Therefore, if food items are shipped through one of these services and the food items are not otherwise excluded from prior notice requirements, prior notice is required.

(Comments) One comment questions if the rule applies to the military postal service, which is a subsidiary of the United States Postal Service that operates overseas.

(Response) If the military post offices are located outside of the United States, as defined for the purposes of prior notice, articles of food would be subject to the requirements of prior notice (§ 1.277(a)).

(Comments) One comment states that the costs and resource implications of FDA applying this type of approach to single-piece, person-to-person,

international mailings of manufactured food products may outweigh any perceived benefits. FDA's current approach to prior notice forces the U.S. Postal Service (USPS), FDA, and CBP to dedicate substantial resources simply to attempt effective implementation of these regulations. The comment asks that FDA: (1) Exempt these single-piece, personal use mailings from prior notice; (2) allow CBP to continue using its time-tested strategies for screening and selections of items from mail shipments arriving at the first port of entry; (3) allow the delivery of mail items containing food, even if the contents are not accompanied by prior notice confirmation numbers to the U.S. address, as long as the U.S. authorities find no problem with the contents at border inspection; and (4) work in close coordination with CBP and USPS to promote more clarity of understanding on the procedures for packages where the majority of the contents are not food items. The comment states that these policies will need to be uniformly applied, and also must ensure that proper accountability is provided to the mailers and recipients whose mailed items might have been refused, seized, or destroyed.

Another comment requests an exemption for manufactured food products that are sent via international mail for noncommercial purposes. Some comments complain that the required data are very complex for the average customer and the system is not very customer-friendly, entries take a long time, and each single item has to have a separate prior notice.

A few comments state that most of the required information, such as the manufacturer's registration number, is not available to private persons, and therefore, not available to international mail and mail by express carriers. The comments note that this is particularly problematic, since FDA does not provide information on registration of facilities to private parties. The comments further note that a business relationship between the buyer of the goods (e.g., a private person), the mail service and the manufacturer will in general not be present. In addition, the comments state that to file prior notice, Internet access and knowledge of the English language is required. The comments contend that mail users will have to bear unreasonable disadvantages and unequal treatment. The comments argue that this seems disproportionate because most shipments are of low value. Therefore, the comments suggest that FDA simplify the prior notice requirements through FDA's PNSI for mail users.

In addition, the comments suggest that: (1) Private persons should be excluded from prior notice; (2) the requested information should be limited to some key-information, such as the submitter and the type of food; (3) all mail services, including express carriers, should fall under the definition of "international mail;" and (4) FDA should provide on their Web site dedicated information for companies and consumers about international mail, in different languages.

(Response) The act does not exempt noncommercial shipments with a noncommercial shipper. FDA explained this position in the preamble to the IFR (See 68 FR 58992) and believes that this rationale is still valid. However, under the Prior Notice Final Rule Draft CPG, when food is purchased or otherwise acquired by an individual for nonbusiness purposes and sent to an individual with a noncommercial shipper, FDA and CBP would typically consider not taking regulatory action if prior notice is not submitted. This proposed enforcement discretion policy would be continued from the Prior Notice Interim Final Rule CPG.

Express consignment operators or carriers or other private delivery services, unless such service is operating under contract as an agent or extension of a foreign mail service, are not considered international mail. (See § 1.276(b)(8) of the final rule). The IFR created a category for international mail because the rule imposed slightly different requirements for such imports. For example, given the nature of international mail imports, prior notice required the planned date of mail instead of the anticipated arrival information; it required the identification of the recipient instead of the importer, owner, and consignee; and it did not require the mode of transportation, carrier, planned shipment information, and hold information. In addition, for international mail the prior notice must be submitted before the article of food has been sent in order to allow the prior notice confirmation number to accompany the package. We do not believe these changes are relevant for shipments arriving by express consignment operators or carriers or other private delivery services. For example, if the express carrier submits the prior notice, it will be able to include the mode of transportation, carrier, and other data elements not included in the international mail category. In situations where the submitter and/or transmitter is not the express consignment operator or carrier, the final rule now allows the

submission of the express consignment operator or carrier tracking number in lieu of anticipated arrival and certain planned shipment information. Thus, we do not believe the final rule should be revised to expand the definition of international mail to include express consignment operators or carriers or other private delivery services.

FDA also does not agree the prior notice requirements should not apply to low-value shipments, as neither the Bioterrorism Act nor experience with samples support this approach. See FDA's responses to comments previously under section III.D.7 of this document "Additional Exclusions Requested—Samples" for further discussion on this point.

(Comments) A few comments suggest that FDA modify the existing procedures for commercial shipments arriving by international mail. The comments state that complying with the requirements of FDA's prior notification procedure results in an unbearable workload for mail order companies, which sometimes mail thousands of packages at one time, with each package requiring a prior notice. The comments suggest that manufacturers submit their company information and product information for similar items once and then add the different recipients' addresses at the end.

(Response) FDA's PNSI has been designed to accommodate repetitive information so that the basic prior notice can be created and saved, and each U.S. recipient can be added at the end of each subsequent prior notice. A separate prior notice confirmation number is generated for each article of food (and recipient). Similarly, a number of the software programs that customs brokers use to file prior notice and entry submissions with ABI/ACS do allow for repetitive information to be saved on the filer's computer and used for future shipments, as appropriate.

9. Additional Exclusions Requested—Gifts

(Comments) Several comments recommend that FDA expand the exemption already provided for homemade food products sent as gifts (§ 1.277(b)(2)) or food items carried in for "personal consumption" (§ 1.277(b)(1)) to include all gifts, regardless of mode of transportation, that are intended for personal use. Another comment asks for clarification regarding food articles sent as gifts to persons in the United States for personal consumption. This comment believes that prior notice is only required for food articles that will be

distributed or traded in the United States.

(Response) If the food was made by an individual in his/her personal residence and sent by that individual as a personal gift (i.e., for nonbusiness reasons) to an individual in the United States, prior notice is not required (§ 1.277(b)(2)). Other food products sent by an individual and imported for noncommercial purposes with a noncommercial shipper are not excluded from prior notice requirements. FDA explained this position in the preamble to the IFR (See 68 FR 58992) and believes that this rationale is still valid. However, under the Prior Notice Final Rule Draft CPG, when gifts are shipped by an individual for nonbusiness reasons to an individual without prior notice, FDA and CBP should typically consider not taking regulatory action. This proposed policy would apply regardless of the mode of transportation.

10. Additional Exclusions Requested—Low-Value

(Comments) Many comments request a *de minimis* exemption from prior notice for all low value shipments (less than \$200). The comments assert that the prior notice requirements can be quite onerous for small shipments and that low value shipments of prepared food sent from and to individuals for their personal use are of little risk to the U.S. food supply, especially relative to the individual size and large number of commercial shipments entering the country. One comment states that a low value exemption from prior notice for shipments under \$200, whether for personal or commercial use, would be consistent with CBP's *de minimis* exemption. In addition, one comment states that foreign individuals shipping low value gifts to the United States will not know the Bioterrorism Act's requirements and will not be able to obtain the manufacturer's phone and registration numbers. The comment states that these numbers are not readily available to the consumer when products are purchased in small quantities. One comment requests an exemption for small dollar value mail-order sales to U.S. customers (\$100 or less) since the prior notice system is difficult and costly to implement for this type of business.

(Response) FDA disagrees. Low-value shipments are clearly subject to the terms of section 801(m) of the act as they are "articles of food imported or offered for import." Moreover, low-value articles of food can pose the same threat level to the U.S. food supply as do articles of food that cost more, as we

explained in the IFR (68 FR 58974 at 58993). However, under the proposed enforcement discretion policy, described in the Prior Notice Final Rule Draft CPG, when food is sent by an individual for noncommercial purposes with a noncommercial shipper without prior notice, regardless of the article's value, FDA and CBP should typically consider not taking any regulatory action.

(Comments) Two comments recommend that FDA consider incorporating into the final rule a limited exemption for very small quantities of food. One of those comments considers a small quantity to be under 80 pounds or less than 100 bottles.

(Response) FDA disagrees and will not place a weight or quantity restriction on the requirements for prior notice. "Small quantity" shipments are clearly subject to the terms of section 801(m) of the act as they are "articles of food imported or offered for import." Similar to low-value articles of food, small quantity shipments can pose the same threat level to the U.S. food supply as do articles of food that arrive in larger quantities. If we were to exempt small quantity food shipments, small quantities of poisoned food (with the potential to do a high level of damage) could be imported into the United States without prior notice, thereby negating the purpose of the Bioterrorism Act.

11. Additional Exclusions Requested—Couriers

(Comments) One comment reports that many of the express couriers refuse to do the necessary paperwork for shipments being sent via their services. Therefore, the manufacturers are required to submit prior notice. However, the manufacturer does not have the necessary information needed to complete the form, such as flight number, departure and arrival time, etc. The comment suggests that express courier shipments should be treated in the same manner as mail shipments.

(Response) FDA disagrees but has modified the rule to address the underlying concern. Food imported or offered for import via these private delivery services are subject to prior notice, which must be submitted within the timeframe of the applicable mode of transportation—water, air, or land (§ 1.279). In the prior notice CPG published in November 2004 (November 9, 2004; 69 FR 64959), FDA and CBP stated that they generally would consider not taking regulatory action if the prior notice is inadequate because it does not include the required

anticipated arrival information and/or planned shipment information and if, among other criteria, the prior notice includes the shipment's tracking number in lieu of the required anticipated arrival information and/or planned shipment information. A person shipping food into the United States via an express courier will have access to the tracking number to use in lieu of the flight number or other planned shipment information. FDA has incorporated this policy in § 1.281 of the final rule, which allows the submitter and/or transmitter to submit the express consignment operator or carrier tracking number in lieu of anticipated arrival and certain planned shipment information as long as neither the submitter nor transmitter is the express consignment operator or carrier and prior notice is submitted via PNSI.

12. Additional Exclusion Requested—Gift Packs

(Comments) One comment requests clarification of the interpretation pertaining to gift baskets. The comment states it is unclear whether prior notice is based upon the description of the entire gift basket as an entity, which is currently the case for CBP entry processing, or on the individual items within the basket. One comment asks FDA to exempt gift baskets because they are "no-risk."

(Response) Under the final rule, a gift pack is not considered a single article of food (e.g., a gift pack consisting of four articles of food would require four prior notice submissions). This is because a gift pack is not manufactured/processed as a single product, but is packed by consolidating a variety of articles of food into a unit, with or without other nonfood articles. However, FDA and CBP are proposing to continue their enforcement discretion policy for gift packs, which the agencies first announced in their March 2005 CPG (March 4, 2005; 70 FR 10657). Under that policy, "FDA and Customs Border Protection (CBP) staff should typically consider not taking regulatory action if there is a prior notice violation because a single prior notice is submitted for a gift pack and the identity of the facility that packed the gift pack is submitted in lieu of the identity of the manufacturer(s), provided that the gift pack is purchased or otherwise acquired by an individual and imported or offered for import for nonbusiness purposes."

There is no CBP rule or regulation, nor is there a General Rule of Interpretation (GRI) under which gift packs are classified. In the case of "gift packs" that contain multiple products,

CBP tries to classify the gift pack using the concept of a set. That is, if the products included in a gift pack are part of a common activity, the gift pack may be classified under the HTS code that is most applicable. However, CBP does not consider eating to be a common activity, even when all items in a gift pack are to be consumed. Therefore, unless there has been an applicable CBP ruling, entries of gift packs should be declared to CBP using the HTS code for each item included within the gift pack. This principle applies even when there are food and nonfood items in the pack (e.g., a soup mug and a can of soup) as well as for make-your-own gift packs (e.g., if you created a gift pack by personally selecting individual items from a list of available products).

13. Additional Exclusions Requested—Household Goods and Unaccompanied Baggage

(Comments) Many comments suggest that the final rule exempt unaccompanied food that is included in a shipment of personal household goods, if the food is owned by and intended to be consumed by the shipper of the household goods, their family or friends, and if the food is not to be offered for sale or distribution. In addition, several comments suggest that food contained in unaccompanied baggage should be exempt from the requirements of prior notice. The comments state that the owner of the food never changes, and that there is no sale or transfer of the goods. The comments believe that shipping food items contained in household goods or unaccompanied baggage to the United States is equivalent to carrying the items in baggage for personal use. The comments further state that household goods are even more personal than food accompanying a traveler because although it travels from one personal residence to another, it remains part of the same household or home. The comments suggest that FDA not require as many data elements for these types of shipments, and allow a minimum amount of food/consumables to be imported without prior notice. The comments believe that it will be unnecessarily tedious and exhaustive for individuals to input the required information into the FDA PNSI, and that it is unreasonable to ask individuals to destroy or leave behind hundreds of dollars of canned goods.

Additionally, one comment suggests that persons on duty in the United States as members of the armed forces of a North Atlantic Treaty Organization (NATO) or Partnership for Peace or civilian component attached to or

employed by NATO Headquarters, Supreme Allied Commander Transformation Atlantic and their immediate families be granted an exemption from prior notice. The comment contends that these individuals have undergone an intense screening process prior to being selected for a NATO position. One comment requests that FDA exempt Department of Defense active duty military and civilian personnel unaccompanied baggage and household good shipments.

(Response) Section 801(m) of the act does not authorize an exclusion from prior notice for food imported as part of unaccompanied baggage or food included as part of a shipment of personal household goods. Therefore, food contained in household goods and accompanied baggage are subject to prior notice requirements.

However, a proposed enforcement discretion policy in the Prior Notice Final Rule Draft CPG would apply to most or all of the household goods and unaccompanied baggage shipments described in the comments. Under the proposed policy, FDA and CBP should typically consider not taking any regulatory action when an article of food is imported or offered for import for noncommercial purposes with a noncommercial shipper without prior notice. We consider food in household goods, including military and civilian transfers, to be food imported or offered for import for a noncommercial purpose. This enforcement discretion policy would be a continuation of the policy in effect since FDA issued the June 2004 Prior Notice Interim Final Rule CPG (June 29, 2004, 69 FR 38906).

14. Additional Exclusions Requested—Noncommercial Use

(Comments) One comment asserts that shipments for personal consignment when sent from a business are, by definition, noncommercial, due to the fact they are purchased for personal use and not for resale. The comment suggests that FDA define noncommercial shipments to include any consignment to an individual for personal, noncommercial use, as exempt from the requirements of prior notice, regardless of whether the shipper is a business entity or an individual.

(Response) FDA disagrees. As we described in the IFR, there is no basis in the statute for an exemption based on shipments that are for personal use, regardless of whether the shipper is a commercial or noncommercial (i.e., an individual) entity (68 FR 58974 at 58992). However, we are proposing an enforcement discretion policy in the Prior Notice Final Rule Draft CPG for

food imported or offered for import for noncommercial purposes with a noncommercial shipper without prior notice, irrespective of the type of carrier. Under the proposed policy, FDA and CBP should typically consider not taking any regulatory action when an article of food is imported or offered for import for noncommercial purposes with a noncommercial shipper without prior notice. The noncommercial shipper, under this policy, would be an individual (e.g., the individual delivers the food to a post office or common carrier for delivery to self, family member, or friend for nonbusiness purposes).

When a business ships a food, it is for a commercial or business purpose. The situation as described in this comment, therefore, would not meet the criteria covered by the enforcement discretion policy since the shipper is a business.

(Comments) One comment requests that private persons should be excluded from the requirements of prior notice. The comment states that commercially-produced food imported for the personal use of an individual, even if included in a shipment of personal effects, should not require prior notice.

(Response) Section 801(m) of the act does not authorize a broad exclusion from prior notice for food imported or offered for import by private persons. Therefore, food that is commercially produced that is imported for the personal use of an individual, as described in the comment, would be subject to this final rule.

However, we are proposing an enforcement discretion policy in the Prior Notice Final Rule Draft CPG for food imported or offered for import for noncommercial purposes with a noncommercial shipper, irrespective of the type of carrier without prior notice. Under the proposed policy, FDA and CBP should typically consider not taking any regulatory action when an article of food is imported or offered for import for noncommercial purposes with a noncommercial shipper without prior notice. This policy would cover the food described in the comment, commercially produced food imported for the personal use of an individual, as long as the shipper is noncommercial. This enforcement policy would continue the policy initially announced in our June 2004 Prior Notice Interim Final Rule CPG. The draft CPG describes a noncommercial purpose as one where the food is purchased or otherwise acquired by an individual for nonbusiness purposes, and a noncommercial shipper is one where the shipper is an individual (e.g., the individual delivers the food to a post

office or common carrier for delivery to self, family member, or friend for nonbusiness purposes, i.e., not for sale, resale, barter, business use, or commercial use). Examples of foods imported or offered for import that may be covered by this noncommercial category are: (1) Food in household goods, including military and civilian transfers; (2) food purchased by a traveler and mailed or shipped to the traveler's U.S. address by the traveler, not the commercial establishment; and (3) gifts purchased at a commercial establishment and shipped by the purchaser, not the commercial establishment.

(Comments) One comment suggests that older wines already owned by a U.S. individual and imported solely for personal consumption be exempt from prior notice. Another comment provides an example of an individual who owns a wine cellar overseas and arranges for cases of wine to be sent to him/herself in the United States for personal consumption.

(Response) As discussed previously, there is no basis in section 801(m) of the act to exclude food imported or offered for import for personal use. Although this importation is subject to the provisions of this final rule, if the wine is imported or offered for import by an individual for noncommercial purposes and shipped by himself to himself using a noncommercial shipper without prior notice, the proposed enforcement discretion policy in the Prior Notice Final Rule Draft CPG would apply. Under the proposed policy, FDA and CBP generally should typically consider not taking regulatory action when an article of food is imported or offered for import for noncommercial purposes with a noncommercial shipper without prior notice.

(Comments) One comment suggests that small shipments of nominal value for personal, noncommercial use should be exempted from the requirements of prior notice. The comment states that the express industry handles many of these shipments now, which include purchases from a growing number of Internet-based sellers. The comment asserts that these small shipments for personal use do not qualify as a risk to the domestic food supply, and should be exempt from prior notice.

(Response) As we discussed previously, section 801(m) of the act does not authorize an exclusion for small quantity or low-value shipments. FDA notes that under the Prior Notice Final Rule Draft CPG, FDA and CBP should typically consider not taking regulatory action when an article of food is imported or offered for import for

noncommercial purposes, such as small shipments for personal use, with a noncommercial shipper without prior notice. However, this proposed enforcement discretion policy would not extend to situations where the shipper is a commercial entity (e.g., a retail store, an Internet company, etc.).

15. Additional Exclusions Requested—U.S. Goods Returned

(Comments) A few comments request exemptions for unadulterated U.S. goods being returned. The comments state that these items do not pose an adequate threat to the nation's food supply. In addition, these comments indicate that it is not possible to provide the manufacturer's registration number for merchandise that was manufactured in the United States and then exported overseas, where the merchandise can be purchased and then shipped back to the United States. The comments state that the original manufacturer in the United States will not provide their registration number in these scenarios.

(Response) FDA disagrees. As discussed in the IFR, FDA believes that, for the purpose of section 801(m) of the act, the phrase "imported or offered for import into the United States" applies to articles of food of U.S. origin that are "reimported" back into the United States (68 FR 58974 at 58990). FDA believes that this interpretation, and the underlying rationale for it, are still valid. We also believe, as explained in the IFR, that section 801(m) of the act does not authorize us to exclude "low-risk" food shipments from prior notice requirements (68 FR 58974 at 58993).

The inability to submit the manufacturing facility's registration number is not a valid reason for excluding such a shipment from prior notice requirements. However, we are revising § 1.281(a)(6) of the final rule to provide flexibility in submitting the identity of the manufacturer. In addition to the name of the manufacturer, the submitter may submit either the registration number, city, and country of the manufacturer, or both the full address of the manufacturer and the reason why the registration number is not provided.

(Comments) One comment requests that FDA provide clear direction whether prior notice is required for food shipments of U.S. products that are returned to the United States after refusal by a foreign government.

(Response) FDA requires prior notice for an article of food that has been exported from the U.S. and is being "reimported" back into the U.S., as we consider such a shipment as being "imported or offered for import into the

United States" (§ 1.277(a)), regardless of whether it was initially a U.S. export that was refused by a foreign government. We would require prior notice for these shipments even if entry is not required by CBP. In these cases, we recommend that prior notice be submitted via PNSI.

16. Additional Exclusions Requested—In-Transit Shipments

(Comments) Several comments request that in-transit shipments be excluded from the prior notice requirements. The comments express concern that submitting prior notice for such shipments presents a tremendous burden on industry. Companies may seek to avoid the potential cost and disruption by diverting freight to other routes rather than use transshipment facilities through U.S. territory for destinations in Mexico and Canada.

The comments note that requiring prior notice for shipments not intended for consumption in the United States appears to be beyond the statutory authority provided by the Bioterrorism Act. The comments reason that in-transit shipments are under strict CBP regulations and control by the carrier with respect to movement and are secured by a bond, and thus, the food cannot be diverted to enter the U.S. food supply.

(Response) FDA disagrees. The IFR contains FDA's rationale and legal support for determining that for the purpose of section 801(m) of the act, the phrase, "imported or offered for import into the United States," applies to articles of food of U.S. origin that are "reimported" back into the United States, as well as to food that transits the United States (See 68 FR 58974 at 58990). FDA continues to believe this determination is correct and is not convinced it should be revised. Moreover, the comment implies that these shipments should be exempt from prior notice requirements since the shipments are under strict CBP control and are secured by a bond, i.e., that these shipments are low-risk. However, section 801(m) of the act does not authorize an exemption for articles of food that are "low risk" or covered by programs of other agencies, such as CBP or foreign government regulatory authorities.

(Comments) One comment requests that the final rule exempt foreign-to-foreign transit mail; i.e., mail shipments that simply transit the United States for delivery in a third country. The comment reasons that these items are not intended for U.S. consumption (i.e., not intended for a U.S. recipient); represent the transfer of universal

service obligation mail between sovereign governmental entities; and are items from foreign mailers who would not know when to submit the required prior notice data as they do not always know whether their mail dispatches will be transiting the United States.

(Response) As we explained in the IFR and elsewhere in this notice, food that is not intended for U.S. consumption is still within the scope of "imported or offered for import" (68 FR 58974 at 58991) and is subject to prior notice requirements. However, we understand that in the case of foreign-to-foreign mail, the sender does not have control over the transportation route that the foreign-to-foreign shipment will transit. Therefore, we are proposing an enforcement discretion policy in the Prior Notice Final Rule Draft CPG that would address this situation. Under that policy, FDA and CBP should typically consider not taking any regulatory action when an article of food is imported or offered for import via international mail without prior notice and there is no U.S. recipient.

(Comments) Comments filed by express carriers request that FDA exempt all non-U.S. destination shipments from the requirement to provide prior notice. The comments note that the shipment is in the custody of the express carrier at all times and the risk of diversion from the highly-controlled environment in which express shipments move, particularly in-bond shipments, is low. The comments also reason that foreign shippers and foreign consignees do not submit the required prior notice data because they are, by design, not aware that their shipments will transit the United States on their way to a third country because express carriers do not disclose flight routes of packages either to shippers or consignees due to security concerns. If prior notice must be submitted, express carriers will be required to make the customers aware of routes, nullifying this simple but effective security precaution.

(Response) As described in the previous comment, prior notice applies to food imported or offered for import notwithstanding that the food is not intended for U.S. consumption. However, we recognize that, when shipping via express carrier or other private delivery service, the sender does not have control over the transportation route that the foreign-to-foreign shipment will transit. For example, a person in Europe intends to mail an article of food to South America via an express carrier. This person has no control over the package entering the

United States if the express carrier, for example, chooses to consolidate shipments going to South America in Florida. The proposed enforcement discretion policy in the Prior Notice Final Rule Draft CPG states that FDA and CBP should typically consider not taking any regulatory action when an article of food is imported or offered for import and the carrier is an express consignment operator or carrier; neither the submitter nor transmitter is the express consignment operator or carrier; and the importer, owner, or recipient/consignee is not located in the United States.

(Comments) Several comments request that FDA exempt shipments of food that move from Canada to Canada under bond by rail through Northern Maine. These comments note that such shipments moving by rail in bond cannot be delivered to points within the United States, must move from Canada to Canada, and that the food products in trailers on rail cars cannot be diverted to enter the U.S. food supply. The comments state that having to submit prior notice puts the U.S. rail carriers at a competitive disadvantage when competing for Canadian rail business. Other comments request that FDA exempt shipments of food that move from Canada to Canada by marine and trucking companies. The comments reason that their Canada to Canada in-transit shipments move in sealed containers and that providing detailed information for products that are never going to enter the U.S. food supply is a hardship to U.S. businesses.

(Response) FDA disagrees. The Bioterrorism Act does not create any exemptions for this situation and therefore, there is no basis for excluding such business operations from prior notice requirements. The preamble to the IFR provides our rationale for determining that food that transits the United States falls under the scope of this rule (68 FR 58974 at 58990) and we continue to hold this view. Moreover, the comment implies that these shipments should be exempt from prior notice requirements because they pose a relatively low risk by moving by rail, in bond, and/or under seal. Even if such food shipments are a low risk, as discussed elsewhere in this notice, section 801(m) of the act does not authorize a "low risk" exemption. However, the proposed guidance in the Prior Notice Final Rule Draft CPG (which would continue the policy established in the March 2005 revision to the Prior Notice Interim Final Rule CPG) addresses imported food arriving from and exiting to the same country. It describes the situations and conditions

under which FDA and CBP should typically consider not taking regulatory action when prior notice is not submitted.

(Comments) Another comment suggests that the FDA work cooperatively with CBP such that transshipments that follow the CBP transshipment procedures are not required to enter additional information for FDA prior notice purposes, and that shipments that may pose a risk are identified through the CBP process. The comment also states that the current requirements in the agreement for secure in-transit procedures could be modified to meet the objective of the prior notice IFR to prevent the entry of products that have been intentionally adulterated. Shipments that follow the proposed secure in-transit procedures would not be distributed in the United States and would be of minimal risk to human or animal security and safety. The comment also suggests that FDA can achieve certainty of safety of overseas shipments that are transiting to the United States through Canada by conducting examinations at the first point of arrival in North America and through the expansion of existing bilateral harmonized risk screening and lockout sharing systems to accommodate additional high-risk commodities.

(Response) CBP's secure in transit procedures cannot substitute for the submission of prior notice for in transit shipments because they do not meet the requirements of the Bioterrorism Act, such as providing FDA with certain specified information. The information in a prior notice is necessary for FDA to determine whether it should examine the food at the U.S. port of arrival. In addition, section 801(m) of the act does not authorize an exemption for articles of food that are covered by programs of other agencies, such as CBP, even if those programs would "prevent the entry of products that have been intentionally adulterated."

(Comments) One comment notes that there are many ocean containers crossing into the United States for transshipment purposes and prior notice is not being submitted. The comment asks how to ensure that ocean containers that arrive in Canada or Mexico and cross into the United States by rail have prior notice submitted in a timely fashion, or submitted at all, when shippers are not always aware of when the containers are due to cross or on which train.

(Response) FDA addressed this issue in the IFR when it allowed any person with knowledge of the required information to submit prior notice. In

§ 1.285 of the proposed prior notice rule (68 FR 5428, February 3, 2003), FDA provided that a purchaser or importer of an article of food who resides or maintains a place of business in the United States or an agent thereof was authorized to submit prior notice. FDA further proposed that if the article of food is imported for in-bond movement through the United States for export, the prior notice must be submitted by the arriving carrier or, if known, the carrier making the in-bond entry. Many comments to the proposed rule objected to the limitation that only a person who resides or maintains a place of business in the United States can submit the prior notice. In addition, comments pointed out that under some circumstances, the U.S. importer or purchaser or carrier would not have all the information required by prior notice, but that other entities, e.g., the foreign manufacturer/ processor, shipper, or exporter, would have the required information. Many comments stated that entities other than U.S. firms or carriers should be allowed to submit prior notice.

In response, FDA modified this provision in the IFR and removed the restriction on who can submit prior notice. Accordingly, § 1.278 of the IFR provides that any person with knowledge of the required information may submit prior notice to FDA. FDA has retained this provision in the final rule.

17. Additional Exclusions Requested—Diplomatic Pouch

We have determined that prior notice does not apply to food in diplomatic pouches because Art. 27(3) of The Vienna Convention on Diplomatic Relations (1961) states that: “The diplomatic bag shall not be opened or detained.”

(Final Rule) Section 1.277(b)(7) of the final rule adds a new exclusion to the rule: “Articles of food subject to Art. 27(3) of The Vienna Convention on Diplomatic Relations (1961), i.e., shipped as baggage or cargo constituting the diplomatic bag.”

18. Additional Exclusions Requested—Seeds for Planting

(Comments) One comment requests that FDA exempt imported seed that is destined solely for planting purposes, even if small amounts found unsuitable for planting will end up in the food supply. The comment also requests that the FD3 flags be removed from HTS codes that cover seed for sowing or planting or, alternatively, to clarify that FD3 flagged HTS codes may be “disclaimed” at entry.

(Response) Whether seeds are subject to prior notice depends on whether the seeds meet the definition of food. Some seeds, such as sesame seeds for baking or as a garnish, are food for which prior notice must be submitted to FDA before the seed is imported or offered for import into the United States. Some seeds are capable of both food and nonfood uses, such as seeds that are sometimes processed into cooking oil and other times processed into industrial-use oil. As discussed elsewhere in this document, FDA considers such seed to be food for the purpose of prior notice if the seed is reasonably likely to be directed to a food use. Even when seed is for a nonfood use, such as seeds for growing flowers, if a small portion of that seed is reasonably likely to be directed for use in animal feed, prior notice would be required. Because seeds, including seeds for planting, may be subject to prior notice under section 801(m) of the act, we believe they are properly flagged as FD3.

Nonetheless, we note that the draft Prior Notice Final Rule CPG, announced elsewhere in this issue of the **Federal Register**, proposes an enforcement policy regarding seeds for planting. Under the draft policy, FDA and CBP should typically consider not taking any regulatory action regarding seeds that will be used for cultivation if they are imported or offered for import without prior notice. The policy would apply when no more than a small portion of that seed is diverted from cultivation to animal feed or other food use. It would not apply, however, where the seed is used for the production of edible sprouts, such as alfalfa seeds for the production of alfalfa sprouts.

E. Who is Authorized to Submit Prior Notice? (§ 1.278)

Section 1.278 of the IFR states that prior notice may be submitted by any person with knowledge of the required information and identifies this person as the submitter. The IFR also states that the submitter also may use another person to transmit the required information on his/her behalf and identifies the person who transmits the information as the transmitter. The IFR also states that the submitter and transmitter may be the same person.

(Comments) Several comments note that carriers often do not have access to the information required to classify articles in the FDA system (the commercial invoice and packing list) because it is proprietary information that the owners of the goods will not want to give to intermediaries in the transportation chain. Also, there is

confusion regarding who is responsible for submitting prior notice. This causes particular problems for carriers of in-bond cargo transiting the United States. The comment suggests that exempting in-bond shipments from prior notice would allow carriers to move the shipment without having to submit prior notice and permit the broker at the port of entry, who does get the necessary documents, to properly submit the prior notice. (Response) FDA disagrees that there is confusion regarding who is responsible for submitting prior notice. The IFR and this final rule expressly state in § 1.278 that any person with knowledge of the required information may submit the prior notice. FDA provided this flexibility as to who could submit prior notice in response to comments that FDA received on the proposed rule, which urged FDA not to limit who could file prior notice to either a purchaser or importer of an article of food who resides or maintains a place of business in the United States or an agent thereof, or to the arriving carrier or the carrier making the in-bond entry if the article of food is imported for in-bond movement through the United States for export. (See 68 FR 58974 at 58994.) Comments to the proposed rule also pointed out that under some circumstances, the U.S. importer or purchaser or carrier would not have all the information required by prior notice, but that other entities, e.g., the foreign manufacturer/ processor, shipper, or exporter, would have the required information. Many comments stated that entities other than U.S. firms or carriers should be allowed to submit prior notice. In response, FDA modified this provision in the IFR and removed the limitation on who can submit prior notice.

(Response) FDA disagrees that there is confusion regarding who is responsible for submitting prior notice. The IFR and this final rule expressly state in § 1.278 that any person with knowledge of the required information may submit the prior notice. FDA provided this flexibility as to who could submit prior notice in response to comments that FDA received on the proposed rule, which urged FDA not to limit who could file prior notice to either a purchaser or importer of an article of food who resides or maintains a place of business in the United States or an agent thereof, or to the arriving carrier or the carrier making the in-bond entry if the article of food is imported for in-bond movement through the United States for export. (See 68 FR 58974 at 58994.) Comments to the proposed rule

also pointed out that under some circumstances, the U.S. importer or purchaser or carrier would not have all the information required by prior notice, but that other entities, e.g., the foreign manufacturer/processor, shipper, or exporter, would have the required information. Many comments stated that entities other than U.S. firms or carriers should be allowed to submit prior notice. In response, FDA modified this provision in the IFR and removed the limitation on who can submit prior notice.

Accordingly, § 1.278 of the IFR provides that any person with knowledge of the required information may submit prior notice to FDA. FDA noted in the preamble to the IFR that any person may now take responsibility for submitting prior notice for a particular article of food, as long as that person can provide all the required information. This person is referred to as the submitter in the IFR. The IFR also states that the submitter may use another person to transmit the required information to FDA. For ease of reference, the person who transmits the prior notice is referred to as the transmitter in the IFR. FDA has retained these provisions in the final rule. FDA further notes that to the extent that there is confusion, the parties to the transaction may want to consider a means for identifying which party is responsible for submitting prior notice as part of their business arrangements (e.g., within their contract).

(Comments) Several comments note that problems arise because the IFR creates no particular obligation on any particular party within the distribution system to submit prior notice. One comment states that because prior notice can be submitted by any person who has the information, there are many cases of duplicate prior notices filed by different parties for the same shipment. Another comment suggests that FDA select one party to be responsible, suggesting the appropriate party would be either the exporter or the importer-broker.

(Response) Please see the response to the previous comments. FDA's proposed rule did specify a limited class of individuals who could provide prior notice and this limitation received significant adverse comment. Accordingly, both the IFR and this final rule provide that any person with knowledge of the required information may submit the prior notice (§ 1.278). FDA notes that the parties to a transaction can elect to take steps among them to identify which party should submit the prior notice and ensure that the party submitting prior

notice has the appropriate and correct information.

(Comments) One comment suggests that it is improper for a carrier to require the shipper to submit prior notice when the shipper is not shipping goods into the United States, but the carrier unilaterally moves the goods through their hub in the United States, thereby causing the shipment to enter the United States. Another comment notes that the data elements required in a prior notice are not available to the shipper, inferring that it is not possible for a shipper to submit prior notice.

(Response) Neither the IFR nor this final rule specifies who must file prior notice. Rather, the rule provides that any person with knowledge of the required information may submit prior notice to FDA. Accordingly, it is not for FDA to say whether it is proper for a carrier to require a shipper to submit prior notice as a condition of shipment, as that is a matter between two contracting parties. We note that the Prior Notice Final Rule Draft CPG proposes an enforcement policy for foreign-to-foreign mail. Under the proposed policy, if there is no prior notice FDA and CBP should typically consider not taking any regulatory action in the case of international mail where the recipient is not in the United States since the sender does not have control over the transportation route that the foreign-to-foreign mail will transit.

(Comments) One comment asks whether there are any prior notice obligations to fulfill if the exporter is not required to register with the FDA under the Bioterrorism Act (21 CFR part 1, subpart H).

(Response) Prior notice and registration are separate obligations under different regulations and with differing applicability. For example, registration applies to facilities that manufacture, process, pack or hold food that will be consumed by humans or animals in the United States. By comparison, prior notice generally applies to FDA-regulated food being imported or offered for import into the United States, regardless of whether it will be consumed in the United States and regardless of whether the exporter must register.

(Comments) One comment asks for clarification of the legal responsibility of the submitter.

(Response) Among the requirements of the final rule, the prior notice information must be accurate and timely. As described in § 1.283, if an article of food is imported or offered for import and the notice is inaccurate or untimely, the food is subject to refusal

of admission. Other consequences under the act for those who fail to comply with the prior notice requirements, such as by submitting inaccurate or untimely notice, are described in § 1.284.

(Final rule) Section 1.278 of the final rule states that prior notice may be submitted by any person with knowledge of the required information and identifies this person as the submitter. The final rule also states that the submitter may use another person to transmit the required information on his/her behalf and identifies the person who transmits the information as the transmitter. The final rule also states that the submitter and transmitter may be the same person.

F. When Must Prior Notice Be Submitted to FDA? (§ 1.279)

Section 801(m)(2)(A) of the act states that FDA shall by regulation prescribe the time of submission of the notification in advance of importation or the offering of the food for import, which period shall be no less than the minimum amount of time necessary for the Secretary to receive, review, and appropriately respond to such notification, and any timeframe FDA adopts in the final rule must be justified under this standard. Section 1.279(a) of the IFR requires FDA to receive prior notice and confirm it for review no less than 2 hours before arriving at the port of arrival by land via road, no less than 4 hours before arriving at the port of arrival by air and land via rail, and no less than 8 hours before arriving at the port of arrival by water. We explained in the preamble to the IFR that the "interim final rule provides for greatly reduced timeframes for foods [from what we had proposed] based on mode of transportation. These timeframes are what FDA has determined are the minimum timeframes necessary to allow it to satisfy the statutory mandate that the timeframes give the agency the time it needs to 'receive, review, and respond' to prior notices." (68 FR 58974 at 58995)

Under § 1.279(b) of the IFR, prior notice may not be submitted more than 5 calendar days before arrival, except in the case of food imported or offered for import by international mail. Under § 1.279(c) of the IFR, if the article of food is arriving by international mail, the prior notice must be submitted before the food is sent to the United States.

Section 1.279(d) of the IFR provides that the time of submission is fixed and the prior notice time will start for purposes of determining if prior notice is timely when the prior notice submission is confirmed by FDA for

review. FDA will confirm a prior notice once all required information has been submitted and confirmed as facially complete. For example, if the information submitted failed to include an FDA Product Code, the system will not provide a confirmation for that prior notice. The transmitter has an opportunity to correct the rejected information. When the information is corrected, transmitted, and determined to be facially valid, the system will then notify the transmitter and provide the prior notice confirmation number.

Under § 1.279(e) of the IFR, the prior notice confirmation number must accompany any article of food arriving by international mail. Under § 1.279(f), a copy of the confirmation (with the prior notice confirmation number) must accompany any article of food carried by or otherwise accompanying an individual (unless excluded under § 1.277(b)(1)), and be provided to CBP or FDA upon arrival. Additionally, under § 1.279(g) the prior notice confirmation number must accompany any article of food for which the prior notice was submitted through the FDA PNSI when arriving in the United States and must be provided to CBP and FDA upon arrival.

We further stated in the IFR's preamble that we also were interested in exploring flexible alternatives for submission of prior notice for foods or firms covered by programs of other agencies, such as C-TPAT, or imported by other agencies. We explained that FDA and CBP would publish a plan, including an implementation schedule, to achieve the goal of a uniform, integrated system, and to coordinate timeframes for import prior notice information while fulfilling the Bioterrorism Act mandates for air and truck modes of transportation with timeframes finalized by CBP when they finalize their rule entitled "Required Advance Electronic Presentation of Cargo Information" (the Advance Electronic Information Rule) (68 FR 58995). On December 5, 2003, CBP issued the Advance Electronic Information Rule (68 FR 68140), which requires CBP to receive, by way of a CBP-approved electronic data interchange system, information pertaining to cargo before the cargo is either brought into or sent from the United States by any mode of commercial transportation (water, air, rail, or truck). The cargo information required is that which is reasonably necessary to enable high-risk shipments to be identified for purposes of ensuring cargo safety and security and preventing smuggling under the laws enforced and administered by CBP. The Advance

Electronic Information Rule implements the provisions of section 343(a) of the Trade Act of 2002, as amended by the Maritime Transportation Security Act of 2002. The relevant timeframes provided in the Advance Electronic Information Rule are as follows:

- For arrival by land via road at ports that are fully equipped to accommodate CBP's Advance Electronic Information Rule, no later than 1 hour prior to the arrival of the truck at the border, or for Free and Secure Trade (FAST) participants, 30 minutes;
- For arrival by land via rail at ports that are fully equipped to accommodate CBP's Advance Electronic Information Rule, no later than 2 hours prior to the arrival of the train at the border; For arrival by air, no later than the departure time ("wheels up") of the aircraft from any foreign port or place in North America, including locations in Mexico, Central America, South America (from north of the Equator only), the Caribbean, and Bermuda, and from other areas into ports that are fully equipped to accommodate CBP's Advance Electronic Information Rule no later than 4 hours prior to the arrival of the aircraft in the United States.

On April 14, 2004, FDA and CBP announced their "Joint FDA-CBP Plan for Increasing Integration and Assessing the Coordination of Prior Notice Timeframes" (69 FR 19765), which the agencies amended in August 2004 (<http://www.cfsan.fda.gov/~pn/pnplan2.html>). As stated in the plan regarding the agencies' assessment of reduced timeframes "FDA and CBP continuously are assessing the completeness of prior notice submissions received as well as the amount of time necessary to receive, review, and respond to those submissions requiring a human review. However, that process is not yet complete, as we are currently operating under the enforcement policies outlined in the Prior Notice Compliance Policy Guide (CPG). See Compliance Policy Guide Sec. 110.310—Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. (Issued December 15, 2003, and revised June and August 2004; <http://www.fda.gov/ora> under Compliance References.) We currently do not receive prior notice for all shipments."

In our plan, we also stated that we would assess existing procedures and staffing needed to receive, review, and respond to the prior notices submitted in accordance with the Prior Notice IFR; identify what changes to work practices and staffing would be necessary to determine if FDA could continue to

receive, review, and respond to all prior notice submissions with reduced timeframes for land and air consistent with CBP's rule; and implement necessary changes and make appropriate adjustments to ensure we could receive, review, and respond to all prior notice submissions with reduced timeframes before issuing the final rule, consistent with our obligation to ensure that any timeframe selected is sufficient to receive, review, and respond to prior notice submissions, as set out in section 801(m)(2)(A) of the act. We also emphasized that "the evaluation of whether to reduce the timeframes for prior notice review will depend on the level of compliance industry achieves during the assessment. If we are unable to make such an assessment, our intended timeframe for issuing a prior notice final rule may be delayed."

Comments received on the prior notice IFR addressed the timeframes required in the IFR, as well as integration of those timeframes with the timeframes covered by CBP's advance electronic information rule. Comments also covered the IFR's requirement that prior notice must be submitted at least 5 days prior to arrival. We respond to the issue of timeframes for submitting prior notice here, and respond to the other questions raised in our Joint Implementation Plan and April 14, 2004, reopening of the comment period later in this preamble.

1. IFR Timeframes (2, 4, and 8 hours)

(Comments) One comment asks FDA to permit prior notice to be submitted at the port of entry, instead of at the port of arrival, in order to align the prior notice process with long-standing, existing CBP clearance processes and infrastructures at the port of entry. The comment reasons that since according to FDA's own estimates, 80 to 90 percent of prior notice data will be filed by the ABI filer, it is logical that prior notice should be filed at the same port where clearance entry is filed. The comment also suggests that FDA may want to consider a two-step process for submitting prior notice, under which the CBP "ACI data" is accepted as the first step, filed at port of arrival as part of the "ACI data," followed by complete prior notice in its current form, filed as a second step at the port of entry, i.e., concurrent with the clearance entry. Another comment suggests that to ensure consistency with ACE, the prior notice should be required and calculated from the port of entry and not the first point of arrival, as is currently the case.

Another comment recommends that to fully achieve the FDA-CBP goal of coordinating timeframes, FDA should adopt the “point of entry,” rather than the “point of arrival” in the United States to measure the timeliness of the prior notice filing. CBP’s “point of entry” is well known to importers and its use for purposes of the Bioterrorism Act not only will alleviate unnecessary confusion, but also will facilitate the stream of U.S. commerce without compromising food safety.

The comment also states that with the growing partnership between FDA and CBP, FDA’s concern regarding limited personnel should no longer be an issue now that FDA and CBP collectively are using their respective enforcement officials for this joint endeavor.

(Response) FDA discussed the “port of entry/port of arrival” issue extensively in the preamble to the IFR and is not persuaded by the comments that its initial position should be changed (See 68 FR 58974 at 58988). The Bioterrorism Act established that prior notice be provided by a specified period of time in advance of the time of the importation of the article of food involved or the offering of the food for import, which period shall be no less than the minimum amount of time necessary for the Secretary to receive, review, and appropriately respond to such notification, but may not exceed 5 days. That means that prior notice must be submitted before the article of food arrives in the United States. Moreover, we explained in the IFR that the overall purpose of the Bioterrorism Act is to improve the ability of the United States to prevent, prepare for, and respond to bioterrorism and other public health emergencies, thereby making essential the ability to examine or hold a suspect article of food when it first arrives at a port of entry in the United States, rather than later at the port where CBP will process the entry. Thus, the final rule uses the term “port of arrival” rather than “port of entry” as the food may not arrive at the port of entry until long after it has arrived in the United States. In addition, CBP’s advance electronic information rule also requires notice in advance of “arrival” in the United States, and not at “entry.”

The IFR and final rule define “port of arrival” and “port of entry.” Neither, however, use the terms “point of arrival” or “point of entry.” FDA could not find reference to “point of entry” in CBP rules or regulations.

FDA does agree that FDA’s staffing at certain U.S. ports is much less of an issue. Under an MOU between FDA and CBP signed by the respective commissioners of both agencies on

December 3, 2003, FDA has commissioned thousands of CBP officers in ports and other locations to conduct, on FDA’s behalf, investigations and examinations of imported foods. This unprecedented FDA-CBP collaboration significantly strengthens the implementation of the Bioterrorism Act to ensure the security of imported foods, particularly with respect to implementing the prior notice rule. Building on FDA’s and CBP’s long history of close cooperation, the MOU upgrades the two agencies’ teamwork in training, day-to-day operations, and information sharing. As part of the MOU, FDA and CBP have provided specialized training for the commissioned CBP employees who carry out this work, and both agencies have expanded their existing cooperative arrangements to directly share information affecting the safety and security of imported foods, including co-locating FDA’s PNC with CBP staff. Although the FDA and CBP partnership benefits the prior notice process in many ways, this partnership does not mean that the PNC no longer would have staffing concerns such that the prior notice timeframes could be reduced, as the comment implies. Please see the discussion later in this document regarding “Integration of FDA and CBP timeframes” for further discussion on reducing timeframes.

(Comments) One comment noted that the time difference between their country and the United States makes it difficult for the agent to start submitting prior notice immediately upon the receipt of necessary information. Therefore, some food transported by air, as well as by water, has actually missed the appointed timeframe. The comment requests that prior notice be accepted until immediately before the arrival of the food.

(Response) FDA disagrees. FDA’s PNSI is available 24 hours a day to submit prior notice. The timeframes established in the final rule are the minimum amount of time that FDA needs to receive, review, and respond to prior notice submissions.

2. Integration of FDA and CBP Timeframes

(Comments) One comment states that “no shorter timeframes should be allowed.” However, the remainder of the comments addressing consistency of timeframes between FDA and CBP recommend that FDA timeframes for imported food arriving by air and land be reduced and be consistent with those set forth by CBP in their advanced electronic information rule. No comments recommend aligning the

prior notice timeframe for imported food arriving by water with the CBP advanced electronic information rule timeframe of 24 hours prior to loading on the vessel. The reasons for recommending that prior notice timeframes be the same as CBP’s advanced electronic information timeframes for food arriving by air and land are that it would minimize the complexity of the process by presenting a more streamlined flow of information and avoid unnecessary duplication, result in fewer errors, provide better compliance rates, allow for fewer disruptions at the border, significantly reduce the burden on the trade community without creating additional security risks, and allow operators at close border points to load and verify truck loads and travel routes prior to submitting notice. One comment suggested that there is no basis for concluding that more time is needed for food shipments than for other shipments. Another comment states that utilizing one system and one set of timelines should provide adequate notice to FDA and improve compliance with the prior notice requirements.

(Response) The timeframes established in the final rule represent the minimum amount of time FDA needs to meet our statutory responsibility to receive, review, and respond to prior notice submissions. In accordance with our Joint Implementation Plan, we evaluated the feasibility of conducting prior notice reviews in a reduced time period in an effort to more closely harmonize the submissions with CBP timeframes. As part of our assessment, we analyzed data regarding prior notices we received in the first 9.75 months of fiscal year (FY) 2005—specifically from prior notices received and responded to by the PNC between October 1, 2004, and July 23, 2005. Based on the results of our assessment, in the final rule we have maintained the timeframes that are in the IFR:

- If the article of food is arriving by land by road, no less than 2 hours before arriving at the port of arrival;
- If the article of food is arriving by land by rail, no less than 4 hours before arriving at the port of arrival;
- If the article of food is arriving by air, no less than 4 hours before arriving at the port of arrival; and
- If the article of food is arriving by water, no less than 8 hours before arriving at the port of arrival.

FDA and CBP established these timeframes for the IFR based on the information available at the time. By necessity, though, these decisions regarding timeframes were not informed

by actual experience in operating the prior notice program. We now have that experience, and the information gained during our assessment shows that the minimum timeframes for submitting prior notices contained in the IFR closely match the minimum time necessary for FDA to receive, review, and respond to the prior notices. During the assessment period, FDA was able to receive, review, and respond to almost all notices within the established timeframes. In a relatively small number of situations, FDA was not able to make a decision regarding whether to inspect the food at the port of arrival by the end of the timeframe. In these situations, when the food arrived at the port of arrival, it was delayed while FDA completed its review. The number of such shipments, however, has been relatively low, and the resulting impact on government resources and the flow of traffic at ports has not been significant. Thus, we do not believe we should increase the timeframes to account for this relatively small number of outliers whose review takes longer than the IFR's timeframes.

Our assessment also shows that, because the IFR's timeframes closely match the minimum time necessary for FDA to receive, review, and respond to the prior notices, those timeframes could not be significantly reduced. If we were to change the timeframes to be consistent with those of CBP's advance electronic information rule, not only would this go against the statutory standard for setting the timeframes, but it would also significantly increase the number of shipments where FDA would not be able to decide whether it should examine the food at the port of arrival by the end of the timeframe. Based on current and projected staffing levels in the PNC, such shipments would be delayed at the port of arrival until FDA has either completed its review or decided to examine or not examine the food at the port of arrival without the benefit of a complete review. FDA could expend additional resources to increase capacity to review and reduce the timeframe, but it would be at considerable cost to assist a small number of shipments that have difficulty meeting these timeframes. In the nearly 4 years since the end of the transition enforcement period for the interim final rule, very few shipments have arrived without prior notice and as such, the timeframes are both reasonable, and economically efficient. The prior notice review process, information from our assessment, and the consequences of reducing the timeframes for conducting the prior

notice review are discussed in more detail below.

To implement the Prior Notice IFR, FDA established the PNC that operates 24 hours a day, 7 days a week, all days of the year to receive, review, and adequately responds to these notices as they are submitted. PNC staff is also responsible for responding in real-time (by e-mail, fax, or telephone) to inquiries they receive from affected parties about pending prior notices and/or operational issues.

The purpose of prior notice is to help identify food that potentially poses a significant health risk to the American public and to deploy resources to the port of arrival so that inspections can be conducted before the shipment ever enters the United States. Regardless of whether a prior notice is submitted electronically to FDA through CBP's ABI/ACS or FDA's PNSI, the prior notice information undergoes a validation process and is then screened against food safety and security criteria.

If the results of our initial validation indicate that the prior notice requirements have been met and the results of our screening indicate that the shipment does not appear to be a potential bioterrorism or significant public health threat, the submission is considered to have satisfied prior notice requirements and the associated article of food is allowed to proceed for further processing, including FDA admissibility review under section 801(a) of the act. Alternatively, if the results of the initial screening of the prior notice information indicate there is a potential bioterrorism or other significant public health threat, the prior notice undergoes additional intensive review by the PNC using other databases and sources of information to determine whether the article of food should be held at the port of arrival for examination or should be allowed to proceed into 801(a) status for admissibility review. PNC personnel make this determination using their experience with imported foods and the expertise within FDA's CFSAN for human food or FDA's CVM for animal feed, the inspectional information obtained by FDA's ORA, and the expertise of CBP. FDA's goal is to complete its review within the 2, 4, or 8 hour timeframe for submitting prior notice so that the review is complete before the shipment arrives at the port of arrival. If the intensive review takes longer than the timeframe and the shipment arrives at the port of arrival, then FDA may delay the shipment at the port of arrival until its review is completed. FDA could increase staffing at the PNC in order to decrease timeframes, but the effect has

diminishing returns. When a shipment must undergo intensive review, PNC staff members are reviewing databases and sorting through information to determine whether the shipment poses a potential threat. Reviewing one source of information leads to other sources of information to investigate. It would not necessarily be effective to expend, for example, five staff members on one intensive review at the start because not all sources of information for review are known at the beginning of an intensive review. Doubling or tripling staff, as discussed in Option 2B of the Final Regulatory Impact Analysis of this document, also would result in a significant amount of unused office space and equipment during the slowest time periods. Staffing at increased levels at all times would result in wasteful unproductive staff waiting for shipments to arrive.

Moreover, the constant unpredictability of the submission times for high risk prior notices requiring the shortest timeframe review (2 hours for food arriving by land via road) is a significant issue. The exact busiest times are variable, and are very difficult to predict on a daily basis. In addition, PNC targeting for high risk shipments also varies based on contemporaneous targeting intelligence and changing risk assessment strategies. Having constant two to three times the number of staff to cover those short bursts of time when the highest volume of high risk shipments, with the lowest timeframes are at their peak would be inefficient and wasteful.

In addition, it has been suggested that the PNC reduce their time frames and hold only those shipments it needs more time to review. There are two very significant reasons why this would be impractical. First, from a security perspective, doing so would result in holding only potential high risk shipments at the border and would make PNC targeting strategies widely visible and predictable to both those involved in legitimate trade, and those with nefarious pursuits looking to exploit weaknesses in U.S. food cargo security. Second, the holding of high risk shipments at the port would cause logistical challenges for port operators, and would almost certainly have a negative impact on all food and nonfood shipments processed through those ports. In contrast, with the current PN timeframes which have been in place for more than 4½ years, these logistical challenges have been almost nonexistent, and PNC targeting strategies are virtually transparent to the import trade.

The other factor to consider is the tremendous growth of imported foods year to year (approximately 14 percent growth over the past 4 years), which far exceeds what FDA projected in the IFR. FDA has been able to maintain the existing timeframes without adversely impacting trade. Given that we continue to expect imports to increase in volume, FDA does not believe that reducing timeframes is warranted. For all the above reasons, FDA believes that its current and projected staffing levels are sufficient and appropriate, and the timeframes are both reasonable, and economically efficient.

FDA receives approximately 167,000 prior notices each week. The distribution of prior notices by mode of transportation during our assessment that were flagged by the initial screening and that received an intensive prior notice review by the PNC is as follows:

TABLE 1.—PROPORTION OF PRIOR NOTICES FLAGGED AT THE INITIAL SCREENING, BY MODE OF TRANSPORTATION

Truck	27.6%
Car	2.9%
Air	17.6%
Rail	0.8%
Sea	39.2%
Mail	11.1%
Other	0.8%

As indicated, a significant portion (approximately 31 percent) of the prior notices reviewed by the PNC on a daily basis are land/road border entries, which under the IFR are subject to submission timeframes of at least 2 hours before arrival. On average, during the assessment period, the PNC conducted intensive security reviews on 225 to 250 prior notices per day from all modes of transportation, which means that, on average, the PNC conducted intensive security reviews on about 77 prior notices (31 percent of 250) each day that are subject to the 2-hour timeframe. Moreover, the prior notices are not evenly distributed over an 8 hour shift or 24-hour day. The actual dispersal pattern of the prior notice submissions is not uniform; an overwhelming majority of prior notice submissions arrive between a certain 12-hour period.

The amount of time the PNC has needed for its intensive review has ranged from 20 minutes to 315 minutes (5 hours and 25 minutes) from when

FDA received the prior notice and confirmed it for review. Using data collected on articles of food arriving by land via truck and car during our assessment period, the PNC expended an average of 61 minutes to receive, review, and make a decision on whether or not a shipment should be refused or held for examination under section 801(m) of the act, or allowed to proceed into 801(a) status for admissibility review. The PNC completed about 99 percent of its intensive reviews of prior notices submitted for land/road border arrivals within 120 minutes of receiving and confirming the prior notice for review. Only about 57 percent of the intensive reviews were completed within 1 hour. Reviews for the remaining 43 percent (8,900 prior notices for the assessment period, or more than 10,000 for FY 2005) took longer. If the timeframe were set at 1 hour for these articles of food instead of the IFR's 2 hours, the PNC would have had to either delay the food at the port of arrival until it completed its review or decide whether to examine the food at the port or arrival without the benefit of a complete review, based on current and projected staffing levels in the PNC.

FDA does not have data to accurately analyze the impact of changing the timeframe to 30 minutes for FAST participants because FAST membership is not one of the data elements that we currently require in a prior notice submission. FDA instead did the analysis based on the total number of prior notices submitted that the PNC could review based on a timeframe of 30 minutes. The PNC completed less than 10 percent of its intensive reviews of prior notices submitted for land/road border arrivals within 30 minutes of receiving and confirming the prior notice for review. If the timeframe for all articles of food arriving by land by truck and car during our assessment period had been 30 minutes (i.e., the timeframes for FAST participants) instead of 2 hours, the PNC would not have completed approximately 68 percent of its intensive reviews (over 14,000 during the assessment period, which equates to approximately 16,000 for FY 2005 of the land/road border prior notices) within the applicable timeframe. As a result, the PNC would have had to either delay the food at the port of arrival until it completed its review or decide whether to examine the food at the port of arrival without the benefit of a complete review, based on current and projected staffing levels in the PNC. This assessment is an overestimate of the number of articles of food that would be eligible for FAST

timeframes, as we do not know how many articles of food arriving in the United States subject to the prior notice requirements are from FAST and C-TPAT participants. Moreover, there are other impediments to integrating prior notice with the C-TPAT and FAST programs. These are discussed in section III.D.6 of this document ("Additional Exclusions Requested—Special Programs (C-TPAT/FAST) and Flexible Alternatives").

We also conducted a similar assessment on prior notices submitted for articles of food arriving by air between October 1, 2004, and July 23, 2005. The IFR requires prior notices for these shipments to be submitted and confirmed for review at least 4 hours before the food arrives at the U.S. port of arrival. If the timeframes for articles of food arriving by air during our assessment period had been reduced to "wheels up," the PNC would not have completed approximately 21 percent of the intensive prior notice reviews for articles of food with flight times less than 3 hours. These articles of food (2,700 for our assessment period, or an estimated 3,230 for FY 2005) also would have been subject to cargo delays and/or increased cargo examinations, based on current and projected staffing levels in the PNC.

Neither FDA nor CBP have sufficient personnel or resources to accommodate the number of additional cargo delays and/or food shipment examinations that would result under either 60- or 30-minute timeframes for articles of food arriving by land by road. This would include the significant additional personnel and resources needed to track, facilitate, and coordinate the evaluation and/or examination of the delayed cargo. Coordination of the handling of delayed shipments is a resource intensive process that can last for multiple days per shipment, and includes communicating with both FDA and CBP personnel at the border, and the brokers/filers and importers involved in the shipment.

To handle the extra work, the PNC would need to shift its personnel based on current and projected staffing levels in the PNC, resulting in fewer staff being available to review prior notices for all categories of shipments including shipments arriving by water. The PNC's current approximate average time for the PNC intensive review for shipments arriving by water is 5 hours, which is within the 8 hour submission timeframe. We would expect, based on our assessment, that the time taken away from prior notice review work for the increase in coordination due to the increase in delays and examinations for

land and air shipments would increase the time needed to complete intensive review of prior notices for shipments arriving by water by 25 percent at the minimum. As a result, over 7,000 shipments by water during our assessment period (estimated as 7,370 for FY 2005) would have been delayed at the port of arrival while the PNC completed its intensive review and determined whether the shipment in fact presented a significant health threat, based on current and projected staffing levels in the PNC.

In setting the timeframes, the act provides that we may consider, among other considerations, the effect on commerce (section 801(m)(2)(A) of the act). Assuming current and projected PNC resources, lowering the timeframes to 60 or 30 minutes would likely result in delays at the border, not only for those shipments delayed for intensive review longer than the timeframe, but also for other shipments passing through the port, especially at the busiest land border ports where traffic lanes, parking, and inspection facilities are extremely limited. In some ports, the lack of holding facilities could result in an increase in trucks being turned around at the border. As we have mentioned above, there have been a relatively small number of situations where FDA was not able to make a decision regarding whether to inspect the food at the port of arrival by the end of the timeframe, causing a small number of shipments to be delayed when it arrived at the port of arrival. Since the impact of these small number of delays on trade has not been significant, continuing to maintain that the current IFR timeframes is the most efficient use of resources.

Thus, based on current and projected resources and other high-priority activities FDA is addressing, reducing the timeframes would lead to an increase in delays at the ports of arrival, causing FDA to shift some resources away from conducting intensive reviews of prior notices so they can conduct the coordination and other activities necessary for these delayed shipments. The shift in resources away from conducting intensive reviews would, in turn, further increase the number of shipments that are delayed because FDA has not been able to finish its intensive review within the applicable submission timeframe. This ultimately would cause a delay in getting cargo to its final destination, which would have an adverse impact on trade.

Moreover, the number of prior notices identified for intensive review has increased over time, as intelligence and other risks are identified. We expect the

number of intensive reviews to continue to increase relative to the assessment period, resulting in even more food shipments that would be delayed or held for examination under shortened timeframes.

We did not get any comments asking us to coordinate the timeframes for articles of food arriving by water in our prior notice rule (8 hours before arrival) with those in CBP's rule (24 hours before arrival). We received one comment asking us to reduce the time for articles arriving by water. We stated in the preamble to the IFR "In determining the actual timeframes for submission of prior notice for each mode of transportation, FDA considered the need to provide sufficient time for the agency to review and respond to the information submitted, as well as the current ability of the food industry to provide the information required within the stated timeframe given the differences in lead time before arrival among different modes of transportation. We determined that information for shipments whose transport time is measured in days or weeks (e.g., ocean shipments) is available further in advance of arrival than shipments whose transport time is measured in hours (e.g., land and air shipments.) Staggered prior notice submission timeframes will allow FDA reviewers to direct additional resources to shipments with short transport times and to defer review of shipments with longer transport times. Based on these considerations, FDA established the prior notice timeframes in the interim final rule to associate with the mode of transportation." (69 FR at 58995). We continue to hold this view for shipments arriving by water in light of our assessment for articles of food arriving by land and air.

For all of the previously stated reasons, we did not reduce the timeframes for submitting prior notice in the final rule for any mode of transportation, as these timeframes still are the minimum amount of time FDA needs to fulfill its statutory obligation to receive, review and respond to prior notices while having the minimal impact on trade.

(Comments) One comment suggests that it would be preferable for FDA to harmonize the prior notice timelines to the future ACE transmission timelines, ensuring consistency and compliance of the trade community and efficiencies in both agency and industry workforces.

(Response) FDA agrees that timeframes for submission of prior notice may be further evaluated in light of new trade programs such as ACE, when it is implemented and in effect.

CBP is planning to bring its ACE system on line in the next few years, which will accommodate prior notice submissions and eliminate or change ABI/ACS and PNSI prior notice submissions. FDA will continue to assess and pursue the integration of timeframes as policies, processes, and strategic IT systems are improved. FDA believes that the most opportune time for coordinating timeframes will coincide with the startup of CBP's ACE. We will determine at that time or after ACE is operational whether the prior notice timeframes should and can be reduced further. Until that time, the timeframes for submission of prior notice will remain the same in the final rule as issued under the IFR (see § 1.279).

3. Phase-In of FDA and CBP Timeframes

When FDA reopened the comment period for the IFR on April 14, 2004 (see 69 FR 19763), FDA asked Flexible Alternative Question 6: "If FDA adopts reduced timeframes in the prior notice final rule, should FDA phase in the shorter timeframes as CBP phases in the advance electronic information rule?"

(Comments) Most comments recommend integration of the phase-in of reduced timeframes in association with CBP's schedule to promote consistency between the programs, reduce errors, and minimize disruption of supply chains through conflicting requirements. However, one comment, in addition to recommending adherence to CBP's phase-in schedule, also notes that they would not want FDA to delay adopting a reduced timeframe for submitting prior notice merely because CBP is not yet ready to implement the counterpart provisions of its advance notice programs. In addition, they state that the deadlines are minimum periods, and any shipper can provide more notice of imports, to FDA, CBP or both, than the minimum timeframes in either regulation. They recommend that FDA should shorten its lead times to match those in the CBP regulations, even if the CBP requirements are not yet in place. Another comment states that the phase-in plan, which is a port-by-port implementation according to a time schedule, would be very problematic to industry. The comment further explains that systems and operations do not necessarily have the flexibility to switch on by individual site or location and the current plan would introduce complication and confuse the trade community. The comment recommends further discussion with CBP and FDA as to development of a more viable and achievable implementation plan.

(Response) This issue is moot, as the final rule retains the timeframes

established in the IFR, for the previously stated reasons.

4. Prior Notice Confirmation Number

(Comments) One comment asks for clarification regarding when the prior notice confirmation number is required to accompany the food.

(Response) The prior notice confirmation number must accompany any article of food arriving by international mail, when the food is carried by or otherwise accompanying an individual, or when the prior notice was submitted via FDA's PNSI.

Under § 1.279(e), the prior notice confirmation number must accompany any article of food arriving by international mail. Under § 1.279(f), a copy of the confirmation (with the prior notice confirmation number) must accompany any article of food carried by or otherwise accompanying an individual (unless excluded under § 1.277 (b)(1)), and be provided to CBP or FDA upon arrival. Additionally, under § 1.279(g) the prior notice confirmation number must accompany any article of food for which the prior notice was submitted through the FDA PNSI when arriving in the United States and must be provided to CBP and FDA upon arrival.

(Comments) One comment asked FDA to confirm whether it is sufficient for an ocean carrier to have the prior notice confirmation number on arrival or whether they are required to have the actual prior notice confirmation also.

(Response) Under § 1.279(e), the prior notice confirmation number must accompany any article of food arriving by international mail. Additionally, under § 1.279(g) the prior notice confirmation number must accompany any article of food for which the prior notice was submitted through the FDA PNSI when arriving in the United States and must be provided to CBP and FDA upon arrival. Therefore, although a prior notice confirmation number is required, the final rule does not require that the actual prior notice confirmation has to be supplied for food arriving by ocean carrier.

(Comments) One comment states that when food arrives in the United States, the carrier should present a copy of the prior notice confirmation and the food to CBP. The comment asks if the submitter should send the prior notice confirmation to the carrier company or to the vessel that transported the food to the United States.

(Response) As stated previously, § 1.279(e) requires the prior notice confirmation number to accompany any article of food arriving by international mail. Additionally, under § 1.279(g) the

prior notice confirmation number must accompany any article of food for which the prior notice was submitted through the FDA PNSI when arriving in the United States and must be provided to CBP and FDA upon arrival. How persons importing or offering for import food into the United States choose to comply with this requirement is a private matter (e.g., persons may decide to specify these obligations in the contract between the exporting company and the carriers to ensure that the logistics are worked out in advance).

(Comments) Comments stated that the data requirements should be reassessed to simplify and make the requirements more manageable. The comment states that one data element should link all information secured by prior notice, which would be beneficial for locating shipments in the event of a possible crisis. The comments suggest that FDA use bill of lading numbers as a single reference point because all shipments that are moved are repeatedly covered by this number. This would render the prior notice confirmation number currently used redundant.

(Response) FDA does not agree that the waybill/Bill of Lading can be used as a single reference point for all shipments instead of the prior notice confirmation number. A Bill of Lading number is not always assigned to a shipment at the time of prior notice submission. For certain shipments, such as those sent by international mail, no Bill of Lading may exist. Thus, FDA has determined that it is better to use a unique confirmation number provided by the FDA system to transmitters.

(Comments) One comment notes that a separate prior notice is required for each distinct food product and a prior notice confirmation number is returned for each prior notice. Therefore, if a shipment consists of multiple food products, the carrier would have multiple prior notice confirmations upon arrival. The comment states multiple prior notice confirmations do not align well with the commercial realities of international trade, where the focus is on the entire shipment, not the individual components. The comment recommends that FDA provide a prior notice confirmation number that encompasses the entire shipment.

(Response) FDA disagrees. The carrier could be carrying articles of food for different submitters or recipients. If it was necessary to hold an article of food, the entire shipment would be held under the above scenario suggested by the comment. Under the final rule, the article of food that is subject to a hold can be offloaded and the rest of the

shipment allowed to proceed. This would not be the case if there was only one prior notice confirmation number for the entire shipment.

5. 5-Day Maximum Pre-Arrival Limitation

(Comments) Many comments requested that prior notice be allowed to be submitted more than 5 days before arrival. This would allow exporters to complete their documentation at the same time the bill of lading and health certification is usually completed in the case of food shipped by water. One comment contends that the 5 day limit does not reflect the variable and unpredictable nature of transport and does not reflect a risk-based approach to a potential bioterrorism threat. Another comment contends that the limitation of the timeframe to 5 days is problematic and is due to a misinterpretation of the statute. The comment asserts that the statutory language does not preclude a party from voluntarily providing prior notice more than 5 days in advance. The comment also maintains that 10 days prior to arrival would provide the necessary flexibility for their industry. A foreign government, apparently assuming that prior notice must be submitted by the foreign shipper or exporter, recommends that the time should be extended because it may take the shipment 2 weeks to reach a U.S. port.

(Response) In response to the concerns raised by the comments, we have revised § 1.279(b) to allow submission of prior notice more than 5 days before arrival (except for articles of food imported or offered for import by international mail). Specifically, this provision permits prior notice submissions to be submitted no more than 30 calendar days before the anticipated date of arrival for submissions made through ABI/ACS and no more than 15 calendar days before the anticipated date of arrival for submissions made through PNSI. Due to system limitations, the timeframes between ABI/ACS and PNSI are not identical. Also, because of the way ABI/ACS is programmed, when prior notice is submitted through ABI/ACS, the prior notice confirmation number cannot be provided more than 5 calendar days before the anticipated date of arrival.

Please note that if any of the prior notice information, except the anticipated arrival information, the estimated quantity, or the planned shipment information, changes after FDA has confirmed the prior notice submission for review, the prior notice must be resubmitted, as provided by § 1.282(a). The resubmission must be

confirmed by FDA for review no less than 2, 4, or 8 hours before arriving at the port of arrival, with the minimum time depending on the mode of transportation (§ 1.279(a)). If prior notice is resubmitted, the previous prior notice should be cancelled (§ 1.282(b), (c)).

6. International Mail

(Comments) There were no comments received regarding the timeframes established for prior notice covering food arriving by international mail.

(Response) FDA retained the timeframes for submission of prior notice for food arriving by international mail that are in the IFR.

(Final rule) The final rule at § 1.279(a) requires that you must submit prior notice to FDA and the prior notice submission must be confirmed by FDA for review as follows: If the article of food is arriving by land by road, no less than 2 hours before arriving at the port of arrival; if the article of food is arriving by land by rail, no less than 4 hours before arriving at the port of arrival; if the article of food is arriving by air, no less than 4 hours before arriving at the port of arrival; or if the article of food is arriving by water, no less than 8 hours before arriving at the port of arrival.

Under § 1.279(b), except in the case of an article of food imported or offered for import by international mail, prior notice may be submitted no more than 30 calendar days before the anticipated date of arrival for submissions made through ABI/ACS and no more than 15 calendar days before the anticipated date of arrival for submissions made through PNSI.

Under § 1.279(c), if the article of food is arriving by international mail, the prior notice must be submitted before the article of food is sent to the United States.

Under § 1.279(d), FDA will provide notification that the prior notice has been confirmed for review with a reply message that contains a prior notice confirmation number. The prior notice will be considered submitted and the prior notice review time will start when FDA has confirmed the prior notice for review.

Under § 1.279(e), the prior notice confirmation number must accompany any article of food arriving by international mail. The prior notice confirmation number must appear on the Customs Declaration that accompanies the package. We provide CN22 or CN23 or a U.S. equivalent as examples of the Customs Declaration.

Under § 1.279(f), a copy of the confirmation, including the prior notice

confirmation number, must accompany any article of food that is subject to this subpart when it is carried by or otherwise accompanies an individual when arriving in the United States. The copy of the confirmation must be provided to CBP or FDA upon arrival.

Under § 1.279(g), the prior notice confirmation number must accompany any article of food for which the prior notice was submitted through the FDA PNSI when the article arrives in the United States and must be provided to CBP or FDA upon arrival.

G. How Must You Submit the Prior Notice? (§ 1.280)

Section 1.280 of the IFR required that prior notice must be submitted electronically to FDA in the English language, except that an individual's name, the name of a company, and the name of a street may be submitted in a foreign language. All information, including these items, must be submitted using the Latin (Roman) alphabet. The IFR provided for two methods of electronic submission of prior notice: (1) The CBP ABI/ACS; or (2) FDA PNSI at <http://www.access.fda.gov>.

The IFR required submission of prior notice via FDA's PNSI for articles of food imported or offered for import by international mail, other transaction types that cannot be made through ABI/ACS, and articles of food that have been refused under section 801(m)(1) of the act and 21 CFR part 1, subpart I.

The IFR also provided for contingencies if certain systems were not working, e.g., a custom broker's or self-filer's system, ABI/ACS, PNSI, or OASIS. The IFR required that prior notice must be submitted through PNSI if a custom broker's or self-filer's system or if the ABI/ACS interface is not working. The IFR also required that prior notice must be submitted via e-mail or fax if PNSI or OASIS is not working. The IFR did not exempt any specific categories of food articles from prior notice if systems are not performing.

In August 2004, FDA and CBP published guidance covering a Contingency Plan for System Outages. This guidance can be accessed at <http://www.cfsan.fda.gov/~pn/pndguid.html>. Comments addressing contingencies will be discussed later in this section.

Comments regarding how to submit prior notice are addressed according to issue: General comments; comments about the ABI/ACS and PNSI systems, including technical issues and security of the systems; and comments about contingencies.

1. General Comments

(Comments) One comment suggests that FDA should have CBP collect and review all prior notices with one prior notice submission timeframe for all agencies.

(Response) FDA disagrees. The Bioterrorism Act, while providing for the ability to commission other agencies to help implement the provisions of the Bioterrorism Act, specifies that the Secretary is to receive prior notice for all food imported or offered for import into the United States. FDA personnel are trained and knowledgeable about the risks and hazards involving food products under its jurisdiction and have the expertise to review the prior notice submissions. The integration of prior notice submission timeframes is discussed earlier in this document under the discussion for § 1.279.

(Comments) Several comments suggest allowing the option of submitting prior notice by fax or mail because not everyone has Internet capability, access to a computer, or proficiency in English. One comment asks that they be allowed to continue sending prior notice by fax (as is allowed during certain contingency situations). Several other comments suggest that international mail shippers are at a disadvantage because many mail customers have no access to the Internet, the pre-notification system is not customer-friendly, entries take a long time, and the data requirements are too complex and difficult for customers to determine.

(Response) FDA does not agree that a process for manual transmission is needed, except on a contingency basis. FDA believes that persons engaged in international commerce have, or can get, access to the Internet. If the Internet is not accessible by the submitter, he or she can use a customs broker to submit prior notice through ABI/ACS or another person to transmit prior notice through the FDA PNSI. Allowing manual transmission would not give adequate time for FDA personnel to receive, review, and respond, unless the timeframes for prior notice in the final rule were greatly extended. Thus, manual transmission will be used only as a contingency alternative.

FDA also notes that the data quality of manual systems is usually less than satisfactory, because no automated data validation takes place during data entry. The U.S. Government has a strong commitment to reducing paper-based processes and moving toward e-commerce for all business transactions. Accordingly, under the final rule, paper-

based submissions will not be allowed, except on a contingency basis.

In response to the comment that international mail shippers are disadvantaged, FDA also notes that it has compliance policies to address this situation. Its compliance policy under the IFR had been that "FDA and CBP should typically consider not taking any regulatory action when an article of food is imported or offered for import for non-commercial purposes with a non-commercial shipper" without prior notice. This applied to all such food subject to prior notice, including food shipped by international mail. The Prior Notice Final Rule Draft CPG, announced elsewhere in this issue of the **Federal Register**, would continue that enforcement policy.

(Comments) One comment suggests that instead of submitting prior notice via PNSI, mail shippers be allowed to complete an alternate form requiring minimal information that is similar to the Customs Declaration form in the native language to be completed at the post office. This comment argues that the current requirements are too cumbersome for the average consumer. Similarly, another comment suggests that FDA accept Customs Declaration Forms CN22 and CN23 in lieu of submitting prior notice via PNSI for mail shippers. This comment argues that such forms are much easier to complete and are official documents prescribed by the Universal Postal Convention and are used around the world. In the alternative, this comment suggests that FDA accept data submitted by mail shippers via PNSI in a condensed form determined by the foreign government's postal agency.

(Response) FDA disagrees. Section 801(m) of the act requires the prior notice submission to contain certain data elements, such as the identity of the article of food, manufacturer and shipper of the article, grower, country from which the article originates, country from which the article is shipped, and the anticipated port of entry of the article. Customs Declaration Forms are not adequate substitutes for providing this information to FDA since such forms do not typically require this kind of comprehensive information. Likewise, allowing a foreign government's postal agency to determine which information to submit to FDA also does not guarantee that we will receive the information required by section 801(m) of the act. Therefore, FDA has not provided an alternative form of prior notice submission for food arriving by mail for commercial purposes.

FDA again notes that it has compliance policies that address some of the concerns raised by the comments. Its compliance policy under the IFR had been that "FDA and CBP should typically consider not taking any regulatory action when an article of food is imported or offered for import for non-commercial purposes with a non-commercial shipper" without prior notice. This applied to all such food subject to prior notice, including food shipped by international mail. The Prior Notice Final Rule Draft CPG, announced elsewhere in this issue of the **Federal Register**, would continue that enforcement policy. FDA believes that this proposed compliance policy should not be extended to food that is imported or offered for import for commercial purposes or with a noncommercial shipper without prior notice. Mail shipments associated with a commercial purpose pose a higher risk with respect to ability to reach a greater number of people, and most commercial entities already are familiar with submitting information to FDA and CBP.

(Comments) One comment proposes a two-step process for filing prior notice, whereby FDA would accept the same data submitted for CBP ABI to satisfy the prior notice requirements at the first port of arrival. Then, after accepting ABI data at the port of arrival, complete prior notice data would be filed at the port of entry as step two of the process. The comment contends that utilizing ABI data for prior notice at the port of arrival would allow faster processing, which is a significant issue considering FDA's concern about timely processing of prior notice under a shorter time schedule. This more complete data would be filed concurrent with the CBP clearance entry, and therefore provide FDA with the level of data desired, while removing the issue of time constraints under a reduced schedule measured against the port of arrival.

(Response) FDA disagrees. The purpose of section 801(m) of the Bioterrorism Act is to ensure that FDA has sufficient information before arrival so it can determine what foods to inspect at the border. Therefore, all information required for prior notice must be submitted prior to arrival, not just a portion of the information.

Additional information may be required after arrival and for entry admissibility decisions. That process is completed after arrival for those foods offered for consumption in the United States. (See 68 FR 58974 at 58976 in the preamble to the IFR for additional discussion about the relationship and differences between the prior notice

determination and the admissibility determination.)

(Comments) One comment suggests the agencies should synchronize the different filing systems so as to ensure that all notices can be made via Automated Manifest System (AMS). Other comments request FDA to coordinate prior notice with CBP's AMS to eliminate duplication of data submissions.

(Response) FDA disagrees. No interface currently exists between AMS and the existing interface with FDA's OASIS through the ABI/ACS entry processes, which means FDA does not have access to AMS data. FDA and CBP have discussed interfacing with AMS for manifest data and determined that the general cargo data in AMS are not suitable to accommodate the detailed information requirements of section 801(m) of the act. For example, AMS does not collect the country of origin. In addition, its collection of the identities of the article of food and its manufacturer differs from the way those are collected under the prior notice interim final and final rules in such a way that the data would not meet our needs in carrying out the purpose of section 801(m) of the act.

(Comments) One comment urges FDA to upgrade its systems to coincide with normal commercial flow times and recommends that FDA consider the approach used by the Census Bureau, i.e., providing a range of automated filing options for meeting electronic filing requirements by offering an Internet application, a direct link for certified filers, and a personal computer (PC)-based application.

(Response) FDA provides two methods for submitting prior notice: One via ABI/ACS (a PC-based link for certified filers) and another via PNSI (an Internet-based application). Prior notice is not required to be filed at a specific time or during specific hours of the day, but may be submitted 24 hours/day, 365 days of the year. The rule requires FDA to receive the prior notice before the food arrives in the United States, and the time frame is based on the mode of transportation (see § 1.279).

(Comments) One comment suggests that FDA participate in the International Trade Data System (ITDS), which provides for one-window filing of trade-related information by motor carriers and other parties through CBP's ACE system, to more effectively execute its Bioterrorism Act mission.

(Response) FDA is actively participating in the development of CBP's ACE system and has long been a participant in the ITDS. However, ACE is not yet a complete reality and prior

notice requirements have been in effect since December 12, 2003. FDA is working with CBP and others in the international trade community to ensure that the prior notice requirements are reflected in ACE once ACE is fully operational.

(Comments) One comment notes that exporters use different kinds of transmission formats to send prior notice-related information to importers or brokers in the United States. The comment further states that since none of its member companies have received any notice from FDA requesting changes in content or formatting of the transmitted information, they assume that FDA is satisfied with their industry's approach to regulatory compliance. In the event that FDA requires a change to format or content of the reporting now conducted, the comment requests that FDA notify companies well in advance of any such requested change.

(Response) FDA receives prior notice information via ABI/ACS or PNSI. FDA expects that the transmitted information discussed in the comment is submitted to FDA via one of these two methods in the proper format. If the information is inaccurate, the food is subject to refusal. Customs brokers are notified using typical procedures regarding any changes relating to the rule that require a 90-day lead time before implementation of the IT change. FDA also provides tutorials on its Web site that explain changes to PNSI (see <http://www.cfsan.fda.gov/~pnfs/pnsitut.html>).

2. English Language

(Comments) Many comments suggest that FDA program PNSI in other languages, such as Japanese, Korean, German, and Spanish. These comments state that "mail users" must rely on PNSI to submit prior notice, and in many cases, English may not be the native language for many of these users and puts them at a disadvantage, e.g., foreign filers experience higher burdens and are frequently being timed out of PNSI because it takes them longer to complete a prior notice. One comment argues that a reason for noncompliance of prior notice requirements is the inability to understand English well enough to submit prior notice via PNSI.

(Response) FDA agrees that a system available in multiple languages would be advantageous for some users. However, the agency has assessed the feasibility of providing and maintaining PNSI in multiple languages, and has determined that the cost of developing translations into one or more additional languages cannot be accommodated at

this time. The cost of updating the translations as new versions of the system are developed would also be substantial. In addition, FDA notes that other import documents required by FDA and by CBP must be filed in English. Therefore, FDA does not plan to program PNSI in other languages and the final rule will continue to require submission of prior notice in the English language.

FDA and CBP nonetheless have taken into account many of the concerns referenced in the comments. For example, the final rule does not apply to homemade foods shipped from an individual to an individual in the United States (see § 1.277, *Scope*, discussed supra). In addition, the agencies' compliance policy under the IFR had been that "FDA and CBP should typically consider not taking any regulatory action when an article of food is imported or offered for import for non-commercial purposes with a non-commercial shipper" without prior notice. This applied to all such food subject to prior notice, including food shipped by international mail. The Prior Notice Final Rule Draft CPG, announced elsewhere in this issue of the **Federal Register**, would continue that enforcement policy.

(Comments) One comment requests that other pieces of the prior notice system also be available in other languages, such as the tutorials for determining the FDA product code. Another comment suggests that FDA provide foreign governments and trade organizations with a detailed outline of the "prior notice form" with explanations of the individual requirements so that they could be translated into a foreign language and provided to affected companies.

(Response) While many of the documents regarding prior notice requirements have been translated into other languages, the PNSI tutorials (available at <http://www.cfsan.fda.gov/~pnfs/pnsitut.html>) and the FDA Harmonized Tariff Schedule Codes guidance (available at <http://www.cfsan.fda.gov/~dms/htsguid3.html>) have not been translated. FDA intends to continue translating these and other prior notice documents as resources permit. Documents that are available in other languages are posted at <http://www.cfsan.fda.gov/~mow/internat.html>. Foreign governments and trade organizations are welcome to translate these documents and provide them to affected companies.

3. Technical Issues Concerning Both Systems

(Comments) One comment suggests that both systems provide a link to HTS codes.

(Response) FDA agrees. Both PNSI and ABI/ACS provide a link to HTS codes. FDA also has provided guidance regarding HTS codes and a companion list of HTS codes flagged with prior notice indicators. The guidance is posted at <http://www.cfsan.fda.gov/~dms/htsguid3.html> and the updated list is posted at <http://www.cfsan.fda.gov/~pn/htscodes.html>.

(Comments) One comment states that railroads will not load cargo until a prior notice confirmation number is provided, and a prior notice confirmation number cannot be provided without complete planned shipment information, including a railcar number.

(Response) FDA notes that, while this situation seemed to be an issue early in the implementation of the prior notice IFR, it is our understanding and experience that the rail industry has now changed business practices to address this concern. FDA received only one comment on this issue and has not received any other feedback to suggest this matter is still of concern. A check with a large rail shipping company revealed that the restrictions for loading cargo are not at issue; i.e. rail cars can be physically loaded with shipments containing food prior to obtaining prior notice (Ref. 1). Therefore, the prior notice filer does have the ability to obtain the rail car number in order to file prior notice. The rail company did however indicate that rail cars are not connected/added/attached to the U.S. in-bound train until the rail company receives documentation that prior notice has been filed.

(Comments) One comment states that the FDA Help Desk, and other methods now established for resolution of operational issues, simply are not yielding a workable "fix" to the "kinks" in the new PNSI/ABI system. Another comment recommends the establishment of a system for swift resolution of technical and operational problems for both systems.

(Response) FDA agrees and has established an FDA Help Desk to deal with technical issues involving PNSI. Questions and concerns about operational, rather than technical, problems involving prior notice should be directed to FDA's PNC. While the FDA PNC is available 24 hours a day, 7 days a week to respond to operational issues, it is not equipped to resolve technical issues involving PNSI or ABI.

However, the PNC has a process in place to handle calls involving technical issues and will forward those calls to the Help Desk. CBP also has a well-established system of client representatives to deal with technical problems involving ABI/ACS. CBP client representatives are available to assist users with ABI issues. ABI operational issues are the sole responsibility of CBP.

(Comments) One comment states that the systems go down from time to time, and all the time-consuming entry-work has to be repeated.

(Response) PNSI has been enhanced to allow copying and saving of prior notices within a Web entry and copying of a Web entry, with or without the associated prior notices. Copying allows you to avoid repetitive data entry for similar Web Entries and associated Prior Notices. You also may cancel a Web Entry and then copy it, to correct errors in a Web Entry you have already completed. Instructions for copying a Web entry prior notice are available on FDA's Web site at <http://www.cfsan.fda.gov/~pn/pnstep2.html#copywe>. ABI users are responsible for their own software and its capability to save and/or copy information that has not been transmitted.

(Comments) One comment urges FDA to harmonize their efforts with CBP with respect to the prior notification of food articles and to work with CBP to integrate its joint administration and enforcement of prior notice for both CBP and FDA. One comment recommends that both the FDA and CBP systems be simplified to allow for both a decrease in data entry time and a more efficient method for multiple data entries.

(Response) FDA agrees and is continuously working with CBP to make the administration and enforcement of prior notice as integrated and efficient as possible. Both agencies recognize that ACE, when initiated, will allow for a more harmonized process.

With respect to multiple data entries, PNSI does offer several features that make prior notice data entry faster and reduce the amount of redundant data entry, such as the Copy Web Entry feature, Copy Prior Notice feature, and other shortcuts. Please refer to Time Saving Tips from the FDA PNC for PNSI (<http://www.cfsan.fda.gov/~pn/pntips.html>) for a description of these features. Many private ABI software programs also have features that provide a means for multiple data entries.

(Comments) Several comments express concern about the timeliness of receipt of the prior notice confirmation number. One comment states that it can

take an hour or more to receive the prior notice confirmation number that is needed to move the cargo. Another comment states that there have been several instances when the confirmation response has been delayed and asks FDA to improve the timeliness of this response.

(Response) Generally, for prior notice submission via PNSI, the user should receive their confirmation number immediately upon submission of the correctly completed form. For those prior notices submitted via ABI on the anticipated date of arrival, users can expect to receive a response message (confirmation number or rejection) within 15 minutes of submission. For ABI submissions submitted prior to the anticipated date of arrival, users can expect to receive their response message no later than midnight (Eastern Time) on the anticipated date of arrival.

(Comments) One comment states that there are glitches in the software that has been released. The comment notes that perfume is a nonfood product that is subject to FDA's 801(a) jurisdiction, but it does not require prior notice. However, in a procedures memorandum from CBP, it appears that if you disclaim FDA in FD3, it is disclaimed for all purposes. Similarly, if you acknowledge FDA jurisdiction in FD3, then prior notice must be submitted whether or not the importation involves food.

(Response) We have provided instructions describing how to disclaim an article for prior notice, while still sending information required for FDA 801(a) admissibility. The instructions were included in at least four separate ABI Administrative Messages issued by CBP beginning in March 2004 (e.g., Administrative Message 04-0586, dated March 24, 2004). If merchandise marked FD3 in the Tariff Record is subject to prior notice and 801(a) reporting requirements, the required prior notice and 801(a) information should be transmitted. In cases where 801(a) information is required, and prior notice information is not required, filers should transmit the "PN disclaimer" (PND) and the information required for 801(a). In this case, the PND Affirmation of Compliance (AofC) code must be the first AofC code recorded (FD01 Record-Positions 20-22) in the ABI transmission. The PND affirmation does not require a qualifier. If the merchandise marked FD3 represents an article exempt from all FDA reporting requirements, the line should be disclaimed using the FD0 marker in the

OA Record,⁵ as has always been done for FDA disclaims.

(Comments) One comment believes there is a problem with the in-bond system. The comment states that if it is assumed that a shipment arrives in Los Angeles, but is destined for in-bond travel to New York, the shipment is subject to prior notice upon arrival. In order to properly comply with CBP requirements, the arrival date is entered based upon the expected arrival date in New York. The data exchange between CBP and FDA is then triggered by the New York arrival date rather than the Los Angeles arrival date. The comment is concerned that prior notice could be transmitted in a timely manner to CBP, but be held up due to computer programming, making the prior notice untimely. The brokers have fixed this problem in the short term by inputting the Los Angeles arrival date in both places for prior notice purposes and then changing it after prior notice has concluded.

(Response) The anticipated arrival date is a requirement of prior notice and is independent of CBP entry requirements. The Bioterrorism Act requires submission of prior notice before the food arrives in the United States, and not upon arrival as stated in the comment. Therefore, in the example provided, prior notice is required before the article of food arrives in Los Angeles notwithstanding any other CBP entry requirements.

For ABI entries requiring prior notice, the filer must enter separate dates for purposes of entry and prior notice. The filer enters an anticipated arrival date at the entry header level for CBP. For purposes of prior notice, the filer also enters the anticipated arrival date as an affirmation of compliance code "ADA." Therefore, there should not be a problem with choosing which date to submit as raised by the comment.

(Comments) One comment suggests that the systems provide a drop down list of reasons that provide an explanation for the absence of the registration number.

(Response) FDA agrees. In the November 2004 revision of the CPG that explained how FDA intended to enforce the prior notice IFR, a list of reasons was provided as Appendix 1, Reason Codes for Registration Number of Manufacturer Not Provided. This list of reasons is available in both PNSI and ABI/ACS, and the reasons are available as a drop down menu in PNSI. ACS is

⁵ This is a "Conditional Other Government Agency Declaration" input record that provides a code indicating that there are/are not other government agency review requirements.

programmed in "batch mode" which does not lend itself to drop down menus. CBP also has issued Administrative Messages to ABI filers in December 2004 and March 2005 concerning these reason codes. The Prior Notice Final Rule Draft CPG that is announced elsewhere in this issue of the **Federal Register** provides an updated list of reasons to be used in certain limited situations when the manufacturer's facility registration number is not provided in a prior notice submission.

(Comments) One comment recommends that the required data elements be identified so that shippers will know which elements are mandatory and which are not.

(Response) In the preamble to the IFR, FDA provided a table of the data elements for reference describing in which situations the information is mandatory (68 FR 58974 at 58980). The preamble of this final rule also contains table 2 which describes the information requirements. FDA also notes that PNSI is programmed such that if a data element does not apply, the data element is not requested during the prior notice submission process.

(Comments) One comment states that when a prior notice confirmation number is submitted to CBP and FDA, it is sometimes returned with a different prior notice confirmation number. The comment asks why this is and what happens to the original prior notice confirmation number.

(Response) FDA acknowledges that this problem occurred in the early stages of prior notice; however, we have rectified the situation. When we received a report concerning this prior notice confirmation number problem, we immediately modified our software to prevent the reported problem from reoccurring.

4. ABI/ACS Interface

(Comments) One comment states that the ABI system has been proven to be the most efficient means for meeting the prior notice time requirements.

(Response) FDA agrees that for many submitters, the ABI interface is the most efficient means for providing prior notice, as it allows the data to be saved and used for entry purposes. FDA also acknowledges that not all submitters have a custom broker, nor does ABI accommodate all transactions subject to prior notice (e.g., food imported by international mail or inside personal baggage not for personal use). Accordingly, the final rule continues to provide for electronic submission of prior notice via either ABI/ACS or PNSI.

(Comments) One comment points out that some problems with electronic submission of prior notice are being encountered by virtue of the fact that not all brokers interact with FDA in a completely electronic environment. ABI allows for the fully electronic transmission of CBP and FDA data, but "dual mode" brokers must also submit information to FDA in paper form. The comment recommends that FDA encourage all brokers to participate in paperless electronic processing.

(Response) "Dual mode" filers are those who must submit paper entries when transmitting entry information for FDA admissibility consideration. However, for prior notice, any customs broker or self-filer, including "dual mode" filers, may transmit using ABI/ACS or PNSI.

(Comments) One comment urges that for rail intermodal shipments between points in Canada where the transportation transits the United States, FDA should agree that data submitted to the CBP via AMS constitutes advance notice under the FDA regulations.

(Response) FDA disagrees. Under section 801(m) of the act, FDA, not CBP, must receive prior notice. Furthermore, no interface currently exists between AMS and the existing interface with FDA's OASIS through the ABI/ACS entry processes, which means FDA does not have access to AMS data. FDA and CBP have discussed interfacing with AMS for manifest data and determined that the general cargo data in AMS are not suitable to accommodate the detailed information requirements of the prior notice rule. For example, AMS does not collect the country of origin. In addition, its collection of the identities of the article of food and its manufacturer differs from the way those data points are collected under the prior notice final rule in such a way that the data would not meet our needs in carrying out the purpose of section 801(m) of the act.

(Comments) One comment reports that foreign exporters are obliged to use FDA's PNSI as they cannot register as users of CBP's ABI. The comment contends that these exporters, not being able to combine prior notice and a customs declaration for import in one operation, will be in a disadvantaged position compared to U.S. importers because the foreign exporter, after having completed his prior notice, will receive a prior notice confirmation number, which he then has to transmit to his U.S. importer or customs broker.

(Response) FDA disagrees. Prior notice may be submitted electronically through either ABI/ACS or PNSI. Typically, ABI/ACS is used by a person

who contracts with a filer who is licensed and approved by CBP to use ABI/ACS. The submitter provides the filer with the information necessary to transmit a complete prior notice through ABI/ACS to FDA. This process is often used to combine the prior notice and entry processes and many importers and foreign exporters find this to be the most advantageous process. FDA and CBP provided the ability to use ABI/ACS in response to comments to the proposed rule. As expected, the ABI/ACS process is used in around 83 percent of prior notice transmissions. PNSI was developed for those submissions that cannot be accommodated by ABI/ACS, and for those who choose not to use a customs broker for prior notice submissions, and these transmissions represent about 17 percent of the total prior notice submissions.

(Comments) One comment asks that the customs broker be allowed access to all pertinent information by electronic means in order to reduce the amount of paperwork required by the prior notice process.

(Response) The means by which the submitter provides the transmitter with the required information is a matter of communication between the submitter and transmitter. The final rule neither requires nor precludes processes the parties select to handle these communications.

(Comments) Several comments request that the agencies change the process for resubmission of prior notice after the original prior notice or entry has been cancelled and when prior notice is submitted after the food is already in the United States. One comment asks that the system interface be modified so that the resubmission automatically cancels the original. Another comment suggests that in the case where the foods are already in the United States and the CBP entry has had to be cancelled and resubmitted, it should not be necessary to repeat the prior notice filing; filing entry should be sufficient. Another suggests that when the second entry is made, CBP allow for submission of the previous prior notice confirmation number rather than the creation of a new prior notice with an accompanying new prior notice confirmation number. Other comments suggest that ABI submission of prior notice be allowed for food in the United States. An additional comment states that CBP entry can be made for articles of food that are already in the United States without adequate prior notice. Another comment recommends that FDA consider allowing the submission of prior notice through the ABI interface even when that prior notice will not be

timely. Finally, one comment suggests that a new prior notice should not be required when errors are made and that an easier way should be created to provide for corrections.

(Response) In the case of a prior notice submitted after the food has arrived, the prior notice is inadequate because of no prior notice and the food may be refused. The post-refusal prior notice (i.e., the prior notice submitted after arrival) may only be submitted via PNSI until such time as ACS or its successor system can accommodate such transactions. The changes to the system requested by the comments cannot be accommodated since such revisions would require programming changes to ACS, which CBP is currently only maintaining, and not enhancing since its replacement system (ACE) is being developed.

(Comments) One comment suggests that because errors in the ABI system need to be corrected in a timely manner to facilitate transmission of prior notice, CBP should be required to be available 24 hours a day, 7 days a week to allow for correction of these clerical errors.

(Response) Inasmuch as the filer has submitted a certified summary that the filer wishes to change, the cancellation of the entry is more than just a simple correction to an ABI transmission. This change requires review because it affects the integrity of cargo release. Accordingly, any corrections to certified entry information must be done during normal business hours.

(Comments) Several comments suggest that PNSI, in its validation processes, should include a check to see if other notices are already on file for the same article and that a warning message should be established to indicate a duplicate prior notice is being filed.

(Response) FDA disagrees. The prior notice submission process allows for transmission through either ABI/ACS or PNSI. The prior notice confirmation number is unique to a transmission through either system but cannot be matched against other transmissions at this time. Programming PNSI to locate duplicate prior notices would require a considerable amount of resources, which would yield minimal benefit since the submitter would know about the duplicate submission after transmitting the prior notice.

(Comments) Several comments request resolution of a PN/ABI system interface obstacle that requires that CBP entry and prior notice be made at the same time. The comment contends that prior notice must be submitted before entry can be made (e.g., for quota class merchandise subject to CBP "live entry"

requirements) and current system configurations can make it impossible to comply with both CBP and prior notice requirements. The comment recommends that CBP and FDA create a procedure in ABI/ACS that allows the CBP entry to be generated, but not filed, at the time a prior notice is submitted.

Another comment states that filers are insisting on submitting the entry information to CBP via ABI at the same time that they are submitting the prior notice information to the FDA. This apparently creates situations where the food is loaded and ready for shipment before there is a form of electronic release and this situation negates CBP's Customs-Trade Partnership Against Terrorism (C-TPAT) and the Free and Secure Trade (FAST) program requirements. The proximity of certain border points means that although the timeframe has been met with CBP for electronic release via CBP's PAPS, it is difficult to meet the present timeframes of the prior notice as the filer takes a longer time to submit both entries via ABI.

(Response) We disagree. Prior notice and entry need not be made at the same time. Prior notice is a precondition of entry and must be made first but may be done independently of the entry by use of FDA's PNSI or CBP's "WP" transaction in ABI. These systems allow for an independent submission of prior notice even if no entry has been filed. The entry filer may then provide the prior notice confirmation number to CBP as part of the entry. The entry will be validated in the CBP/FDA interface and will be allowed if the prior notice has been completed. The importer and filer may make a business decision to file the prior notice with the entry, and FDA and CBP's systems can accommodate this practice.

Because the entry and prior notice submissions may be completed independently, the timeframes are dependent on how the parties at interest choose to file entry and prior notice: The one-step (prior notice with entry) or two-step (independent prior notice followed by entry) process. This allows them to meet both timeframes, which represent two agencies, two processes, and two different sets of requirements.

(Comments) One comment contends that the lack of uniformity between the PNSI and CBP requirements for transmission of carrier information causes confusion to filers and FDA/CBP staff. The comment contends that providing the Standard Carrier Abbreviated Code (SCAC) code for the carrier in lieu of the carrier's name and country is only available when transmitting via PNSI because the CBP

system, which is how the majority of prior notices are being transmitted, requires the name and country and does not provide the SCAC option.

(Response) FDA disagrees. The SCAC or International Air Transportation Association (IATA) codes can be transmitted via ABI/ACS via an Affirmation of Compliance. The CBP requirement to provide the name and country of the carrier is for purposes other than prior notice.

(Comments) Several comments recommend an interface between the CBP manufacturer identity (MID) codes and the FDA food facility registration numbers. Specific recommendations include that: (1) CBP allow the MID system to be updated via prior notice submissions; (2) FDA develop an interface with CBP that allows for validation and coordination of data between these two systems; (3) ABI provide a notification to the filer if the information from the MID does not match the facility registration information on file with FDA; and (4) the agencies permit incorrect and duplicate MID information to be corrected through a secure CBP system. Another comment recommends the establishment of a system that validates data and resolves any conflict between CBP and FDA data.

(Response) With respect to correcting and updating MIDs, CBP does not believe it is possible to eliminate all differences between MIDs and related FDA manufacturing facility registration numbers. The same manufacturer may have numerous MIDs, and conversely, a MID may identify more than one manufacturer due to the nature of the algorithm that is employed.

With respect to the comment that asks that FDA develop an interface with CBP to allow for validation and coordination of data, FDA and CBP currently exchange facility data electronically as part of the prior notice and 801(a) processes. CBP sends FDA the MID and facility information (including registration number, when applicable). FDA performs edits to ensure that the MID matches the firm represented by the registration number. In certain cases, FDA will reject a prior notice submission that does not match a MID submission. Filers will receive an ABI rejection communication identifying the mismatch when this occurs. Once the facility and all other required information has been received and validated, FDA will confirm the prior notice submission.

(Comments) Several comments suggest that when a prior notice is transmitted via ABI/ACS and confirmed for review by FDA, the data should be

moved from ACS to OASIS regardless of the estimated time of arrival (ETA) date.

(Response) The ABI/ACS system is not configured to certify information nor transfer information to FDA in real-time as PNSI does. ACS is programmed to collect data in batch mode and does not transmit the data to FDA instantaneously. Therefore, prior notices submitted via PNSI will continue to receive a real-time system response when the prior notice is confirmed for review by FDA. However, prior notices submitted via ABI/ACS will continue to be transmitted in a batch mode and to receive systematic confirmation responses in the pre-arranged timeframes developed by CBP. For those prior notices submitted via ABI on the anticipated date of arrival, users can expect to receive a response message (confirmation number or rejection) within 15 minutes of submission. For ABI submissions submitted prior to the anticipated date of arrival, users can expect to receive a response message no later than midnight (Eastern Time) on the anticipated date of arrival, i.e., the message generally is sent before 11:59 p.m. on the day before the anticipated date of arrival.

(Comments) Several comments state that although PNSI is designed to not require changes in the location of the anticipated port of arrival (thus allowing a shipment to be diverted to a port other than the intended port of arrival transmitted in the prior notice), the CBP ABI system precludes the CBP entry from being accepted at other than the reported port of entry. When this occurs, the CBP entry and original prior notice must be deleted and a new entry must be submitted with a new prior notice creating a new timeframe. The comments recommend that the requirement be consistently applied and that the ABI/ACS system be revised to allow for changes to the port of entry without causing cancellation of the CBP entry.

(Response) FDA disagrees. The prior notice rule does not require a new prior notice when the anticipated port of arrival changes after the prior notice has been confirmed for review by FDA. CBP does require cancellation of entry documentation for entry purposes when the port of entry changes. The cancellation of an electronic ABI entry for CBP results in the cancellation of any associated prior notices filed with the entry in ABI. Amending ABI/ACS to allow amendments, such as when the port of entry changes, would entail substantial and costly revisions to the system; such technical changes are not cost-effective or a good use of limited resources given the development of the

Automated Commercial Environment, which will replace ACS.

(Comments) One comment recommends that for a short trial period, the full prior notice edits, with warning messages, should be turned on without rejection of CBP entry processing. The comment reasons that this would be a method of alerting ABI/ACS transmitters to errors without jeopardizing the movement of the food. Another comment suggests that a significant reason for a high rate of noncompliance on data submissions is the lack of the automated systems' capability to advise filers of data inadequacies.

(Response) The systems provide for error messages to be transmitted to filers that identify the reasons for errors in prior notice submissions that can be determined during the data entry process (e.g., certain required data elements are missing or product code submitted is invalid). Over time, the agencies have seen the prior notice rejection rate go down. Both agencies have been providing industry with information regarding error messages.

(Comments) One comment points out that the PNSI Web portal has changed to allow multiple containers to be reported against a single prior notice line but that CBP has not changed their specifications to allow more than a single container to be reported on a prior notice line in ABI. The comment recommends that this change to the FDA Web portal be communicated to CBP so they may change their ABI specifications.

(Response) ABI currently allows filers to submit multiple container numbers per FDA line by sending multiple FD05 records containing affirmation of compliance code "CNO." The first affirmation goes in the FD01 record, with subsequent affirmations in the FD05 record which can be repeated as often as necessary. Filers are able to submit multiple records using the affirmation of compliance code "CNO" and provide a different container number in each record.

5. PNSI

(Comments) One comment suggests that to more effectively screen shipments entering the United States, FDA must work to integrate OASIS with the prior notice system.

(Response) FDA's OASIS has always been an integral part of the prior notice process as OASIS provides for internal systematic screening of prior notice submissions in order to assist the agency in making a determination regarding inspection of the food at the border. OASIS also provides for

systematic screening to assist FDA in making admissibility decisions.

(Comments) Several comments request extension of the time one is permitted to be logged into a session using PNSI. Comments state that it is difficult to complete entering data before the system times out. Several comments suggest that completing the process in time was difficult for many persons whose native language is not English.

(Response) For security reasons, PNSI is currently configured with a 30-minute time-out. FDA notes that Internet commerce systems are typically configured with a similar, or more stringent, time-out setting. FDA also notes that the time-out setting applies only to a period of user inactivity; no limit is set on the total amount of time the user may be logged into a particular session, nor is there a limit to the amount of time taken to prepare and save or submit a specific Web entry or prior notice. Users are "timed-out" only if their session remains inactive for longer than the time-out setting.

Users may also save their entry while it is partially completed. The data are retained and will be available when the user logs back into the system.

(Comments) Several comments express concern about the capacity of the FDA computer systems to process the volume of submissions. These comments suggest that the system needs additional capacity to meet the loads expected when full enforcement is instituted. Several comments also believe that performance issues (e.g., slow response) are hampering their usage of the system.

(Response) FDA recognizes these concerns and is committed to providing systems that will meet user needs. FDA designed the prior notice systems to process a volume of users far in excess of the projected usage. Prior to implementation, FDA thoroughly tested the performance of its system against loads in excess of that anticipated. These tests have shown the system capable of maintaining acceptable response even at these loads. Currently, FDA handles approximately 167,000 prior notices each week and could handle a much higher volume without a capacity problem.

Many factors influence the responsiveness of an Internet based system, including factors beyond the FDA's control, such as the user's computer system (hardware, software, and Internet connection) and traffic on the Internet as a whole. Since prior notice was implemented in December 2003, FDA has carefully monitored both PNSI and OASIS system usage and

performance. During this period, no issues related to load on these systems have been identified. FDA has worked to resolve specific issues, such as hardware failures, which have hampered system performance and availability for short periods.

FDA and CBP also have increased the capacity of the communications link between their systems to ensure that additional bandwidth is available for future increases in load. FDA continues to monitor its system and to test for performance as the system is upgraded and enhanced. Users may obtain current system status information for PNSI at the FDA Industry Systems home page (<http://www.access.fda.gov>) and are requested to contact the Help Desk if they encounter any performance issues currently not identified on the system status page.

(Comments) Several comments recommend that FDA develop an alternate system that supports batch submission of prior notices. The comments suggest that a batch system would save submitters a vast amount of input time and allow the agency faster processing capability. The comments also assert that a batch system would reduce the costs incurred due to double entry between the user's existing systems, e.g., for order entry and filing with FDA. One comment proposes that they be given a defined quantity of registration numbers at their disposal for printing onto their dispatch labels (presumably by registration number they are referring to the prior notice confirmation number). The comment says they would like a fully automated process, where all data relevant for prior notice would be created and then transmitted electronically to CBP and FDA, instead of the current procedure of manual input of all details.

(Response) FDA agrees that a mechanism to facilitate batch/fully automated filing would provide some advantage to certain filers. However, FDA believes that the existing systems (PNSI and ABI) currently provide substantial capabilities in this area. PNSI offers several features that make prior notice data entry faster and reduces the amount of redundant data entry such as the Copy Web Entry feature, Copy Prior Notice feature and other shortcuts. Please refer to Time Saving Tips from FDA's PNC for PNSI (<http://www.cfsan.fda.gov/~pn/pntips.html>) for a description of these features. ABI software can often provide similar copying features, depending on the ABI software package used by the transmitter.

FDA also recognizes that the resources to develop and maintain an

additional system would be significant. Therefore, FDA is not prepared to undertake the development of a batch system at this time; following completion of any system upgrades that will be released in conjunction with implementation of the final rule, FDA will reassess the need for and feasibility of developing a batch submission system. FDA notes that some submitters have created their own internal programs that are designed to organize data in "batch" mode, which in turn submits their prior notices to PNSI in rapid succession.

(Comments) One comment states that they frequently ship the same article of food in multiple containers. The comment believes that since there is only one article of food, only one prior notice should be required. The comment notes that the FDA Web Portal only allows the input of one container per prior notice; therefore, they have to submit multiple prior notices instead of only one. The comment requests that the FDA Web Portal be changed to allow for the input of multiple containers per article of food.

(Response) FDA agrees. The FDA Web Portal has been changed to allow multiple containers to be reported against a single prior notice line in the above situation.

(Comments) One comment states that most of their orders contain multiple food items in one box and the process of filing prior notice in PNSI for each item is very time consuming because one can only enter one item at a time. The comment suggests updating PNSI to allow users to enter multiple items on one screen (i.e., the user creates a Web entry for each shipment and the system then allows them to specify all items in that shipment on one screen).

(Response) A prior notice contains information on not just the article of food being imported, but also the facilities related to that article such as the manufacturer, shipper, owner and ultimate consignee. Since this information can be unique for each article, it must be provided for each article individually. PNSI does offer several features that make prior notice data entry faster and reduce the amount of redundant data entry such as the Copy Web Entry feature, Copy Prior Notice feature and other shortcuts. Please refer to Time Saving Tips from FDA's PNC for PNSI (<http://www.cfsan.fda.gov/~pn/pntips.html>) for a description of these features.

(Comments) One comment states that FDA's Web Portal does not accept the input of CBP entry numbers. The comment further states that there are times when an entry number is not

required for an article of food that requires prior notice. The comment questions why the FDA Web Portal does not accept an entry number when a CBP entry is required and known at the time of filing prior notice. Another comment recommends that the Web Portal software be redesigned in order for filers to receive the relevant entry identifier information with the prior notice confirmation number.

(Response) FDA disagrees. PNSI does accept the CBP entry number. If there is no entry number or other entry identifier, PNSI will provide a system-generated entry identifier to the prior notice submission. We also posted guidance on FDA's Web site at <http://www.cfsan.fda.gov/~pn/pnentgui.html> that describes the entry types and the entry identifiers. (See also discussion infra on the CBP entry identifier in section III.H.5 of this document.)

(Comments) Several comments express concern about system outages for PNSI and/or ABI. These comments suggest that one or both systems had not been available for extended periods in the past or were frequently unavailable. Comments also recommend that FDA provide an alternate method, such as facsimile, for submission during periods when the systems are not available. One comment notes that PNSI has not been functioning properly. The comment states that the System Status update pages indicates that the system is operating as "normal," but the system is really down.

(Response) FDA recognizes that system outages could have the potential to disrupt trade. To minimize outages, FDA has built redundancy into these computer systems (e.g., multiple servers and backup systems) and, to the extent possible, combined planned maintenance activities to be accomplished during a single outage. Planned outages are scheduled for a timeframe with the minimum possible impact to users and notice is provided as far in advance as possible, allowing users to plan their access to the system. System status information, including planned outages, is posted at <http://www.access.fda.gov> and at <http://www.cfsan.fda.gov/~furls/fisstat.html>. Users are requested to contact the Help Desk if any performance issues not identified on the system status page are encountered.

FDA also provides alternate options for users to file prior notice during system outages. Filers who use CBP's ABI/ACS system can utilize PNSI when ABI, ACS, and/or OASIS are unavailable. In addition, FDA has provided a method for filing via facsimile or e-mail when PNSI is

unavailable for an extended period (see the Contingency Plan for System Outages at <http://www.cfsan.fda.gov/~pn/pndguid.html>). These contingency plans are designed to ensure that the flow of trade is not interrupted when system outages cannot be avoided (see also the discussion on contingency plans below).

(Comments) One comment notes that companies continue to report technical difficulties when using PNSI, including the inability to access reliable technical advice through the hot-line. Another comment indicates that the waiting time for the helpline is very long, with a minimum wait time of 15 minutes.

(Response) FDA has made a number of enhancements and has fixed several issues with earlier releases of PNSI. FDA also continues to work to provide the best possible service addressing technical issues through the Help Desk. Users are encouraged to continue to contact the Help Desk for technical assistance. The Help Desk is available Monday through Friday from 7:30 a.m. to 11 p.m. Eastern Time. Users may leave a message or send e-mail at other times, which will be addressed on the next business day.

(Comments) Several comments address the complexity of PNSI. The comments state that the system requires the complete re-creation of all data for each prior notice even when shipments are repetitive with minimal variables in information; that the full address should not be necessary for registered facilities; and that PNSI should allow submitters to save and store data for replication or provide for self-populating fields. One comment, however, notes that their users have had relatively little problem using PNSI.

(Response) FDA continues to provide, to the extent possible, a "user-friendly" PNSI application. Several features have been added since the initial release (PNSI 1.0) to assist users, including a feature that allows users to copy individual prior notices and Web Entries, with or without the associated prior notices. Where possible, lists of standard values (e.g., entry types, SCAC & IATA Codes, firm types, quantity and packaging descriptions) are provided to facilitate entry of these values. These enhancements minimize the need for users to enter repetitive information. Similar to the IFR, the prior notice final rule does not require the full address in all cases. When a registration number is provided, name, city and country can usually be provided instead of the name and full address (e.g., § 1.281(a)(6)). FDA continues to work to enhance the system, in response to user comments,

as well as to changing business requirements.

(Comments) One comment asks if PNSI will provide guidance on formatting of the information for identification of the submitter, transmitter, and manufacturer. The comment is concerned that PNSI may only accept certain formatting, without providing guidance to the submitter, thereby, causing problems with PNSI accepting and processing prior notice.

(Response) PNSI is supported by several tutorials and help screens which lead the user through correct inputting of data.

(Comments) Several comments address specific issues with the PNSI software (potential "bugs") or suggestions for enhanced capabilities. Examples include questions about the completeness of the lists of values (drop-down lists), issues with browser settings and compatibility, and suggestions for additional bar code printouts.

(Response) FDA welcomes user suggestions for improvements to the PNSI system. Discrepancy reports are investigated thoroughly to ensure the system meets both FDA's requirements and user needs to the extent possible. Suggested improvements are also prioritized and reviewed by a Change Control Board who continue to determine appropriate and feasible improvements to the system. FDA encourages users to continue to contact the Help Desk with any technical questions, issues, or suggestions.

(Comments) One comment suggests that PNSI should be revised to create a view screen similar to the printed confirmation with all the information in one place before submission. The comment also suggests that when creating a prior notice for different commodities, the system should not have all commodities default onto prior notice, but should allow the user to use a check box to choose a commodity, rather than to cancel the commodity.

(Response) FDA agrees. The PNSI software has been enhanced to provide a screen that includes all of the information about the prior notice prior to a transmitter completing the submission step. PNSI also has been enhanced to allow copying of prior notices within a Web Entry and copying of a Web Entry, with or without the associated prior notices. A user thus can copy a Web Entry with all associated prior notices, then use the cancel function to remove any prior notices not required for the new entry.

FDA welcomes any additional comments or suggestions on how to improve PNSI; these can be submitted to

the Help Desk using the telephone number or e-mail provided at <http://www.cfsan.fda.gov/~furls/helpf.html>.

6. Security of the Systems

(Comments) One comment suggests that FDA create a mechanism whereby interested parties may assert protection from public disclosure under FOIA for information contained in prior notices that they believe is confidential business information.

(Response) We believe that there is no need to create such a mechanism because the agencies would review the prior notice information to determine if it is protected by a FOIA exemption before disclosure to the public.

(Comments) One comment states that in order to complete the PNSI submission, several security settings on their respective computers had to be disabled.

(Response) PNSI is designed to work with the browsers listed at <http://www.access.fda.gov/>, using standard settings. PNSI requires that the browser be set to accept cookies. FDA does not believe that these settings present a security risk to users. Users are encouraged to contact the Help Desk for assistance with specific issues regarding access and system settings.

7. Contingency Plans

In § 1.280(b), (c), (d), and (e) of the IFR, FDA requires that if a custom broker's or self-filer's system is not working or if the ABI/ACS interface is not working, prior notice must be submitted through PNSI. It further states that if the PNSI is not working and/or OASIS is not working, FDA will issue an Internet notification, and submission of prior notice must be by e-mail or by facsimile to FDA. FDA posts the e-mail or facsimile information on its Web site. The prior notice information will only be accepted at the posted e-mail or facsimile locations if FDA determines that PNSI or OASIS is not working.

On August 12, 2004, FDA and CBP published guidance covering a Contingency Plan for System Outages (see <http://www.cfsan.fda.gov/~pn/pndguid.html>). FDA and CBP identified seven potential system downtime scenarios that could impact transmission, confirmation, and processing of prior notice submissions and developed alternative submission options for each of the identified scenarios.

(Comments) One comment states that FDA and CBP need to formulate and communicate a realistic contingency plan for commercial importations that takes into account CBP ABI downtime, FDA OASIS downtime, and broker

downtime. Two comments express concern that contingency plans include a dependency on PNSI and their experience has shown that PNSI was intended for the casual importer and never intended for commercial operations. The comment states that significant delays will be experienced if 80 percent of the transactions are suddenly routed from the ABI/ACS system to the PNSI system.

(Response) FDA is committed to providing systems that will meet user needs. FDA designed PNSI to process a volume of users far in excess of the projected usage, and tested performance at these volumes. As noted previously, FDA and CBP published guidance covering a Contingency Plan for System Outages (see <http://www.cfsan.fda.gov/~pn/pndguid.html>) and anyone may submit comment on it.

(Comments) One comment suggests that FDA and CBP provide guidance that defines an appropriate timeframe to wait for prior notice confirmation before assuming the system is down and/or that resubmission is required.

(Response) Generally, for prior notice submissions via PNSI, the user should receive a confirmation number immediately upon submission of the correctly completed form. For those prior notices submitted via ABI on the anticipated date of arrival, users can expect to receive a response message (confirmation number or rejection) within 15 minutes of submission. For ABI submissions submitted prior to the anticipated date of arrival, users can expect to receive a response message no later than midnight (Eastern Time) on the anticipated date of arrival, i.e., the message generally is sent before 11:59 p.m. on the day before the anticipated date of arrival.

The FDA/CBP Contingency Plan states that "notice advising of any available downtime specifics will be posted at <http://www.access.fda.gov>, <http://www.fda.gov>, <http://www.cfsan.fda.gov/~furls/fisstat.html>, and <http://www.cfsan.fda.gov/~pn/pnoview.html>, and through messages in ABI/ACS (see 21 CFR 1.280(d))." Section 1.280(c), (d), and (e) of the IFR also lists three of these four Web sites to advise of system downtimes, and specifies in what form prior notice should be submitted during certain system outages (i.e., e-mail or fax). In order to simplify the Web addresses for these notifications and the instructions for submitting prior notice when PNSI or OASIS is not working, the final rule has been revised by providing the outage notification at one Web address (<http://www.fda.gov>). In order to provide more flexibility to respond to

various contingencies, the final rule has also been revised by stating that FDA will accept prior notice submissions in the format it deems appropriate during the system(s) outage.

FDA has posted information on the Systems Status Web site located at <http://www.cfsan.fda.gov/~furls/fisstat.html> regarding system downtime that states "Most problems will be temporary. Try accessing the system again in 15 minutes." This site also provides information about scheduled maintenance, which states that "Periodically FDA Industry Systems will need to undergo maintenance and upgrades. All scheduled maintenance will take place on Saturdays 3 a.m. to 8 a.m. Eastern Time (Saturday 8 a.m. to 1 p.m. GMT). If you are having trouble accessing FDA Industry Systems during that time, please try again after 8 a.m. Eastern Time on Saturday (1 p.m. GMT)." This site also provides a status history of the system.

(Comments) One comment suggests that FDA should develop and publish a form that could be used if it were ever necessary to file prior notice by fax. The comment asserts that a form also would assist importers in gathering the information necessary to file a prior notice and also would clear up the confusion that currently exists in foreign countries. The comment believes that it was obvious that FDA contemplated issuing a form when it first proposed the prior notice regulations and complains that no explanation has been given by FDA for not producing the form.

(Response) FDA disagrees. A form to be used during contingencies is posted on FDA's Web site only when an applicable system outage is encountered. During a system outage when fax submissions are being accepted, FDA will publish the fax telephone number for the PNC at <http://www.access.fda.gov>, <http://www.fda.gov>, <http://www.cfsan.fda.gov/~furls/fisstat.html>, and <http://www.cfsan.fda.gov/~pn/pnoview.html>, as well as through messages in ABI/ACS. Fax transmission is not allowed except when posted and submitted during PNSI downtimes or specified emergencies. FDA believes that if the form was available and posted even as a reference, there is the potential for misuse or confusion. Our experience with use of the fax form is that submitters will continue to fax the form even after they have been instructed that the form will not be accepted.

(Comments) Some comments express concern that submission of all prior notices relies on electronic systems (even the fax). The comments suggest

that the usual flow of goods should be allowed to continue unhindered, with the paperwork sorted out afterwards. One comment further suggests that rather than providing for PNSI as a contingency system when ABI is down, prior notice submissions should function according to all other submissions processed through ABI when CBP declares either a "national snow day" or "power outage." The comment recommends that if ABI is not working, the shipment should be allowed to proceed, pending later issuance of a prior notice confirmation via ABI.

(Response) FDA does not agree that if ABI is not working the shipment should be allowed to proceed. In that instance, prior notice can, and therefore should, be submitted via PNSI.

In all contingency situations, except for power failure, some electronic means of prior notice submission is required, either by PNSI, e-mail, or fax. However, in the case of a localized or regional power failure, the Contingency Plan guidance recommends that filers should submit the required prior notice information to FDA at the port of arrival, or if there is no FDA officer at a given port, to CBP via a paper copy of the prior notice e-mail contingency form (FDA 3540) at the time of cargo release.

(Comments) One comment explains that various companies are organizing contingency plans whereby the prior notice confirmation number will be included in the delivery order, which then will be faxed to the office of the steamship line at the port of entry so that the requisite paperwork is in hand when the product is offloaded from the carrier. The comment further explains that this contingency plan takes into account the unique circumstances posed by transporting goods by steamship line insofar as the customs broker or purchaser may not always be able to send the prior notice confirmation number to the carrier prior to the carrier's arrival. The comment asserts that the procedure satisfies FDA's requirements that the prior notice confirmation number must accompany the food when it "arrives in the United States" and be provided to CBP or FDA "upon arrival." The comment further urges FDA to include this course of action in its guidance documents.

(Response) FDA agrees that the described scenario satisfies the requirement under § 1.279(g) that the prior notice confirmation number must accompany any article of food for which the prior notice was submitted through PNSI when the article arrives in the United States and must be provided to

CBP or FDA upon arrival. FDA does not believe, however, that it is necessary to include this specific business practice in its guidance documents, as there are various means that private entities may choose to use to comply with the regulation.

As described in the contingency plan guidance, if prior notice already has been submitted via ABI/ACS prior to an interface outage, and confirmation from FDA already has been received, then the submitter may proceed with prior notice using the standard process under the following scenarios:

- ACS, OASIS, and PNSI are all operational, but the link between ACS and OASIS is down on FDA's or CBP's side of the system interface;
- ACS, PNSI, and the link between ACS and OASIS are operational, but OASIS is non-operational;
- ACS and the link between ACS and OASIS are operational, but OASIS is non-operational or unavailable due to Internet service interruptions;
- OASIS, PNSI and the link between ACS and OASIS are operational but ACS is non-operational; or
- ACS is non-operational, PNSI is non-operational or unavailable due to Internet service interruptions, and OASIS and the link between ACS and OASIS are either operational or non-operational.

The standard process does not include presentation of the prior notice confirmation number to FDA or CBP upon arrival if the prior notice was submitted by ABI/ACS.

If prior notice already has been submitted via ABI/ACS and confirmation from FDA has not been received prior to the interface outage, FDA and CBP recommend that rather than resubmitting via PNSI, submitters should provide to CBP officers, at the time of cargo release, an endorsed (signed) copy of the ABI transmission or some other evidence adequate to show that prior notice has been submitted via ABI/ACS.

If prior notice has been submitted via PNSI prior to the system outage and a confirmation number already has been received, the confirmation number must accompany the article of food (§ 1.279(g)). In addition, FDA and CBP recommend that the submitter also provide the PNSI confirmation page, including the prior notice confirmation number and time stamp, to CBP officers for cargo release. If the prior notice confirmation page is not provided, this may delay cargo release while the CBP officer contacts FDA for verification of the prior notice confirmation number(s) and time of submission.

(Final rule) The final rule in § 1.280(a) requires that prior notice must be submitted electronically to FDA in the English language, except that an individual's name, the name of a company, and the name of a street may be submitted in a foreign language. All information, including these items, must be submitted using the Latin (Roman) alphabet.

Section 1.280(a)(1) and (a)(2) of the final rule provides for two methods of electronic submission of prior notice: (1) The CBP Automated Broker Interface of the Automated Commercial System (ABI/ACS); or (2) The FDA PN System Interface (PNSI) at <http://www.access.fda.gov>. We corrected a reference in paragraph (a) to state that unless § 1.280(c) applies, prior notice must be submitted through either ABI/ACS or PNSI.

The final rule requires submission of prior notice via PNSI for articles of food imported or offered for import by international mail, and other transaction types that cannot be made through ABI/ACS. Prior notice for articles of food that have been refused under section 801(m)(1) of the act must be submitted through PNSI until such time as ACS or its successor system can accommodate such transactions.

The final rule also provides for contingencies if involved systems were not working, e.g., a custom broker's or self-filer's system, ABI/ACS, PNSI, or OASIS. The final rule requires that prior notice must be submitted through PNSI if a customhouse broker's or self-filer's system or if the ABI/ACS interface is not working. The final rule states that if PNSI or OASIS is not working, FDA will post prominent notification and instructions at <http://www.fda.gov>. FDA will accept prior notice submissions in the format it deems appropriate during the system(s) outage. The final rule does not exempt any specific categories of food articles from prior notice if systems are not performing.

H. What Information Must Be in a Prior Notice? (§ 1.281)

The Bioterrorism Act requires the submission to the Secretary of a notice providing the identity of each of the following: The article; the manufacturer and shipper of the article; if known within the specified period of time that notice is required to be provided, the grower of the article; the country from which the article originates; the country from which the article is shipped; and the anticipated port of entry for the article.

The IFR requires in § 1.281(a), (b), and (c) that specific information be submitted in prior notice: Section

1.281(a) covers general information requirements which apply to all shipments except those arriving by international mail; section 1.281(b) covers limited information requirements for food arriving by international mail; and section § 1.281(c) covers information requirements for food refused under section 801(m) of the act (e.g., food that has already arrived in the United States).

The preamble to the IFR discusses the term, "an article of food," and states that "the description of an 'article' of food is not the same as the definition of 'food' in § 1.276(b)(5). An 'article' refers to a single food that is associated with the same complete FDA Product Code, the same package size, and the same manufacturer or grower. These requirements are found in the information required in the IFR in § 1.281(a)(5), (a)(6), or (a)(7) and again in § 1.281(b) and (c)" (68 FR 58974 at 59003).

The comments are discussed in order of the information requirement in the IFR, beginning with comments generally addressing the information requirements.

1. General Comments

(Comments) Several comments express concern that the IFR requires significantly more information than the Bioterrorism Act requires and ask that FDA reduce the number of data elements. One comment notes that the Bioterrorism Act names only six or seven specific items that must be provided. One comment indicates that the information required for prior notice is far in excess of that required in the Codex Committee on Food Import and Export Inspection and Certification Systems Guidelines for Generic Official Certificate Formats and the Production and Issuance of Certificates (CAC/GL 38-2001). One comment adds that the required information far exceeds what is necessary to enable FDA to identify articles of food that need to be inspected. Another comment suggests that some of the information required for a prior notice is already "covered" by the registration requirement of section 305 of the Bioterrorism Act (see the Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 interim final rule, 21 CFR part 1, subpart H, confirmed 70 FR 57505, October 3, 2005), so FDA will already have this information. Another comment suggests that the prior notice could be simplified, thus reducing the possibility of errors and potential trade disruptions, by quoting the registration number and only adding information

specific to a particular shipment. One comment notes that CBP's data fulfill FDA's needs; therefore, the IFR's duplicate system is a waste of resources, and FDA should use CBP's system.

(Response) FDA disagrees with the comments that ask for a reduction in the number of required data elements. FDA has selected those data elements that will allow FDA to meet its statutory obligation to receive, review, and respond to prior notices efficiently and effectively. In addition to the Bioterrorism Act's requirements of the identities of the article of food, the manufacturer and shipper, the grower, if known, the country from which the article originates, the country from which the article is shipped, and the anticipated port of entry for the article, FDA determined that certain additional information is required for efficient enforcement of the Bioterrorism Act, primarily for the means of identifying the article of food and effective enforcement of refusals. For example, the identification of the individual and the firm, if applicable, submitting the prior notice is needed so that FDA knows who is responsible for the information in the prior notice and can communicate with them when necessary via mail, phone, or e-mail. The information also is necessary to follow up when audits, inspections, or enforcement are necessary. Therefore, FDA does not agree with one of the comment's assertions that the prior notice rule should only require the registration number and other information specific to a particular shipment.

The goals of the Bioterrorism Act and the Codex Committee differ, and thus, the requirements of the prior notice rule will differ from that of the Codex Committee on Food Import and Export Inspection and Certification Systems. The purpose of prior notice is to enable FDA to conduct inspections of imported foods at U.S. ports upon arrival and target foods that may pose a significant risk to public health, based on the information submitted. The Codex Committee on Food Import and Export Certification and Inspection Systems is charged with developing principles and guidelines for food import and export certification and inspection systems.

We also do not agree with the comment's assertion that FDA should use CBP's data to fulfill FDA's needs under the Bioterrorism Act. Information that is submitted at the time of CBP entry processing is not useful for prior notice as this information can be submitted or changed after the food has already arrived in the United States and thus does not fulfill the express intent

of the Bioterrorism Act that FDA receive information about a shipment before it arrives in the United States.

FDA also does not agree that some of the prior notice information is already "covered" by the food facility registration requirement. For example, facilities typically provide general product categories as part of the registration process. This generalized information would not provide the identity of the article being imported or offered for import and, therefore, would not meet the prior notice requirements as defined in section 801(m) of the act. Therefore, we do not agree that some of the registration information could be used to meet the prior notice information needs. Moreover, a facility's registration contains all of the general food product categories the facility manufactures, processes, packs or holds; and would not allow FDA to know specifically which article of food is the subject of the prior notice, which precludes an effective assessment of risk.

(Comments) Several comments recommend that the limited information requirements associated with food arriving by international mail in § 1.281(b) be applied to all importations. One comment suggests that by eliminating such data as the entry type and identifier, the port of entry, the FDA Product code, and the HTS code, all prior notices could be submitted via FDA's PNSI at an earlier time. The comment further asserts that the requirement for these types of data is the primary reason that 80 to 90 percent of prior notices are submitted via ABI/ACS rather than PNSI. Another comment reasons that as the manufacturer and facility identification numbers are not provided for homemade food or postal shipments, the necessity of providing this information for other types and modes should be examined. Another comment recommends that the notification procedure should be simplified, and that the data elements should be limited to the minimum, such as the shipper's name and its contact point, the food facility registration number, and food product codes.

(Response) FDA disagrees. The type of information required for prior notice submissions of food arriving by international mail are limited because of the process by which international mail enters the United States. For international mail shipments, the IFR and the final rule requires the identification of the U.S. recipient rather than the importer, owner, or ultimate consignee because mail is sent only to a U.S. recipient rather than the

multiple entities that may be involved in a traditional commercial importation. The final rule does not require an entry identifier because international mail will always receive a system-generated identifier, as international mail shipments cannot be submitted via ABI/ACS. Because the port of entry and time and date of entry are completely subject to the international mail process, the IFR requires only that the submitter identify the date of shipment, i.e., the date the food is shipped, which provides the most information possible to satisfy the anticipated port of entry. Moreover, since international mail is always in the custody of CBP until it is released for delivery to the recipient, no additional shipment information is necessary for communication between FDA and CBP.

FDA also disagrees that information, such as the entry type and identifier, the port of entry, and the FDA Product Code should be eliminated from the prior notice requirements. The anticipated port of entry is specifically required by the statute and FDA has determined that the best possible method of determining product identity is the FDA Product Code. We have eliminated the HTS code in the final rule because it has not been a necessary factor for enhancing communication between FDA and CBP for the purpose of inspection at the port of arrival. However, the entry type and identifier are critical elements in communications between FDA and CBP so that the appropriate food is either held at the port of arrival as appropriate, or allowed to proceed.

FDA also disagrees with the suggestion that the manufacturer and facility registration numbers are not provided for homemade food or postal shipments and, therefore, should not be required for other types of shipments. The IFR excludes homemade food from prior notice requirements entirely, and this exclusion also is in the final rule. Both the IFR and the final rule require submission of the identity of the manufacturer and the manufacturer's registration number in the prior notice for food arriving by international mail.

FDA agrees with the comments that prior notice requirements should be limited to the minimum, and has selected those data elements that will allow FDA to expeditiously meet its statutory obligation to receive, review, and respond to prior notices. FDA, however, does not agree with the comments that the shipper's name and its contact point, the registration number of food facility, and food product codes are the only data elements FDA needs to fulfill this mandate. In addition to the Bioterrorism

Act requirements of the identities of the article of food, the manufacturer and shipper, the grower, if known, the country from which the article originates, the country from which the article is shipped, and the anticipated port of entry for the article, FDA determined that certain additional information is required for efficient enforcement of the Bioterrorism Act, primarily for the means of identifying the article of food and effective enforcement of refusals.

FDA also notes that it is not surprising that 80 to 90 percent of prior notices are submitted via ABI/ACS. Numerous comments on the proposed rule urged FDA to use the existing ACS-OASIS interface between CBP and FDA to accept prior notice information. As stated in the IFR, FDA and CBP agreed with the recommendation that the agencies provide a single point of data entry for CBP and FDA for as many kinds of entries as possible, and modified our systems to allow prior notice to be filed by either CBP's ABI/ACS or FDA's PNSI beginning with the December 12, 2003, effective date of the IFR. FDA also noted at that time that it expected approximately 90 percent of prior notice submissions for all importations of foods to be transmitted by a customs broker or self-filer through the ABI/ACS interface to FDA. (See 68 FR 58974 at 58976, October 10, 2003.) Since implementation, this estimate has proven true, as approximately 83 percent of all prior notices are filed through the ABI/ACS interface.

(Comments) Several comments suggest that all prior notice information requirements that are duplicative of information requirements for CBP via AMS for Advanced Electronic Information or in ABI/ACS for Entry should be eliminated. One comment recommends that prior notice be aligned with CBP "ACI" rules, for both timing and data elements. The comment believes that this could lead to a possible reduction in data elements.

(Response) FDA disagrees. Information that is submitted for CBP entry processing is not useful for prior notice as this information can be submitted or changed after the food already has arrived in the United States and prior notice is required before the food arrives.

Moreover, no interface currently exists between AMS and the existing interface with FDA's OASIS through the ABI/ACS entry processes, which means FDA does not have access to AMS data. FDA and CBP have discussed interfacing with AMS for manifest data and determined that the general cargo data in AMS are not suitable to

accommodate the detailed information requirements of section 801(m) of the act. For example, its collection of the identities of the article of food and its manufacturer differs from the way those are collected under the prior notice interim final and final rules in such a way that the data would not meet our needs in carrying out the purpose of section 801(m) of the act.

(Comments) Many comments suggest that submitters consolidate similar prior notices into one prior notice based on a variety of reasons, e.g., one prior notice per consignee with all food products consolidated; one prior notice per shipment with all information consolidated; one prior notice per commodity regardless of the quantity, size, color or species; one prior notice per bill of lading; one prior notice per truck or conveyance and one prior notice for the same food type regardless of brand.

(Response) The Bioterrorism Act requires notice for each article of food and requires in that notice, for each article of food, certain information. As stated in the IFR, an "article" refers to a single food that is associated with the same complete FDA Product Code, the same package size, and the same manufacturer or grower (68 FR 58974 at 59003). This is consistent with how entry is filed with CBP. An article of food is a unique item related to a specific manufacturer or grower and a specific process or size. All of these pieces of information are critical for a risk-based assessment of the food. The ABI/ACS system provides the capability to submit information for multiple food items as lines in a single entry, when entry level information is consistent for a number of articles in a shipment. For example, shipment level information, such as estimated time of arrival, can be captured once for all articles within a shipment. The ability to minimize data entry by copying specific information from one article, or line, to another depends upon the sophistication of the software being used by the submitter to create the submission to CBP. The FDA PNSI allows for simplified submission of similar articles of food by allowing the submitter to easily repeat common information (e.g., FDA product code, manufacturer, etc.) while entering different quantities (e.g., amount and package size). Both systems thus significantly reduce the amount of repetitive entry. The prior notice requirements in the IFR or the final rule do not require the submission of the brand for the article of food.

(Comments) One comment suggests that different programs should not require different information

requirements. The comment particularly focuses on FAST and C-TPAT and recommends that prior notice submissions for those participating in these programs should be subject to fewer information requirements.

(Response) FDA disagrees. All of the information required in a prior notice is necessary for determining what articles to inspect upon arrival and otherwise carrying out section 801(m) of the act. The information is initially screened electronically in order to expedite the PNC's review. If less information is provided, regardless of whether the food is covered by some other program, then the result of that screening would be less reliable. This issue is discussed further in section III.D.6.a of this document ("Additional Exclusions Requested—Special Programs (C-TPAT/FAST) and Flexible Alternatives—General Comments")

(Comments) Two comments refer to submission of "blanket" prior notices; one referencing repetitive shipments of analytical samples and the other suggesting a summary of daily shipments.

(Response) FDA disagrees that it should change its approach from the IFR. As stated in the preamble to the IFR (see 68 FR at 59003), an article of food is a unique item related to a specific manufacturer or grower and a specific process or size. All of these pieces of information are critical for a risk-based assessment of the food. FDA currently receives most of this information from customs brokers or self-filers via ABI/ACS. The ABI/ACS system also provides the capability to submit information for multiple food items as lines in a single entry, when entry level information is consistent for a number of articles in a shipment. For example, shipment level information, such as estimated time of arrival, can be captured once for all articles within a shipment. The ability to minimize data entry by copying specific information from one article, or line, to another depends upon the sophistication of the software being used to create the submission to CBP. The FDA PNSI is designed to allow for simplified submission of similar articles of food by allowing the submitter to easily repeat common information (e.g., FDA product code, manufacturer, etc.) while entering different quantities (e.g., amount and package size). Both systems will thus significantly reduce the amount of repetitive entry of information while preserving the identity of each article of food. Moreover, the purpose of prior notice is for FDA to receive, prior to arrival, information about each article of food being imported or offered for

import for the purpose of enabling such article to be inspected at ports of entry into the United States. Receiving blanket prior notices would not provide the necessary information nor would a daily summary, which by definition would be after-the-fact, not prior to arrival.

2. The Submitter

In § 1.281(a)(1), (b)(1), and (c)(1), the IFR requires submission of the name of the individual submitting the prior notice and his/her business address, telephone number, fax number, e-mail address, and the name and address of the submitting firm, if applicable. If a registration number is provided, city and country may be provided instead of the full address.

(Comments) Several comments assert that it is duplicative and unnecessary to require not only the corporate name and address of the submitter but an individual's name, telephone number, fax number and e-mail address as well. The comments contend that this information already should exist in the FDA registration database and that the name of the submitting firm should be sufficient. The comments assert that in today's job market, individuals change jobs more frequently, thereby making the maintenance of this level of specificity in a database time consuming with minimal benefit.

However, another comment states that the regulatory provisions in the prior notice IFR are silent regarding which person(s) will be contacted by FDA and/or CBP when an issue or problem arises regarding a prior notice and urge FDA to clarify that in refusal circumstances, the agency will contact the person who submitted the prior notice (i.e., the submitter or the transmitter.) The comment further states that by reason of his or her knowledge and/or access to the necessary information, as well as having the implicit authority and responsibility to properly file the prior notice, the submitter or transmitter typically will be in the best position to take corrective action as expeditiously as possible.

(Response) FDA has determined that a fax number is not necessary for communication with the submitter. However, the identification of the individual and the firm, if applicable, submitting the prior notice is needed so that FDA knows who is responsible for the information in the prior notice and can communicate with them when necessary via mail, phone, or e-mail. The information submitted must provide sufficient information to enable FDA to communicate questions, concerns, or enforcement information

with the submitter. See section III.J.1 of this document regarding inadequate prior notice (§ 1.283(a)(1)) for a discussion of communication of refusals.

(Comments) One comment suggests that there should be an option to identify whether or not the submitter is C-TPAT certified.

(Response) As we previously explained in the discussion under our assessment of timeframes (see section III.F of this document), C-TPAT participation will not affect timeframes, the amount of information required to be submitted under prior notice, or decisions made during the prior notice review process. Thus, the costs to submitters and the government of submitting such information would not provide benefits. FDA will continue to coordinate with CBP for administration of C-TPAT as it applies to FDA-regulated products, particularly as it relates to admissibility decisions under section 801(a) of the act. However, the prior notice final rule will not require that the submitter self-declare as C-TPAT certified or not C-TPAT certified.

(Comments) One comment asks if it is possible for a submitter to have his/her legal residence in the country of origin.

(Response) Neither the IFR nor the final rule limits the residence or location of the submitter. Section 1.278 of the final rule states that any person with the knowledge of the required information may submit a prior notice.

(Final rule) The final rule requires in § 1.281(a)(1), (b)(1), and (c)(1) the submission of the name of the individual submitting the prior notice and his/her business address, telephone number, and e-mail address, and the name and address of the submitting firm, if applicable. We reworded the last sentence of these paragraphs for clarity to state that if the business address of the individual submitting the prior notice is a registered facility, then the facility's registration number, city, and country may be provided instead of the facility's full address.

3. The Transmitter

Section 1.281(a)(2), (b)(2), and (c)(2) of the IFR requires the submission of the identity of the transmitter, if different from the submitter. The IFR requires the name of the individual and firm, if applicable, transmitting the prior notice on behalf of the submitter and his/her business address, and phone number, fax number, and e-mail address. If a registration number is provided, city and country may be provided instead of the full address.

(Comments) A comment states that the regulatory provisions in the prior

notice IFR are silent regarding which person(s) will be contacted by FDA and/or CBP when an issue or problem arises regarding a prior notice and urges FDA to clarify that in refusal circumstances, the agency will contact the person who submitted the prior notice (i.e., the submitter or the transmitter.) The comment further states that due to his or her knowledge and/or access to the necessary information, as well as the implicit authority and responsibility for properly filing the prior notice, the submitter or transmitter typically will be in the best position to take corrective action as expeditiously as possible.

(Response) FDA agrees. The identification of the individual or the firm, if applicable, transmitting the prior notice is needed so that FDA knows who is responsible for transmitting the information in the prior notice and can communicate with them when necessary via mail, phone, fax, or e-mail. Moreover, the information submitted must provide sufficient information to enable FDA to communicate questions, concerns, or enforcement information with the transmitter. See section III.J.1 of this document regarding inadequate prior notice (§ 1.283(a)(1)) for a discussion of communication of refusals.

(Comments) Some comments ask if FDA would clarify what distinguishes the submitter from a transmitter and if it is possible for an authorized transmitter to have his/her legal residence in the USA.

(Response) The submitter is any person with knowledge of the required information. The transmitter is the person who transmits the required information on behalf of the submitter. The submitter and transmitter may be the same person. (See § 1.278) The final rule does not limit the residence or location of the transmitter.

(Final rule) If the prior notice is transmitted by a person other than the submitter, the final rule in § 1.281(a)(2), (b)(2), and (c)(2) requires the name of the individual and firm, if applicable, transmitting the prior notice on behalf of the submitter and his/her business address, telephone number, fax number, and e-mail address. We reworded the last sentence of these paragraphs for clarity to state that if the business address of the individual transmitting the prior notice is a registered facility, then the facility's registration number, city, and country may be provided instead of the facility's full address.

4. The CBP Entry Type

Section 1.281(a)(3), (b)(3), and (c)(3) of the IFR require submission of the