

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

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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 [insert date 180 days after date of publication in the FEDERAL REGISTER].

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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

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.

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 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 of 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 FD⁴ articles requiring prior notice, thereby

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.

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

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.

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 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.

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.

(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 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 transshipped, 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. Tuent 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

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.

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 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 minimus 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 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.

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 an IT change to ABI/ACS, including 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/~pnst/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/~pnst/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

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.

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 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/~furl/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 and PNSI 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 entry type, which for § 1.281(b)(3) will be a mail entry.

(Comments) Two comments ask for clarification of the CBP entry type data element and request a list of all of the options for entry type.

(Response) FDA needs this information both for screening to identify the appropriate articles for inspection and for communication between the FDA and CBP staff at the port. Also, the entry type determines which entry identifiers should be used (entry number, in-bond number) to identify the shipment. In addition, the CBP entry type tells us if the article of food is for consumption in the United States or is for export or other uses.

Some examples of CBP entry types are: consumption entries, warehouse entries, and temporary importation bond entries. Each of these types has a designated CBP code. For prior notice submissions made through ABI/ACS, the entry type will consist of the CBP entry code specific for that type of entry; e.g., "01" for a consumption entry, "21" for a warehouse entry, "23" for a temporary importation bond entry, etc. These codes are ones customs brokers and self-filers provide to CBP at entry.

For prior notice submissions made through the FDA PNSI, applicable entry types will be provided for selection in a drop-down menu; e.g., consumption, IT, T&E, mail, FTZ, etc. Explanations of the different entry types are available on PNSI to help the transmitter choose the right one. There also is guidance posted on FDA's Web site located at

<http://www.cfsan.fda.gov/~pn/pnentgui.html> that describes the entry types and the entry identifiers (§ 1.281(a)(4) and (c)(3)) associated with those entry types.

(Final Rule) The final rule in § 1.281(a)(3), (b)(3), and (c)(3) requires submission of the entry type. For articles arriving by international mail (§ 1.281(b)(3)), the entry type will always be a mail entry.

5. The CBP Entry Identifier (e.g., the Customs ACS Entry Number or In-Bond Number)

Sections 1.281(a)(4) and (c)(4) of the IFR require the submission of the CBP entry identifier (e.g., CBP entry number or in-bond number), if available. This requirement does not apply to articles arriving by international mail, nor to those carried by or accompanying an individual, unless entry is otherwise required by CBP and an associated CBP entry identifier has been assigned. In these cases, the FDA PNSI will apply a system-generated entry identifier.

(Comments) One comment suggests that PNSI should be modified to allow for use of the house air waybill as a CBP identifier.

(Response) FDA disagrees. The CBP entry identifier information is necessary for proper identification of the information in a prior notice with the appropriate articles for inspection. The submission of the entry identifier also is critical for matching the prior notice to the corresponding CBP entry, which is necessary to assess the adequacy of the prior notice when shipments arrive and are presented for review.

For in-bond entries and FTZ admissions, and for prior notices submitted through the FDA PNSI, an entry identifier is critical for matching the prior notice to the corresponding CBP entry if a consumption entry is submitted so FDA and CBP can ensure that prior notice requirements were satisfied. FDA does not agree that the waybill/Bill of Lading can be used as a CBP identifier, nor do we believe that there is a problem with obtaining a CBP identifier. If the

submitter does not have a CBP identifier, a system-generated entry identifier can be provided upon request. The Airway Bill number and Bill of Lading number is a separate data element found in the planned shipment information (§ 1.281(a)(17)(i)). 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 we cannot allow for the use of the house air waybill number as a CBP identifier.

(Comments) Two comments request clarification of the CBP entry identifier data element and where it can be located.

(Response) For transmitters submitting prior notice with CBP entry information through the ABI/ACS interface, the CBP entry number assigned by CBP is also the entry identifier. For customs brokers or self-filers submitting prior notice for a food entering the United States as an IT entry, a T&E entry, or FTZ admission, the CBP in-bond number or FTZ admission number assigned by CBP also is the entry identifier. If prior notice is being submitted through PNSI, the entry identifier will depend on the entry type and the reason for the Web submission. If available to the transmitter (e.g., the prior notice is for a CBP entry but the ABI/ACS interface is not available), the CBP entry number must be used. When appropriate, the in-bond number must be used as the entry identifier. If one of the entry identifiers described above does not exist, the transmitter can request a system-generated entry identifier.

There is guidance posted on FDA's Web site at <http://www.cfsan.fda.gov/~pn/pnentgui.html> that describes the entry types and the entry identifiers (§ 1.281(a)(4) and (c)(4)) associated with those entry types.

(Final rule) The final rule requires in § 1.281(a)(4) and (c)(4) the CBP entry identifier (e.g., CBP entry number or in-bond number), if available.

6. The Product Identity

Section 801(m)(1) of the Bioterrorism Act requires that a prior notice must contain the identity of the article of food being imported or offered for import. Section 1.281 (a)(5), (b)(4), and (c)(5) of the IFR requires the identity of the article of food being imported or offered for import, as follows: the complete FDA product code; the common or usual name or market name; the estimated quantity of food that will be shipped, described from largest container to smallest package size; and the lot or code numbers or other identifier of the food if required by the act or FDA regulations; e.g., low-acid canned foods, at § 113.60(c) (21 CFR 113.60(c)); acidified foods, at § 114.80(b) (21 CFR 114.80(b)); and infant formula, at § 106.90 (21 CFR 106.90).

(Comments) One comment suggests that the definition of “article of food” should be amended to eliminate quantity and product code as distinguishing factors that require a separate prior notice and that separate prior notices should be based on the uniformity of entry level food data. The comment further asserts that the integrity, or lack thereof, of the food product will not be compromised based on the product type, size and/or quantity.

(Response) FDA disagrees. FDA continues to believe that estimated quantity, including base units and total quantity, is a necessary component of product identity. This information is important for communications with FDA and CBP staff at the border and for examinations to determine whether the amount ordered matches the amount received. For example, as discussed in the preamble to the IFR, if more was received than was ordered, FDA guidance recommends an investigation to determine the cause of the discrepancy as additional and unwanted articles may have been added to intentionally contaminate the shipment (68 FR 58974 at 59005). If less product is received than ordered or than shipped, some of the product may have been intentionally diverted. Moreover, the agency’s risk-based decisions are based

upon the food type and size of that product as many foods are processed differently and the health-based problems result from these differences. For example, a manufacturer may have two different low acid canned food (LACF) production lines that are used for filling and sealing different size cans. A problem with pulling a vacuum on one LACF line may cause the food in those size cans to become adulterated; this would not apply to the cans sealed on the other LACF line. FDA would be able to target shipments from this manufacturer for the size cans that may similarly be adulterated. As stated previously, the PNSI system also allows for automatic repeating of like information (e.g., identity of the manufacturer), which decreases repetitive entry of information that is the same for multiple articles of food within a shipment. This also can be accomplished with submission via ABI/ACS, dependent on the filer's own software.

(Comments) One comment requests clarification of the interpretation pertaining to gift packs. The comment asserts that CBP currently processes gift packs according to the description of the entire gift pack as an entity. The comment asks if prior notice is required on the individual items within the gift pack. Another comment recommends that FDA show flexibility and further develop policies that do not create excessive costs for exporters who are shipping multiple food products in the same package.

(Response) A gift pack may contain various articles of food subject to prior notice requirements. In addition, a gift pack may also contain various nonfood articles that are not subject to prior notice requirements. A package with multiple food products, though not a gift pack, is another example of various articles of food. A prior notice is required for each article of food, even when multiple articles of food are designated as a gift pack or are otherwise packaged together.

There is no CBP rule or regulation nor is there a General Rule of Interpretation (GRI) under which gift packs are classified for tariff purposes. In the case of "gift packs" that contain multiple products, for entry purposes, CBP will try 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 with the gift pack. This would apply 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 selecting individual items from a list of available products.

The final rule requires a prior notice submission for each article of food. As we explained in the preamble to 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). Moreover, the "packer" of a gift pack is not the facility that manufactured/processed the food pack. Therefore, each article of food in a gift pack must be covered by a separate prior notice. However, the Prior Notice Final Rule Draft CPG, published elsewhere in this issue of the FEDERAL REGISTER, describes our proposed enforcement policy for gift packs purchased or otherwise acquired by an individual and imported or offered for import for nonbusiness purposes. This draft guidance states that for these types of gift packs FDA and 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) and/or grower(s) for each article of food within the gift pack.

(Comments) One comment states that the regulations should require a separate prior notice for each HTS number in the container and that a detailed description of the product is not necessary.

(Response) FDA disagrees. For prior notice to accomplish its intended purpose and help FDA protect American consumers, a more precise description of the product is necessary than that provided by the HTS number. As we explained in the preamble to the IFR, although the HTS codes are currently utilized by CBP and FDA to identify generally which imports are subject to an FDA admissibility review, these codes are often not sufficient to specifically identify a product for FDA decisionmaking. For example, in many cases, the tariff code does not describe how the product was processed (e.g., commercially sterile or shelf-stable) or how the product is packaged. Thus, several products that FDA considers different from each other (because these differences affect the potential safety of the food) may be combined under one HTS code. (See 68 FR 58974 at 59004.) Moreover, the HTS code has never been sufficient for FDA admissibility decisions; at entry, the FDA product code has been required on FDA-regulated products. Therefore, the FDA product code should be familiar to most submitters of prior notice. Prior notice requires that we now get this information before arrival of the article of food into the United States.

(Comments) One comment asserts that FDA has issued an interim final regulation that requires prior notice needlessly. The comment provides an example of a container containing red wine, under 14 percent alcohol and in multiple varietals and sizes from the same manufacturing facility and asserts that multiple prior notice submissions should not be required.

(Response) FDA disagrees. For prior notice to accomplish its intended purpose and help FDA protect American consumers, a prior notice must be submitted for each article of food. If the food is identified by a single FDA product code, size, and manufacturer, then only one prior notice is required. Currently there are only seven FDA product code designations covering wine: White/still, red/still, rose/still, naturally carbonated sparkling, artificially carbonated sparkling, Champagne, and wine coolers. The identity of the size of the article of food is covered under the requirement to submit the estimated quantity of the article of food (see § 1.281(a)(5)(iii), (b)(4)(iii), and (c)(5)(iii)). In the previous example, although the shipment contains only red wine from the same manufacturer, there are different sizes of bottles within the container and each package size requires a separate prior notice. The reason is that a problem in sealing one size bottle of wine, but not the other size bottles, may result in serious adverse health consequences. As we explained in the preamble to the IFR, FDA believes that package size is necessary and part of product identity. Moreover, the base unit of measure is a characteristic of product identity and is thus necessary for effective review of the prior notice information. Base unit is critical to processing safety requirements and is particularly important when evaluating the safety of low-acid canned foods (68 FR 58974 at 59005).

(Comments) One comment requests that a single prior notice should cover one commodity and alternately suggests that a single prior notice be required for each FDA Product Code. As an example, the comment suggests that a separate prior notice is required for each size of apples in a load with 10 sizes of apples representing one FDA Product Code. Another comment suggests that all products covered by the same FDA product code should require a single prior notice entry.

(Response) A separate prior notice is required for each article of food represented in a shipment or a load. In the example of different sizes of apples, because apples are identified by one FDA Product Code, and assuming that all the apples represent the same grower, if known, and the remainder of the required information is the same for all the apples, then one prior notice would be sufficient. However, if the articles of food represent the same FDA product code but contain different package sizes, then these are different articles of food and a separate prior notice is required for each.

(Comments) One comment states that prior notice would need to be submitted for each brand, and then each bottle size and format.

(Response) In response to comments to the proposed rule, FDA determined that the brand is not critical for risk-based screening and the IFR did not require identification of the brand of the article of food. This determination has been retained in the final rule. Identification of the size of the article of food is covered under the requirement to submit the estimated quantity of the article of food (see § 1.281(a)(5)(iii), (b)(4)(iii), and (c)(5)(iii)).

a. The complete FDA product code. FDA's product code is a unique numeric code currently used by FDA and customs brokers and self-filers to describe food products, as well as other products regulated by FDA. The IFR requires in § 1.281(a)(5)(i), (b)(4)(i), and (c)(5)(i), the complete FDA Product Code be submitted.

(Comments) Several comments ask for clarification about the appropriate FDA product code to use for specific products and for guidance concerning specific types of products. Several comments request that the FDA Product Code Builder be translated into various foreign languages. Two comments request clarification regarding the appropriate product code for gift

packs. One comment requests that submitters be advised of the correct product code for foods subject to prior notice requirements.

(Response) The final rule does not attempt to clarify appropriate coding for specific products. The FDA product codes are frequently updated, revised and changed. The active codes are available in the FDA Product Code Builder at <http://www.accessdata.fda.gov/SCRIPTS/ORA/PCB/PCB.HTM>. The FDA Product Code Builder also contains many synonyms for foods covered by the same product code designations; e.g., Rice Flour (FDA Product Code 02C--01) has the synonyms of Bot Gao (Vietnamese rice flour), Harina De Arroz (Latin American rice flour), and Joshinko (Japanese fine, white rice flour, used to make taffy-like sweets). At this time due to resource constraints, FDA does not plan to translate the FDA Product Code Builder into foreign languages. A product code builder tutorial is available at <http://www.cfsan.fda.gov/~pn/pcb-tut.html>.

As stated previously (see the discussion on the identity of the article of food being imported or offered for import), a gift pack is not a single article of food, but multiple articles of food packed together. Each article of food in a gift pack must be covered by a separate prior notice with an FDA product code for each article. However, FDA is proposing an enforcement policy whereby FDA should typically not take regulatory action if a single prior notice is submitted for a gift pack. More details about this proposed enforcement policy are described in the Prior Notice Final Rule Draft CPG, published elsewhere in this issue of the FEDERAL REGISTER.

b. The common or usual or market name. The IFR in § 1.281(a)(5)(ii), (b)(4)(ii), and (c)(5)(ii) requires the submission of the common or usual name or market name of the article of

food as an element of the identity of the article of food. (See 21 CFR 102.5 for additional information about common or usual names.)

(Comments) Several comments ask for clarification about the appropriate common, usual, or market name to use for specific products and for guidance concerning specific types of products. One comment asks if a sufficient common, usual, or market name would be the name or names of products listed in the FDA Product Code Builder.

(Response) The final rule does not attempt to clarify appropriate common, usual, or market names for specific products. The FDA Product Code Builder contains many synonyms, which are common, usual, or market names, for foods covered by the same product code designations; e.g., FDA Product Code 16A--4 Ocean Perch is also known as Pacific Perch, Red Perch, Red Rockfish, and Rosefish. Therefore, anyone needing information about the appropriate common, usual or market name to use should consult the FDA Product Code Builder, which is accessible at <http://www.cfsan.fda.gov/~pn/pcb-tut.html>.

c. The estimated quantity of food. The IFR in § 1.281(a)(5)(iii) and (b)(4)(iii) requires the estimated quantity of food that will be shipped, described from largest container to smallest package size and for articles of food that have been refused under section 801(m) of the act in § 1.281(c)(5)(iii), the quantity of food that was shipped, described from largest container to smallest package size.

(Comments) Several comments recommend elimination of the submission of quantity for each article of food, and recommend that such situations involving various sizes and quantities of similar articles of food (e.g., same FDA product code and same manufacturer) be covered by one prior notice submission.

(Response) FDA disagrees. FDA continues to believe that quantity is a necessary component of product identity. FDA also believes that package size is a necessary part of product identity. The base unit of measure is a critical characteristic of product identity and is thus necessary for effective review of the prior notice information. Base unit also is critical to processing safety requirements and is particularly important when evaluating the safety of low-acid canned foods. Both base unit and total quantity (which includes knowing the smallest “package size”) are necessary for response (examination) and communication with FDA and CBP staff at the port. As noted in FDA’s “Food Security Preventive Measures Guidance for Importers” (“Guidance for Industry, Importers and Filers, Food Security Preventive Measures Guidance,” March 2003), these elements are also critical for food security examinations to determine if the amount ordered is the amount received. For example, if more was received than was ordered, the guidance recommends an investigation to determine the cause of the discrepancy, as additional and unwanted articles may have been added to intentionally contaminate the shipment. If less is received than ordered or than shipped, some of the food may have been intentionally diverted. Both base unit and total quantity are currently data elements that can be submitted via ABI/ACS to OASIS.

(Comments) One comment asks for clarification as to the requirements in § 1.281(a)(5)(iii) and (b)(4)(iii) for estimated quantity and the requirement in § 1.281(c)(5)(iii) for the actual quantity.

(Response) The requirement for providing estimated quantity in § 1.281(a)(5)(iii) and (b)(4)(iii) apply to those prior notices provided in accordance with the requirements in the final rule; i.e., those submitted before the food arrives at the port of arrival in the United States as required in § 1.279. The requirement for providing the actual quantity in § 1.281(c)(5)(iii)

applies only to those articles of food refused under section 801(m) of the act, i.e., prior notices submitted after the article of food has arrived at the port of arrival without adequate prior notice and has been refused. In this case, since the article of food already has arrived, the quantity is set and the actual quantity can be determined and submitted in the post-refusal prior notice.

(Comments) One comment asserts that a slide entitled "Article of Food vs. Shipment of Food" in an FDA presentation about the IFR provides a conflict of interpretation about the requirement to provide the estimated quantity. The comment asserts that the illustration suggests a separate prior notice is required for each and asks that FDA clarify this presentation.

(Response) The illustration in question (see <http://www.cfsan.fda.gov/~dms/fsbtac17/sld014.htm>) provides the following example:

TABLE 1A.--"ARTICLE OF FOOD" VS. SHIPMENT OF FOOD¹

| | | | |
|------|----------------|-------------|-----------|
| Tuna | 24/12 oz. cans | 2,000 cases | Company 1 |
| Tuna | 48/6 oz. cans | 1,000 cases | Company 1 |
| Tuna | 24/12 oz. cans | 300 cases | Company 2 |
| Tuna | 6/66 oz. cans | 2,400 cases | Company 3 |

¹One shipment; 4 different products; 4 prior notices

FDA reiterates that the previously shown chart illustrates a situation with four different articles of food, each requiring a separate prior notice. The example provides three different manufacturers of the canned tuna; thus, canned tuna from each of these manufacturers requires a separate prior notice submission. Further, the 12 ounce (oz) cans and the 6 oz cans manufactured by Company 1 are different sizes and thus are different articles of food. Accordingly, each requires a separate prior notice submission.

The final rule continues to require submission of the estimated quantity of food that will be shipped, described from largest container to smallest package size. A prior notice will not be inadequate if the estimated quantity changes between the confirmation of prior notice and

the time of arrival. Similar to the IFR, the final rule does not require that a prior notice be cancelled and resubmitted if the estimated quantity changes after confirmation.

d. The lot or code numbers or other identifier. The IFR in § 1.281(a)(5)(iv), (b)(4)(iv), and (c)(5)(iv) requires the submission of the lot or code numbers or other identifier of the food if required by the act or FDA regulations; e.g., low-acid canned foods, at § 113.60(c); acidified foods, at § 114.80(b); and infant formula, at § 106.90.

(Comments) One comment requests clarification concerning when a lot or code number or other identifier is required for an article of food.

(Response) The lot or code numbers are the identification numbers or code of a production lot, which can more specifically identify a product for screening and examination purposes and for communication within FDA and with CBP and the manufacturer, etc. For example, recalls involving serious health risks are often associated with a specific production lot, such as counterfeit infant formula or under-processed canned food. FDA screening can target these food products for examination based on information of public health emergencies or recalls in foreign countries.

FDA regulations require lot/code identifiers for certain foods. Currently, low acid canned foods, acidified foods, and infant formula are required to bear lot codes or other identifiers (see § 113.60(c) (low-acid canned foods); § 114.80(b) (acidified foods); and § 106.90 (infant formula low-acid canned foods)). The interim final and final rules require lot/code or other identifiers only for these kinds of articles of foods. Many other foods may have lot or code identifiers that are not required by FDA regulation; submission of these identifiers is optional under the final rule.

Submission of the required lot/code identifier is accommodated by ABI/ACS as an affirmation of compliance or through PNSI as a production identifier. ACS currently allows for submission of more than one affirmation of compliance per article of food. PNSI also accepts more than one lot identifier per article of food.

(Final rule) The final rule requires in § 1.281(a)(5)(i), (b)(4)(i), and (c)(5)(i) the complete FDA product code. The final rule in § 1.281(a)(5)(ii), (b)(4)(ii), and (c)(5)(ii) requires the submission of the common or usual name or market name of the article of food as an element of the identity of the article of food. The final rule in § 1.281(a)(5)(iii) and (b)(4)(iii) requires the estimated quantity described from the largest container to the smallest package size. For articles of food that have been refused under section 801(m) of the act, the final rule in § 1.281(c)(5)(iii) requires submission of the quantity of food that was shipped, described from largest container to smallest package size. The final rule in § 1.281(a)(5)(iv), (b)(4)(iv), and (c)(5)(iv) requires the submission of lot or code numbers or other identifiers for articles of food if required to bear such numbers by the act or by FDA regulations.

7. Identity of the Manufacturer

Section 801(m)(1) of the act states that a prior notice must contain the identity of the manufacturer of the article of food being imported or offered for import. Section 1.281(a)(6), (b)(5), and (c)(6) of the IFR requires that prior notice for an article of food that is no longer in its natural state include the name and address of the manufacturer and the registration number assigned to the facility that is associated with the article of food. The IFR further states that 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. The IFR also provides that if the article of food is sent by an individual as a personal

gift (i.e., for nonbusiness reasons) to an individual in the United States, he or she may provide the name and address of the firm that appears on the label under 21 CFR 101.5 instead of the name, address, and registration number of the manufacturer. If a registration number is provided, city and country may be provided instead of the full address.

FDA received many comments on the requirement to provide the name, address and registration number, when applicable, as the identity of the manufacturer. For ease in discussing these comments, we are presenting the issues they raise into the following general categories:

- Does “the manufacturer” in section 801(m) of the act mean the place where the food was actually manufactured or can it include other entities? What if more than one entity was involved in the manufacture of the article of food?
- Does FDA have the authority to require the registration number of the manufacturer of the article of food being imported or offered for import as a data element in prior notice?
- Assuming FDA can require the manufacturer’s registration number in a prior notice submission, should FDA continue to do so in the final rule and/or should FDA provide an alternative means for submitters to provide the identity of the manufacturer? and
- Questions Seeking Clarification.

a. Does “the manufacturer” in section 801(m) of the act mean the place where the food was actually manufactured or can it include other entities? What if more than one entity was involved in the manufacture of the article of food? (Comments) Section 1.281(a)(6) of the IFR requires the submission of the identity of the manufacturer of each article of food no longer in its natural state. Several comments recommend that the final rule define “the manufacturer.” Some comments note that for “gray market” or “parallel market” importations (food purchased outside the manufacturer’s distribution chain and imported to the United States), the only identifiable

product information is that which is on the product itself. The comments suggest that in lieu of the name, address, and registration number of the manufacturer of the food, the prior notice submission should include the name and address of the entity that appears on the label on the food. A comment notes that while this information is not as detailed as that required for other imports, it relieves importers of "gray market" foods from having to provide information that in most instances would never be available to them. Other comments suggest that shipments of gifts to individuals but with a commercial purpose, such as business gifts to generate goodwill among colleagues, should be permitted to reference the manufacturer's name and address as shown on the label in lieu of the registration number of the manufacturer.

Several comments request that FDA provide guidance regarding how to complete prior notice for imported food from multiple manufacturing facilities. One comment suggests that the final rule should define the manufacturer as the last entity to conduct a processing operation; e.g., including bottling, but excluding labeling. Another comment provides an example of wine that is produced and bottled at winery "X" and sent to winery "B" for labeling, which sends the wine to another facility for storage, which then transfers the wine to the freight forwarder "F" who stores and consolidates the wine with other wines for shipment to the United States. Another comment provides an example of fresh fruit that is processed in one facility in a foreign country and then is transported to one or several other facilities that re-palletize the fruit, resulting in a finished pallet containing boxes that have been packaged at several packing facilities.

(Response) These comments address, directly or indirectly, the meaning of "the manufacturer" in section 801(m) of the act. In construing the prior notice provision of the Bioterrorism Act, FDA is confronted with the question of whether Congress has directly spoken to the precise question presented ("Chevron step one"). Chevron, U.S.A., Inc. v. NRDC, Inc.,

467 U.S. 837, 842 (1984). To find no ambiguity, Congress must have clearly manifested its intention with respect to the particular issue. Young v. Community Nutrition Institute, 476 U.S. 974, 980 (1986). If Congress has spoken directly and plainly, the agency must implement Congress's unambiguously expressed intent. Chevron, 467 U.S. at 842-843. If, however, the Bioterrorism Act is silent or ambiguous as to the meaning of "the manufacturer," FDA may define this term in a reasonable fashion ("Chevron step two"). Chevron, 467 U.S. at 842-843; FDA v. Brown & Williamson Tobacco Corp., 529 U.S. 120, 132 (2000).

We have determined that in enacting section 801(m) of the act, Congress did not clearly manifest its intention with respect to the meaning of "the manufacturer." When an article of food is made from one or more raw ingredients, there could be several entities involved in its manufacture. For example, boxed macaroni and cheese might involve preparing the dried macaroni, preparing the dried cheese, combining these materials, and packaging and labeling the finished product. Where multiple steps are carried out by multiple entities, the act does not directly and plainly set forth which entity or entities Congress intended as the manufacturer to be submitted as part of the prior notice. Another question regarding "the manufacturer" whose answer is not clearly manifested in the act is whether the manufacturer means the specific facility where the article is manufactured or the entity that owns, or contracts with, the manufacturing facility. Additionally, Congress did not plainly address whether the entity listed on a product's label could be considered the manufacturer. The entity listed on a product's label can be, as provided by 21 CFR 101.5, the packer or distributor. Additionally, under that regulation, the label may state the principal place of business of the manufacturer, packer, or distributor in lieu of the actual place where the food was manufactured or packed or is to be distributed, unless the statement would be misleading.

For the reasons given in the following paragraphs, we have determined that, for purposes of section 801(m) of the act, the phrase, "the identity of the manufacturer," should be interpreted to mean the place where the food was actually manufactured/processed (i.e., the site-specific manufacturing facility). We believe that this interpretation is reasonable and consistent with the goals of the Bioterrorism Act.

In considering whether it is reasonable to interpret the manufacturer as being the actual place where the food was manufactured, we considered the language and purpose of the prior notice provision, as well as the other provisions of the Bioterrorism Act. The 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" (Public Law 107-188). The prior notice provision contributes to this goal by providing the agency with the information it needs to determine whether, due to significant concerns about an article of imported food, it should inspect the food upon arrival in the United States. Having the identity of the actual place where the food was manufactured (i.e., the site-specific manufacturing facility) will inform these risk-based decisions much better than having the identity of the packer or distributor or even the name and address of the manufacturer's principal place of business.

Information about the manufacturer contributes to FDA's inspection decisions under prior notice in two principal ways. One way is that when FDA receives intelligence regarding potential areas of concern about food shipments, this intelligence is often linked to a site-specific manufacturing facility. For example, FDA received intelligence regarding alleged contamination with a harmful chemical substance of certain imported food products from a certain specific foreign manufacturing facility. FDA flagged shipments from this facility for further PNC review, and subsequently recommended the examination and sampling of several

shipments from the site specific facility due to the significant public health threat posed by the articles of food. Because the identity of the site-specific manufacturing facility was included in the prior notices, FDA was able to match the intelligence with the relevant food shipments, without affecting the importation of similar products from other manufacturers. If prior notice only included the name and address listed on the label, FDA could not have confidence that it could flag shipments of the food manufactured at the specific facility, either for further PNC review or for inspection. Matching a third-party distributor or packer with the actual manufacturer that FDA wants to flag based on intelligence would be very difficult and time consuming, and may even be impossible to do with the information available to the agency. If prior notice included the principal place of business of the manufacturer (e.g., the corporate headquarters location) instead of the site-specific manufacturing facility, FDA's ability to correctly target shipments would not be much better. More often than not, when FDA receives intelligence regarding a manufacturer, it is specific to the site-specific manufacturing facility and not just the manufacturer's corporate identity. In these situations, if the prior notice that has been submitted contains only corporate-level information, FDA would have to target every relevant shipment from every plant the firm owns or contracts with, which could be dozens, or even hundreds. As a result, much time would be spent unnecessarily reviewing many shipments that may not be of interest but whose risk could not be discounted based on the supplied manufacturer information.

The other way information about the manufacturer contributes to FDA's inspection decisions under prior notice is the agency's use of this information during its manual review of a prior notice. Regardless of the reason a shipment is flagged for manual review by the PNC, the identity of the manufacturer is one of the key elements FDA relies on in further assessing the

potential risk a shipment poses to the United States. FDA does this by using the identity of manufacturer, as provided in prior notice, to gather additional information from a variety of sources, such as FDA's and other government agencies' databases and research using publicly available information. For example, FDA will often try to determine whether the article of food being imported is consistent with the type or types of food the facility usually makes and ships to the United States, whether the facility's owners, agents, or workers have potential ties to security concerns, and whether FDA has found problems with prior shipments from the facility. The more closely that this information is tied with the site-specific manufacturing facility, the more reliable the risk assessment will be. If prior notice could include the name and address of the firm on the label (in lieu of the site specific manufacturer), and this firm is the product's distributor, then FDA would be able to gather additional information about the distributor but not the manufacturer. A risk assessment based on information concerning the distributor would be much less meaningful than one based on the actual manufacturer because the actual manufacturer has much more control over the product's quality and security than the product's distributor.

For example, when researching the site-specific manufacturer listed in a prior notice to investigate potential security concerns, FDA found information in a government database suggesting the facility had ties to terrorism. Based on this and other information, FDA decided to examine the product covered by the prior notice. If the name and address of a different firm, such as the distributor, had been provided in the prior notice instead, it is unlikely that FDA's research would have turned up this association and unlikely that this shipment would have been flagged for inspection. In its experience under the IFR, when prior notice has not included the identity of the actual manufacturer, FDA has had to attempt to determine the site-specific

manufacturer by using alternative means such as inspection, contacting the submitter, and/or contacting the firm listed on the label, a process that in some cases has taken days and even weeks. The only other way to be sure that the subject article of food is not a threat is to have the food stopped and examined at the port of arrival to determine if it is a threat. Stopping shipments while FDA conducts additional research or an inspection would require significant agency resources and could create inefficiencies for the agency, CBP, industry, and consumers as food shipments back-up at the border.

Similarly, if the prior notice included the principal place of business of the manufacturer rather than the specific manufacturing facility, this information is likely to be too broad to be helpful, particularly if it is a large company. Each manufacturing facility is different, in terms of its employees, the food it manufactures for the United States, its manufacturing processes, and its security standards and procedures. One location of a company may have a higher standard for the security of its employees and manufacturing processes than another location. In those cases where the parent company owns or contracts with multiple manufacturing facilities, FDA would have to determine the risk associated with each of these facilities to ensure our review is adequate. Because FDA is under strict timeframes to review, assess risk, and respond to the prior notices, conducting such wide-ranging research is not practical. Not only would this be prohibitively time-consuming (which would have a detrimental impact on trade), in many situations FDA may not be able to ascertain the identity of each of the firm's manufacturing facilities. Alternatively, FDA could attach a risk to the headquarters location, but doing so would result in a less meaningful prior notice risk assessment and may result in articles of food being assigned a lower or higher risk than they should have based on the specific manufacturing facility.

Our interpretation of "the manufacturer" to mean the actual place where the food was manufactured also furthers the purposes of the Bioterrorism Act by helping to ensure that imported food is from registered facilities. Under section 801(l) of the act, food that is imported or offered for import is subject to being held if it "is from a foreign facility for which a registration has not been submitted to [FDA] under section 415" of the act. FDA checks the information about the site-specific manufacturing facility provided in prior notice to verify that facility's registration status. If the prior notice provided only the name and address listed on the label of the food rather than the actual manufacturing facility, FDA would have no practicable means to readily determine whether the manufacturing facility is registered. As explained previously, the name and address on the label could be, for example, the distributor or the parent company of the facility.

Collecting information regarding the manufacturing facility of an imported product and its registration status goes back to well before prior notice. As part of the admissibility review process for the various types of imported goods it regulates, FDA collects, among other information, the "FDA Manufacturer" and applicable registration numbers. (See, for example, 70 FR 69576, November 16, 2005.)

The Bioterrorism Act expanded the registration requirement with respect to food facilities. New section 415 of the act requires domestic and foreign facilities that manufacture, process, pack, or hold food for human or animal consumption in the United States to be registered with FDA, unless the facility is exempted. Under new section 801(1) of the act, food from a foreign facility that has not registered under section 415 of the act is subject to being held until the foreign facility has registered. It could be argued that FDA should make its determination about the food manufacturing facility's registration status as part of the entry and

admissions process. The reason it is necessary to make this determination at the time FDA is reviewing prior notice is that if the article of food is held under section 801(l) of the act, it may not be delivered to the importer, owner, or consignee and cannot be moved under bond under section 801(b) of the act. Operationally, the only way to implement these movement restrictions is to conduct the registration status review before entry is filed, which is when the prior notice review is conducted.

The comments recommending that the prior notice rule be expanded to allow the identity of the entity shown on the product label in lieu of the identity of the manufacturer are generally based on the argument that information about the manufacturer, especially its registration number, is not always available to the submitter, such as when food is purchased outside the manufacturer's distribution chain. The statute indicates that Congress considered the issue of whether it would be difficult or impossible to provide the identity of the manufacturer but chose to require it nonetheless. Among the data required by prior notice are the identity of the manufacturer and, for food in its natural state, the identity of the grower, if known. Section 801(m) of the act expressly provides that the identity of the grower does not need to be submitted if it is not known within the prior notice timeframes; however, the act does not include this exemption for the identity of the manufacturer. This indicates that this information about the manufacturer must be submitted regardless of any potential difficulties in obtaining it. With respect to the comments that were concerned about situations where the person submitting prior notice does not know the registration number of the manufacturer, as discussed elsewhere in this preamble, FDA and CBP are modifying the final rule such that the identity of the manufacturer can be submitted as the name of the manufacturer and either the registration number, city, and

country of the manufacturer, or both the full address of the manufacturer and the reason the registration number is not provided.

Regarding situations where multiple steps are carried out by multiple entities, we have determined that "the manufacturer" can reasonably be interpreted to mean the last facility that manufactured/processed the article. A facility is the last facility that manufactured/processed the food if the food does not undergo further manufacturing/processing, other than the addition of labeling or any similar activity of a de minimis nature. This interpretation is based on the definition of a foreign manufacturer under the food facility registration provision, section 415(b)(3) of the act, and our implementing rule, 21 CFR part 1, subpart H (see specifically §§ 1.227(b)(2) and 1.226(a)). It also is consistent with the definition of FDA manufacturer collected as part of the entry and admissibility process, which states that if more than one party processed the article, then the manufacturer is the last party who substantially transformed the product. (See, for example, 70 FR 69576, November 16, 2005.)

Applying this definition to the example pertaining to wine in the comments, the manufacturer for purposes of prior notice would be winery "X" since this is the facility that produced and bottled the wine. The other facilities involved in this example perform either manufacturing activities of a de minimis nature, such as labeling, or other activities not related to manufacturing, such as storing and consolidating the wine. Thus, although some of these facilities might have to register with FDA as required by 21 CFR part 1, subpart H as holders or packers of food intended for consumption in the United States, the facilities in the example other than winery "X" are not considered the last facility under the prior notice final rule's definition of "manufacturer." Regarding the comment on fresh fruit, FDA assumes that the comment is using the term "processed" to mean an activity (such as treatment against pests or polishing) that

leaves the food still in its natural state, as explained in the definition of “no longer in its natural state” under §1.276(b)(10). Although subsequent facilities palletize the fruit, these would not be manufacturers because they only pack the food and packing is not considered manufacturing/processing. Under this scenario, no information for any manufacturers would be required for the prior notice. Instead, under § 1.281(a)(7) of the final rule, the prior notice would require the name and address of the grower, if known.

Consistent with the interpretation that the identity of the manufacturer requires site-specific information, we are removing the provision in the IFR stating that if the article of food is sent by an individual as a personal gift to an individual in the United States, then the name and address of the firm that appears on the label could be submitted instead of the identity of the facility that manufactured the food. We note, however, that under the enforcement policy contemplated in the Prior Notice Final Rule Draft CPG, FDA and CBP would typically consider not taking regulatory action when no prior notice is submitted with respect to gifts that are shipped by an individual to an individual.

Given the importance of having the site-specific manufacturer, we are also proposing a change to the CPG regarding the identity of the manufacturer. The Prior Notice Interim Final Rule CPG had a policy that covered situations where, after a good faith effort, the person submitting prior notice did not know the name and address of the facility that manufactured the food. It stated that if the submitter provided certain alternative information, such as the identity of the facility's headquarters, FDA and CBP should typically consider not taking any regulatory action despite this noncompliance with the prior notice requirements. The Prior Notice Final Rule Draft CPG does not continue this policy because, as described above, FDA and CBP believe that knowing the identity of the facility involved in the food's production is critical to

ensuring that FDA can effectively target food for inspection at the border upon arrival and can effectively determine whether food should be held because it is from an unregistered manufacturing facility.

Accordingly, section 1.276(b)(9) of the final rule defines manufacturer for the purpose of prior notice submission as 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 have removed in the final rule the option that was in the IFR to provide the label information in § 101.5 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. Unless excepted elsewhere in the regulation, the identity of the manufacturer must be submitted for an article of food that is no longer in its natural state.

b. Does FDA have the authority to require the registration number of the manufacturer of the article of food being imported or offered for import as a data element in prior notice?

(Comments) Many comments state that the Bioterrorism Act does not require registration numbers to be submitted in prior notice. Some comments further assert that the statute clearly states that the "identity of the manufacturer" must be included for prior notice but it does not allude to nor require the registration number. Another comment explains that if Congress intended FDA to require the registration number, it would have specifically articulated this requirement as it did in section 321 of the Bioterrorism Act for drug and device imports. The

comment concludes that the failure of the Congress to include registration numbers in the enumerated statutory elements of prior notice is powerful evidence that Congress did not intend for FDA to require it. Another comment states that the act does not prescribe how the identity of the manufacturer must be provided, and therefore Congress has not spoken to this issue. Accordingly, FDA is entitled to deference in crafting a permissible construction of the statutory requirements.

One comment notes that all wineries producing wine for consumption in the United States are required under section 415 of the Bioterrorism Act to provide to FDA their name, the street addresses of their facilities and the trade names under which they do business. It further states that as long as the importer provides the name and address of the manufacturer of the wine, this will be sufficient for FDA to identify whether the manufacturer is registered with the FDA, and that additionally requiring the importer to furnish a registration number is unnecessary to implement the Bioterrorism Act.

Another comment asserts that the obligation to verify that the manufacturer of a food article imported or offered for import into the United States is registered, or is required to do so, is an obligation imposed upon the FDA by Congress under the Bioterrorism Act, not upon the importer. The comment further asserts that for FDA to shift its burden to importers who are not related to the facilities required to be registered is, at the very least, unjust and certainly was not the intent of Congress. The comment further states that FDA has the ability and access to the information necessary to verify registration status of manufacturers; unaffiliated importers do not. Another comment asserts that FDA's overly broad interpretation of the prior notice provision of the Bioterrorism Act results in an anticompetitive business environment that is contrary to the spirit of the Bioterrorism Act. Another comment emphasizes that to enforce the

registration requirement through the means of prior notice requirements, which affect persons that are completely unrelated to the party responsible for registering the facility, is inappropriate.

Another comment states that the U.S. Congress placed the burden upon the FDA to ensure that a facility's owner, operator or agent in charge complies with the registration requirements established under the Bioterrorism Act and while it is reasonable for the FDA to request that importers assist them in this task by asking for facility registration numbers on prior notice submissions, the agency must not condition lawful entry on the provision of this number that may, for a variety of reasons, be unavailable to the importer.

Another comment claims that FDA has no jurisdiction to enforce the registration requirements upon the affected foreign facilities. Another comment asserts that domestic food manufacturers are not faced with this dilemma because they are already within the United States, and there are no equivalent requirements to verify that domestic foods are produced at facilities that are properly registered with FDA.

(Response) FDA's position remains that it has the authority to require the registration of the manufacturer as a data element in prior notice. Under section 801(m) of the act, prior notice must include the identity of the manufacturer. The manufacturer's registration number is an identifier, just as, for example, Employer Identification numbers, Social Security numbers, and driver's license numbers are regularly used to help identify establishments and individuals. Such numerical identifiers are much better for matching than name and address information alone. For example, names and addresses often do not have standardize formats, there can be alternative spellings and abbreviations, and misspellings are not uncommon. In addition, many facilities have similar names, even facilities in the same country or city. Unique identifiers are all the more important given the high volume of prior notices that FDA needs to process, FDA's goal of

processing them expeditiously, and the need to ensure that FDA can accurately flag shipments of potential concern.

As contemplated by the Registration of Food Facilities rule, § 1.241(c), FDA also uses the identity of the manufacturer collected as part of prior notice to ensure that imported food is from registered facilities. Section 801(l) of the act, which was enacted as part of the Bioterrorism Act, states that if 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 under section 415 of the act, 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. In the preamble to the IFR, we described how we would use registration in concert with prior notice to carry out our responsibilities under section 801(l) of the act “Registration is designed to work in concert with prior notice at the border, as reflected in new section 801(l) of the FD&C Act, which provides that food from facilities that must register may not be admitted into distribution for consumption in the United States unless the relevant facilities have been registered. To enforce section 801(l) of the FD&C Act as intended by Congress, FDA has determined that it must review registration status of manufacturers and shippers as part of prior notice. The information provided by registration will allow FDA to check prior notice submissions against registration data to confirm the identity. Moreover, the information provided by prior notice submissions can serve as a crosscheck as to whether these facilities are registered as required and have provided the necessary updates * * *. FDA does not agree that it should confirm registration without requiring that the number be submitted. Each registered facility will be assigned a unique registration number by FDA. Thus, the registration number will help identify the manufacturer. Without a registration number, it may be difficult to

determine exactly which registered facility to associate with the article: Different firms may have the same or similar names and more than one firm may operate from a particular location.” (68 FR 58974 at 59001). FDA continues to believe that it should use the information in prior notice to verify the manufacturer's registration status, and that the registration number is the simplest and fastest way for us to do this. FDA further notes that it verifies the registration status of both domestic and foreign facilities. FDA's procedures for enforcing the registration requirements for domestic facilities are explained in FDA's "Compliance Policy Guide -Guidance for FDA Staff, Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002." See <http://www.cfsan.fda.gov/~furl/cpgreg2.html>.

c. Assuming FDA can require the manufacturer's registration number in a prior notice submission, should FDA continue to do so in the final rule and/or should FDA provide an alternative means for submitters to provide the identity of the manufacturer other than the registration number? (Comments) Several comments recommend elimination of the registration number as a requirement for identifying the manufacturer of a food no longer in its natural state. One comment suggests that inclusion of a food facility registration number does not ensure the legitimacy of the shipment and that a black market for certain foods could result if registration numbers continue to be required for prior notice. Many others comments recommend elimination of the requirement for the manufacturer's registration number in various situations:

- The food facility is not required to register because ingredients or finished goods manufactured by it are not consumed in the United States, and thus it has no registration number;
- The manufacturer that has gone out of business and does not have a facility registration number;

- Samples for:
 - Any reason/any type of sample;
 - Any product samples not intended for public consumption or for retail sale;
 - Quality control;
 - Research;
 - Analytical samples that are not intended for human or animal consumption;
 - Quality assurance samples that will be used for taste testing or quality control that includes human consumption;
- Fine wines;
- Registration numbers of the parties in possession of the wine over the past 2 years;
- All wines and distilled spirits, when a registration number is not available;
- Wine produced more than 5 years prior to the date of its import (the year of production is typically indicated on the bottle's label, and label approvals are required under U.S. Tax and Trade Bureau regulations);
- All food produced prior to December 12, 2003;
- All food sent into the country for the personal consumption of the recipient and not for business use or redistribution;
- Gifts arriving in the United States from one individual to another in a business setting;
and
- Consumer-to-consumer shipments.

Some comments state that the requirement to provide the manufacturer's registration number in the prior notice is overly burdensome and unreasonable for some segments of the food industry. The comments suggest that there are numerous legitimate reasons that food companies

may seek to import food products from manufacturers whose registration number is unknown or which are not required to register with FDA.

Other comments recommend alternatives to the requirement to submit the manufacturer's registration number. The most commonly recommended alternative to submission of the manufacturer's registration number is to allow submitters to identify the manufacturer by providing the name and address of the facility with an accompanying reason as to why the registration number was not submitted. One comment specifically recommends a drop-down menu that allows the submitter to explain the reason for the lack of a registration number, such as "product was not obtained from the manufacturer." The comment reasons that this optional approach allows FDA to continue to require registration numbers, but does not per se invalidate a prior notice based on the absence of this single piece of information. Another comment suggests that the submitter affirm that it believes, to the best of its knowledge, that the manufacturer is registered with FDA. One comment recommends that only the manufacturer's name for a "gray market" food should be sufficient for the prior notice when the submitter does not know the manufacturer's registration number.

Another comment asserts that FDA must consider alternative means for ensuring that all facilities subject to the Registration of Food Facilities Rule (21 CFR part 1, subpart H) have an updated registration on file with FDA that has been verified. The comment further suggests that taking such action will allow the FDA to ensure that the regulations are not implemented in a manner that prevents the lawful import of safe and healthy food products based solely upon the unavailability of the confidential facility registration number. Several comments assert that confirmation that a facility is registered can be made without obtaining the registration number of the facility.

One comment states that, though FDA has indicated that it wants the new facility registration requirement to be enforced through the prior notice regime, enforcement can be accomplished without requiring that the facility registration numbers be included in the prior notice. With the name and address of the manufacturer included, FDA can look up the manufacturer in its database of registered manufacturers. If the manufacturer has not registered, then the FDA could deny entry to the articles of food in question. The manufacturers therefore already have a strong incentive to register with the FDA, since that is the only way their products can gain entry into the United States.

Other comments suggest inspection of a food shipment to ensure its safety when the prior notice submission lacks the required registration number, rather than refusal of that food as an acceptable alternative. The comments state that this approach will avoid situations where shipments are rejected while still preserving FDA's regulatory discretion. Another comment states that importers who obtain food from parties other than the original food manufacturers are willing to bear the burden of increased inspections when they do not provide a manufacturer's registration number in the prior notice. Other comments agree that the manufacturer's registration number should be required in prior notice submissions, but that the prior notice should not be deemed inadequate (i.e., the food should not be refused under 801(m) of the act) if the manufacturer is identified by name and address of the facility and a reason for lack of submission of the manufacturer's registration number is provided.

Another comment suggests that the final rule should be amended to provide that the prior notice only need to include such information about the manufacturers of older vintage wines that is readily available to the importer, together with registration numbers for all persons who have owned the wine and all facilities that have stored the wine over the preceding 2 years.

One comment suggests that FDA permit the importation of quality assurance samples that will be used for taste testing or quality control that includes human consumption without the facility registration number of the foreign manufacturer or processor. The comment further suggests that in lieu of the registration number, the prior notice should include the manufacturer's name and location along with the identification of the person sending the samples.

While most comments state that the name and address of the manufacturer could be submitted in prior notice, one comment states that re-sellers will not normally supply the name of their supplier or the name of the manufacturer of a particular product to their customers. The comment asserts that supplying the name of the manufacturer would allow that customer to circumvent the re-seller and attempt to make direct contact with the supplier or manufacturer, thus taking business away from the re-seller. Another comment states that if only the name of the manufacturer is submitted in a prior notice, the prior notice should not be considered inadequate.

Other comments support requiring the registration number of the original processor on prior notice submissions, particularly when a third-party is exporting the product to the United States. One comment further recommends that FDA should revise its rules regarding the use of registration numbers in general, and in the prior notice rule in particular, to protect legitimate buyers and distributors from unauthorized "gray market" imports. Several comments suggest that the manufacturer's registration number should be required and that only the registration number be submitted, not the name and country. Additionally, some comments suggest that if manufacturer and facility registration numbers are provided and the numbers provided are

specific to a particular facility location, the requirement to complete the address information should be removed to avoid duplication of information.

(Response) To effectively implement the prior notice and registration provisions in the Bioterrorism Act, the final rule requires the registration number of the manufacturer or, if the registration number is not provided, the facility's full address and reason the registration is not provided. Reasons for not providing a registration number include, for example, the manufacturing facility is out of business; the manufacturing facility is a private residence and thus is not a "facility" for the purposes of the registration requirements; and the submitter is unable to determine the registration number of the manufacturing facility.

Matching of facilities is vital for making an initial assessment on the accuracy of the prior notice; assessing the risk of the associated article of food based on the associated manufacturing facility, its operations, and history of importations; and verifying registration status. Without the registration number, PNC reviewers have to conduct this matching using the name and address submitted in a prior notice. Due to the potential for human error during data input or deviations in the spelling or format of a facility's name, address or city, FDA may incorrectly think it has found a match between the facility described in the prior notice and a facility in the registration database. Similarly, the facility described in the prior notice may be close, but not exact, to several facilities listed in the registration database, causing uncertainty as to which, if any, is the correct match. This is complicated by the fact that the manufacturing facility submitted as part of prior notice might not be registered. At best this matching process may take significantly longer (depending on the number of manufacturers, products, and other factors involved), impeding FDA's ability to complete its review within the prior notice timeframes. At worst, a

facility mismatch will result in FDA conducting its risk assessment based on incorrect information.

The information provided in a registration thus enables FDA to better assess risk of the product itself, as it gives the PNC more information upon which to base its assessment. PNC reviewers use the registration information to verify whether the articles of food in the shipment match the food product categories that the owner, operator, or agent-in-charge of the facility listed in the site-specific facility's registration with FDA. The registration information also provides alternate names for a facility, lists the parent company and subsidiaries of the facility, verifies addresses, and provides the identity of the officers of the facility and/or their U.S. Agents. This additional information may identify potential terrorist threats (e.g., a facility and/or facility official has ties with a terrorist organization). Not providing the registration number in a prior notice leads to prolonged or incomplete searches, which in turn could lead to additional cargo delays or examinations at the port of arrival as the PNC completes its intensive review (*see* earlier discussion under timeframes). We also note that registered facilities generally do not make their registration numbers public, so they generally have to be obtained directly from the manufacturer or its designee during the importation process as part of completing a prior notice. Thus it is harder to falsify registration information than the facility's name and address, deterring the submission of false manufacturer identification information.

In some cases, the registration number of the manufacturer is not available to the submitter, and therefore, we have revised the rule to provide an alternate means for satisfying the requirement to provide the identity of the site-specific manufacturer in prior notices. For purposes of the prior notice final rule, the identity of the manufacturer is 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 (see § 1.281(a)(6), (b)(5), (c)(6)). One of the following reasons may be submitted when no manufacturer registration number is provided:

- Situations where the facility is out of business, as stated in § 1.235(a);
- Private residence, as stated in § 1.227(b)(2);
- The facility is a restaurant, as defined in § 1.227(b)(10), and qualifies for the restaurant exemption in § 1.226(d);
- The facility is a retail food establishment, as defined in § 1.227(b)(11), and qualifies for the retail food establishment exemption in § 1.226(c);
- The facility is a nonprocessing fishing vessel, as stated in § 1.226(f);
- Nonbottled drinking water collection and distribution establishment, as stated in § 1.227(b)(2);
- The manufacturer satisfies the definition of “farm” in § 1.227(b)(3), and qualifies for the farm exemption in § 1.226(b); or
- The submitter is unable to determine the registration number of the manufacturer.

The full address of the manufacturer has been provided by the submitter.

The Prior Notice Final Rule Draft CPG that is announced elsewhere in this issue of the FEDERAL REGISTER lists these reasons to use when the registration number is not provided and describes our proposed enforcement policies.

As discussed previously, without the registration number, it will be more difficult and/or may take more time for us to verify the identity of the manufacturing facility and its registration status and to determine whether the article of food is subject to being held under section 801(l) of the act. Thus, it is in the interest of the parties involved in the import to provide the

manufacturer's name and registration number, and not simply the manufacturer's name and full address, because the registration number will help us process the shipment more expeditiously. The submitter should exercise a reasonable amount of effort to obtain and provide the registration number before using the reason "the submitter is unable to determine the registration number of the manufacturer."

FDA does not agree with the comments asserting that the registration number is sufficient by itself to "identify" a facility in a prior notice submission. The additional information is needed to verify that the registration number, which is comprised of eleven digits, is accurate. Without additional information, there is a significant possibility of typographical errors, leading to misidentification of facilities, which could lead to foods being stopped at the port for inadequate prior notice and registration. There also is the possibility of someone entering data in an attempt to "guess" at a registration number. Having identifying information in addition to the registration number helps prevent such guessing. Having this confirmatory information also allows us to notify submitters of a mismatch before the prior notice is accepted and confirmed for review, which allows them to correct any inadvertent errors before the food arrives at the port, where it otherwise may be subject to refusal for an inadequate (inaccurate) prior notice.

If the prior notice does not contain either the manufacturer's registration number or the reason and name and full address, the food is subject to refusal of admission under section 801(m)(1) of the act for failure to provide adequate prior notice, as the identity of the manufacturer is incomplete. The food also may be subject to a hold under section 801(l) of the act if the food is from a foreign manufacturer that is not registered under section 415 of the act.

In response to comments from those who are importing food from a facility that is not registered because food manufactured by it is not intended to be consumed in the United States,

FDA notes that these shipments are subject to hold under 801(l) of the act. Under section 801(l) of the act, food is subject to being held if it is imported or offered for import into the United States and it is from a foreign facility that has not registered. This provision applies regardless of whether the food was intended for consumption in the United States at the time it was manufactured, for example where an article of food is made in Country X for consumption in Country X, but is purchased by a third party who re-labels the product for import and resale in the United States.

(Comments) One comment recommends that inter-company gifts be exempt from the requirement to provide the manufacturer's registration number on the prior notice because these items have no commercial value and are sent as business gifts. The comment suggests that FDA use the same approach for business and nonbusiness gifts, by allowing a listing of the manufacturer's name and address as it appears on the product's label.

(Response) The provisions in the final rule regarding the registration number are being revised, and these revised provisions apply to both business and nonbusiness shipments. The final rule no longer allows for submission of the name and address as it appears on the label in any situation. However, the rule also is being changed such that the submitter may submit either the manufacturer's registration number, city, and country or both the manufacturer's full address and the reason why the registration number is not provided.

d. Questions seeking clarification.

i. Designation of grower. (Comments) Two comments state that they are exempt from the registration requirements because they are farms; however, they want guidance regarding the steps these farms should follow to ensure that their products move through the prior notice system without delays at the port.

(Response) If the article of food is no longer in its natural state, such that the identity of the manufacturer is required, the submitter can submit a reason for why the registration number was not provided; i.e., facility is a grower, meets farm exemption. These reasons also are listed in the Prior Notice Final Rule Draft CPG announced elsewhere in this issue of the FEDERAL REGISTER. If the article of food is in its natural state, the identity of the manufacturer is not required and the systems will know that they do not need to verify the manufacturing facility's registration status.

ii. Manufacturer cancels registration. (Comments) A comment asks what designation is appropriate for the scenario where at the time of production the manufacturing/processing facility was legitimately registered with the FDA, but cancelled its registration prior to the importer submitting prior notice.

(Response) If the manufacturing facility still is operational, but chooses to cancel its registration with FDA, then the food from this facility is subject to refusal under 801(l) of the act. As stated therein, "If 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 [FDA], 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." If the facility has canceled its registration because it has gone out of business, then this reason may be entered on the prior notice.

iii. Identity of manufacturer for samples. (Comments) One comment states that there are some circumstances involving market survey and consumer complaint samples where the manufacturing facility is unknown to the submitter of prior notice and the manufacturing facility may not have a registration number because it does not do business in the United States. One

comment provides the example of when shoppers are hired to collect company trademark products, package these according to company-established protocol, enclose purchase information and ship these to designated laboratories in the United States. and the shoppers often have no way of knowing the identity of the specific manufacturing facility. One comment states that it is not likely that a manufacturer's registration number would be available for competitive product samples and for finished product samples used for evaluation purposes, as well as for articles used for research and development purposes. The comment states that the registration number does not fall under the Freedom of Information Act and in some cases, the manufacturer's facility may not be required to register since the article of food was not intended for consumption in the United States. Another comment provides the example of when a consumer expresses a concern about either the quality or safety of a purchased food, and the consumer is instructed to ship that product to the U.S.-based franchise company laboratory for a timely analytical assessment.

(Response) We have revised the final rule such that the identity of the manufacturer must include the name of the manufacturer and either the registration number, city, and country of the manufacturer or both the full address of the manufacturer and the reason the registration number is not provided. Relevant to these comments, one of the reasons for not providing the registration number is that the submitter is unable to determine it. However, as described above, if the article of food is from an unregistered facility, it is subject to being held under section 801(l) of the act. Moreover, without the registration number, it will be more difficult and/or may take more time for FDA to verify the identity of the manufacturing facility and its registration status. As a result, the food may be delayed until the verification is completed.

While the final rule requires prior notice, including the identity of the manufacturer, for shipments of samples, under the enforcement policy proposed in the Prior Notice Final Rule Draft CPG, FDA and CBP should typically consider not taking any regulatory action with respect to prior notice violations when an article of food is imported or offered for import for quality assurance, research or analysis purposes only, not for human or animal consumption without prior notice.

iv. U.S. manufacturer of product being imported. (Comments) Two comments express concern that FDA would reject a prior notice for imported food that contains a U.S. manufacturing facility and that facility's registration number.

(Response) Both ABI/ACS and PNSI accept the identity of a manufacturing facility from any internationally recognized country designation, including the United States. FDA recognizes that some food imported into the U.S. is manufactured in the U.S., exported, and then re-imported. Prior notice applies to these articles of food and identification of the U.S. facility as the manufacturer is correct.

v. Require manufacturer to reveal or conceal the registration number. (Comments) Two comments recommend that FDA compel manufacturers to divulge their food facility registration numbers upon inquiry. Another comment requests that FDA issue guidance stating that: FDA does not require the registration number on commercial documents; the inclusion of a registration number on commercial documents will not facilitate clearance by CBP or FDA of the shipment; and FDA recommends that companies reveal this confidential information once only in a formal letter and ensure by all possible means that their customer (e.g., distributor, importer, or customs broker) also respect the confidentiality of this information. One comment cautions about reported abusive and misleading declaration of a registration number in a prior

notice for shipments that are unconnected with the food facility that actually owns that registration number. Another comment suggests that FDA should revise both the prior notice and registration rules to clarify that those doing business with the owner of a facility should not and have no reason to demand the facility registration number.

Several comments suggest that FDA provide a means for importers and others to verify a facility's registration, even if such verification does not disclose any information beyond affirmation or denial. One comment suggests that FDA compare Manufacturer Identity (MID) data submitted through ABI/ACS to the FDA Food Facility Registration database and notify the transmitter of a MID mismatch while keeping actual registration information secure. The comment reasons that this process would give the submitter and transmitter of a prior notice a noncompliance alert and also would alert the agency of possible additional intensive review requirements even before the prior notice submission has been completed. Another comment encourages the agency to allow American importers to query a database that would do nothing more than confirm whether the details provided are accurate. Another comment suggests that FDA make the registration database available to authorized customs brokers only.

(Response) FDA does not intend to direct registered food facilities to divulge their registration numbers on documents or upon request. However, FDA does agree that guidance regarding divulging registration numbers and prior notice submissions may help to clarify the process, and provided this guidance in our "Guidance for Industry, Questions and Answers Regarding Registration of Food Facilities Final Guidance" available at <http://www.cfsan.fda.gov/~dms/ffregui4.html>.

vi. Exporting facility. (Comments) One comment requests that FDA accommodate the importation of previously manufactured food products that were purchased at retail outlets

outside the United States and recommends that FDA require only the registration number of the exporting facility and information identifying the company responsible for the product. The comment reasons that this information, along with other identity information required by prior notice, should be sufficient for FDA and CBP to make risk decisions about a particular import.

(Response) FDA disagrees. The Bioterrorism Act requires the identity of the manufacturer as well as the shipper. The identity of the shipper or the exporting facility alone is not sufficient to satisfy the requirements of the statute. The facility that manufactured the food must be identified.

vii. Food imported or offered for import for transshipment, storage, and export, or further manipulation and export. 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 exception in the final rule because we have determined that section 801(m) of the act requires the identity of the manufacturer for food imported or offered for import into the United States, regardless of whether that food will be consumed in the United States. Likewise, under section 801(l) of the act, food is subject to being held if it is imported or offered for import into the United States and it is from a foreign facility that has not registered. This provision applies even if the food is not for consumption in the United States. As noted previously, if the submitter is unable to determine the registration number of the manufacturer, the submitter may provide a reason along with the name and full address of the manufacturer.

(Final rule) Section 1.281(a)(6), (b)(5), and (c)(6) of the final rule requires for an article of food that is no longer in its natural state, the identity of the manufacturer, as follows: the name of the manufacturer; and either the registration number, city, and country of the

manufacturer or both the full address of the manufacturer and the reason the registration number is not provided.

8. The Grower, if Known

The Bioterrorism Act requires the submission of the identity of the grower of the article, if that identity is known within the specified period of time that notice is required to be provided. Section 1.281(a)(7), (b)(6), and (c)(7) of the IFR requires for an article of food that is in its natural state, submission of the name and growing location address of the grower, if known. If the submitter does not know the identity of the grower or, if the article has been consolidated, and the submitter does not know the identity of any of the growers, the submitter may provide the name and address of the firm that has consolidated the articles of food from different growers or different growing locations.

(Comments) One comment asks that the requirement to identify the grower not be mandatory in the final rule and suggests exempting the growers and providing the information of growers on a voluntary basis. Another comment asserts that it is virtually impossible to identify each grower once grain is commingled at the country elevator.

(Response) The Bioterrorism Act requires the identity of the grower, if known, in the submission of prior notice. Therefore, we cannot eliminate the requirement to provide the identity of the grower in all cases, as suggested by the comment. If the identity of the grower is not known at the time of submission of the prior notice, and the food has been consolidated, then the submitter may, but is not required to, provide the name and address of the consolidator (§ 1.281(a)(7), (b)(6), and (c)(7)).

(Comments) Another comment states that a single shipment of fresh fruit may represent hundreds of growers, all of whom are known by the submitter of the prior notice. The comment

asserts that requiring submission of an individual prior notice for each article represented by a single grower seems unnecessarily burdensome. The comment suggests that in lieu of requiring identification of all known growers in the prior notice, the rule should require the submitter of the prior notice to retain a complete list of growers and to make this list available to FDA for inspection and copying upon request.

(Response) We do not agree. Periodic access, inspection, and copying of a complete listing of all growers of an article of food does not satisfy the requirement to identify the grower of the article of food, if known, within the specified period of time that notice is required to be provided. FDA responded to a similar comment in the prior notice IFR and explained that FDA does not agree that a list would satisfy the statutory requirement, as it would not tell FDA which grower was associated with the particular article of food as envisioned by the statute (68 FR 58974 at 59006). We affirm the view here.

(Comments) One comment requests that FDA reconsider the requirement to submit the names of multiple growers, if known, in the prior notice. The comment notes that submitters of prior notices must provide separate notices for each grower in the case of consolidated shipments (if the growers are known), which it asserts is onerous and costly for exporters of consolidated shipments of horticulture products. The comment believes that the proposed recordkeeping rules will cause the names of the growers to be recorded and available and the prior notice information is a duplication of effort. The comment asks that, for consolidated shipments, FDA permit the submission of one prior notice providing the name of the consolidator or one notice with the names of all the growers.

(Response) FDA disagrees. Adding the capability to accept a list of growers would add considerable complexity to both the data entry software (PNSI and/or ABI) and the screening

programs. FDA responded to a similar comment in the prior notice IFR and explained that FDA does not agree that a list would satisfy the statutory requirement, as it would not tell FDA which grower was associated with the particular article of food as envisioned by the statute (68 FR 58974 at 59006). And as we explained in the previous response, periodic access, inspection, and copying of a complete listing of all growers of an article of food does not satisfy the requirement to identify the grower of the article of food, if known, within the specified period of time that notice is required to be provided. FDA notes that users of PNSI can create a prior notice for one grower, copy that prior notice, and edit just the grower information and the quantity and packaging information, assuming the imports for each grower are distinctly packaged.

(Final rule) Section 1.281(a)(7), (b)(6), and (c)(7) of the final rule requires for an article of food that is in its natural state, the submission of the name and growing location address of the grower, if known. If the submitter does not know the identity of the grower or, if the article has been consolidated and the submitter does not know the identity of any of the growers, the name and address of the firm that has consolidated the articles of food from different growers or different growing locations may be submitted.

9. FDA Country of Production

The Bioterrorism Act requires the submission of the identity of the country from which the article originates. The IFR in § 1.281(a)(8), (b)(7) and (c)(8), requires that a prior notice contain the FDA Country of Production of the article of food being imported or offered for import into the United States. As set out in the IFR definition at § 1.276(b)(4), the FDA Country of Production is, for an article of food 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, however, 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. For a food that is no longer in its natural state, the FDA Country of Production is the country where the article of food was made. However, if an article of food is made from wild fish, including seafood, that was made aboard a vessel, the FDA Country of Production is the country in which the vessel is registered. The IFR also provides that the FDA Country of Production of food grown and harvested or collected or made in a U.S. Territory is the United States.

(Comments) One comment asks what is required as the country of production in a case where spirits are exported in bulk to a third-country for local bottling and subsequent export from that third-country for consumption in the United States.

(Response) For a food that is no longer in its natural state (e.g. spirits), the FDA Country of Production is the country where the article of food was made (e.g. bottled). For an article of food that undergoes multiple manufacturing steps, as in this comment, the FDA Country of Production would be country where the last facility performs a manufacturing/processing step that exceeds an activity of a de minimis nature.

(Final rule) The final rule retains without change the provisions in § 1.281(a)(8), (b)(7), and (c)(8) of the IFR.

10. Shipper

The Bioterrorism Act requires the submission of the identity of the shipper of the article. The IFR at § 1.281(a)(9), (b)(8), and (c)(9) requires that the shipper be included in a prior notice. The IFR defines shipper (§ 1.277(b)(12)) as the owner or exporter who consigns and ships the article of food from a foreign country or the person who sends an article of food in international mail to the United States.

(Comments) One comment states that the FDA has augmented section 307 of the Bioterrorism Act to require not only supply chain party identification but also the registration number of the shipper. The comment further states that the requirement to submit the shipper's registration number is easily met. There were no other comments received on this issue.

(Response) We revised certain sections pertaining to the identity of the shipper. The IFR required the registration number of the shipper, if the shipper is required to be registered. The final rule requires the identity of the shipper only if the shipper is different from the manufacturer. Moreover, the final rule eliminates the requirement to submit the registration number of the shipper, if the shipper is required to be registered, and made the submission of the registration number optional. The identity of the shipper in the final rule is satisfied by submission of the name and full address of the shipper.

(Final rule) The final rule in § 1.281(a)(9), (b)(8), and (c)(9) requires the name and full address of the shipper, if the shipper is different from the manufacturer. If the address of the shipper is a registered facility, the submitter may submit the registration number of the shipper's registered facility.

FDA revised this requirement to require the shipper's information only when the shipper is different from the manufacturer in order to eliminate duplicative requirements. Moreover, we eliminated the requirement to provide the registration number of the shipper, if the shipper is required to be registered, and made the submission of the registration number optional.

In the IFR, the shipper's 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 exception in the final rule since the shipper's registration number is now optional.

11. The Country From Which the Article is Shipped

The Bioterrorism Act requires the submission of the identity of the country from which the article is shipped. The IFR requires in § 1.281(a)(10) and (c)(10) submission of the identity of the country from which the article is shipped. In § 1.281(b)(9), the IFR requires submission of the identity of the country from which the article is shipped (i.e., mailed).

(Comments) There were no comments received on this issue.

(Final Rule) The final rule retains without change the provisions in § 1.281(a)(10), (b)(9), and (c)(10) of the IFR.

12. Anticipated Arrival Information

Section 1.281(a)(11) of the IFR requires the submission of anticipated arrival information to include the anticipated port of arrival and anticipated border crossing; the anticipated date on which the article of food will arrive at the anticipated port of arrival; and the anticipated time of that arrival. In § 1.281(c)(11), the IFR requires the submission of the actual port of arrival. Anticipated arrival information is not required for food arriving by international mail.

A prior notice will not be inadequate if the anticipated port of arrival, the anticipated date of arrival, or the anticipated time of arrival changes between the time of confirmation of prior notice and the time of arrival, as provided by § 1.282(a) of the IFR.

The anticipated arrival information must specify the anticipated port of arrival and, if there is more than one border crossing location within that port, the specific anticipated border crossing where the food will be brought into the United States.

(Comments) One comment suggests the elimination of the anticipated arrival information as a data element. Another comment suggests that in light of the MOU between FDA and CBP,

arrival data are no longer important, as CBP can provide the personnel to conduct the necessary inspections.

(Response) Section 801(m) of the act requires the submission of the identity of the anticipated port of entry for the article of food, therefore, this data element cannot be eliminated. The anticipated time and date of arrival are needed for planning resources because it relates to when the food will first become available for examination at the border. The coordination procedures between FDA and CBP should not be construed to mean that arrival information is no longer important nor that we will not, whenever possible, conduct necessary inspections at the port. Moreover, FDA's working with CBP personnel does not negate our need for anticipated time and date of arrival since headquarters and field staff still need to know when articles of food plan to arrive.

(Comments) One comment states that the arrival information should be linked to the ABI entry filing at the port of entry because the FDA prior notice requirement is inconsistent with the existing entry clearance processes of CBP. The comment contends that requiring prior notice at the port of arrival will result in severe disruption to flight schedules, with the possible consequence of aircraft offload for any affected food shipment for which prior notice was not submitted.

(Response) FDA disagrees. The Bioterrorism Act requires notification about articles of food prior to arrival in the United States. Although prior notice and entry information can be submitted together through ABI/ACS, prior notice cannot be substituted by the entry process, which legally can occur well after the food has arrived in the United States. Since implementation of the IFR, FDA and CBP have noted no severe disruptions, including to flight schedules due to lack of prior notice of some articles of food within an aircraft, truck, or vessel

load. FDA points out that in December 2003, CBP issued and began implementation of the Advance Electronic Cargo Information rule, which also requires information about cargo before it arrives in the United States and allows for prohibition of landing authorization if such information is not provided in advance of arrival. (See 19 CFR 122.12(c) (international airports), 19 CFR 122.14(d)(4) (landing rights airports); and 19 CFR 122.15(a) (user fee airports).)

(Comments) One comment recommends that FDA ask CBP to change their ABI system to provide for port diversion functionality. The comment acknowledges that, although the FDA prior notice system is designed to allow a shipment to be diverted to a port other than the intended port of entry reported in the prior notice, CBP's ABI system precludes the CBP entry from being accepted at other than the reported port of entry. Another comment requests that when a prior notice is transmitted via either the Cargo or Border Cargo Selectivity application, the data should be moved from ACS to OASIS regardless of the estimated time of arrival date.

(Response) Such changes to the ABI system are not feasible at this time given resource constraints, and the development of CBP's new Automated Commercial Environment. Moreover, CBP transfers information to FDA at 8 p.m. on the day before arrival for truck shipments and 9 p.m. on the day before arrival for air shipment. Information is transferred to FDA on the same day if that information is submitted the same day as anticipated arrival of the shipment. CBP and FDA believe that this is sufficient for meeting the timeframes for receipt, review, and response to prior notice submission.

(Comments) Two comments address the difficulty of obtaining exact arrival information, including a specific time of arrival for air shipments, because many airlines are often closed at

night. The comment also states that including a specific date and time for arrivals by ocean vessel is difficult.

(Response) FDA disagrees. From FDA's standpoint, "time of arrival" relates to when the food will first become available for examination at the port. For vessels, this would be when the vessel docks in the port. For planes, this would be when the plane lands. For land vehicles, such as trucks, buses, and trains, this would be when they cross the border. FDA believes that someone involved in importing or offering for import an article of food has an indication of anticipated arrival into the United States of that food and can inform the submitter and/or transmitter of the prior notice. FDA also emphasizes that the information being requested is "anticipated" information, not "exact" or "specific" information as the comment incorrectly describes.

(Final rule) FDA and CBP have determined that for the purposes of communication, the identity of the border crossing within the port of arrival is no longer necessary. Therefore, that information is not required in the final rule. The final rule requires in § 1.281(a)(11) the anticipated arrival information, including the anticipated port of arrival, the anticipated date on which the article of food will arrive at the anticipated port of arrival, and the anticipated time of that arrival. 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. This revision is being made because anticipated arrival information is often not available to people who ship food using an express consignment operator or courier (see also the discussion in section III.E of this document describing the shipper as it relates to who is authorized to submit prior notice). For food that has

been refused under section 801(m) of the act, § 1.281(c)(11) of the final rule requires the port of arrival. We revised this provision in the final rule to require the actual date on which the article of food arrived at the port of arrival. This information is important for shipments where no previous prior notice was filed so that FDA knows how long it has been since the refused food shipment arrived in the United States. For shipments where a previously refused prior notice was filed, the actual arrival date will help FDA to connect the refused prior notice to the post-refusal prior notice submission. Anticipated arrival information is not required for food arriving by international mail.

13. The Importer, Owner, Ultimate Consignee, and U.S. Recipient

In § 1.281(a)(12) and (c)(12), the IFR requires the name and address of the importer. In § 1.281(a)(13) and (c)(13), the IFR requires the name and address of the owner if different from the importer or ultimate consignee. In § 1.281(a)(14) and (c)(14), the IFR requires the name and address of the ultimate consignee. However, the identity of the importer, owner, and ultimate consignee are not required for an article of food that is imported or offered for import for transshipment through the United States under a T&E entry.

The identity of the importer, owner, or ultimate consignee is not required for an article of food that is imported or offered for import via international mail. Instead, § 1.281(b)(11) of the IFR requires the name and address of the U.S. recipient.

a. Importer. (Comments) There were no comments received on this issue.

(Final rule) The final rule in § 1.281(a)(12) and (c)(12) requires the name and full address of the importer. FDA continues to require the identity of the importer so that FDA can take steps to ensure that food refused admission under section 801(m) of the act is not delivered to the importer illegally. FDA is inserting the word “full” in front of “address” in the final rule to make

clear that the complete address is required. Consequently, FDA also is revising the subsequent sentence of this paragraph to state that if the business address of the importer is a registered facility, then the facility's registration number also may be provided in addition to the facility's full address. Providing the registration number will facilitate FDA's review. The identity of the importer is not required for an article of food that is imported or offered for import for transshipment through the United States under a T&E entry.

b. Owner. (Comments) One comment asks that FDA clarify what it means by owner and provide examples.

(Response) In the preamble to the IFR, in response to a comment, we explained that the "owner" is the entity who owns the article of food at the time of arrival (68 FR 58974 at 59011). However, if a prior notice is given after the article is refused under section 801(m)(1) of the act, then the owner is the entity who owns the article of food at the time the prior notice is submitted (Id.).

(Final rule) The final rule in § 1.281(a)(13) and (c)(13) requires the name and full address of the owner if different from the importer or ultimate consignee. FDA is continuing to require the identity of the owner so that FDA can take steps to ensure that food refused admission under section 801(m) of the act is not delivered to the owner illegally. FDA is inserting the word "full" in front of "address" in the final rule to make clear that the complete address is required. Consequently, FDA is revising the subsequent sentence to state that if the business address of the owner is a registered facility, then the facility's registration number may be provided in addition to the owner's full address. The identity of the owner is not required for an article of food that is imported or offered for import for transshipment through the United States under a T&E entry.

c. Ultimate consignee. (Comments) One comment states that the ultimate consignee, as defined by CBP (Customs Directive No. 3550-079A), is not necessarily the party to whom the merchandise is delivered and asks who is the ultimate consignee for purposes of this rule. Another comment notes that there are a number of manufacturers in Canada who ship their product to public warehouses in the United States to have product available on a just-in-time basis for their customers. The comment states that at the time the product crosses the border, it is still the property of the manufacturer and it does not have a specific customer (consignee) in the United States other than the manufacturer because the consignee is still to be determined. The comment asks for guidance as to how to comply and fill out the prior notice for these types of shipments.

(Response) FDA intends to interpret the "ultimate consignee" consistent with CBP's use of that term in regards to the entry of merchandise. In a case where a customer or consignee has not been identified, as described in the previous comment, the public storage warehouse where the merchandise will be delivered and stored should be identified as the ultimate consignee in the prior notice submission.

(Final rule) Section 1.281(a)(14) and (c)(14) of the final rule requires the name and full address of the ultimate consignee. FDA is continuing to require the identity of the ultimate consignee so that FDA can take steps to ensure that food refused admission under section 801(m) of the act is not delivered to the ultimate consignee illegally. FDA is inserting the word "full" in front of "address" in the final rule to make clear that the complete address is required. Consequently, FDA is revising the subsequent sentence to state that if the business address of the ultimate consignee is a registered facility, then the facility's registration number also may be provided in addition to the facility's full address. The identity of the ultimate consignee is not

required for an article of food that is imported or offered for import for transshipment through the United States under a T&E entry.

d. U.S. recipient. (Comments) There were no comments received on this issue.

(Final rule) The identity of the importer, owner, or ultimate consignee is not required for an article of food that is imported or offered for import via international mail. Instead, the final rule requires in § 1.281(b)(11) the name and address of the U.S. recipient. FDA is continuing to require the identity of the U.S. recipient so that FDA can take steps to ensure that food refused admission under section 801(m) of the act is not delivered to the U.S. recipient illegally.

14. Mode of Transportation

Section 1.281(a)(15) and (c)(15) of the IFR requires submission of the identity of the mode of transportation.

(Comments) There were no comments received on this issue.

(Final rule) The final rule retains without change the provisions in §1.281(a)(15) and (c)(15) of the IFR. The mode of transportation data element is necessary to calculate whether prior notice is timely, as well as for identification of the article of food at the time of arrival for the purposes of planning examinations and communicating with CBP for enforcement and examination.

15. Carrier

Section 1.281(a)(16) and (c)(16) of the IFR requires the SCAC or IATA code of the carrier which is, or will be, carrying the article of food from the country from which the article is shipped to the United States, or if codes are not applicable, then the name and country of the carrier.

(Comments) Several comments ask for clarification of identification of the carrier and provide examples of when the article of food is transferred from one carrier to another both prior to arrival in the United States and after arrival in the United States.

(Response) In the prior notice proposed rule, we had proposed to require the identity of each carrier or transporter firm that transports the article of food from the country from which the article was shipped into the United States. We agree with the comments we received to the proposed rule that asked FDA to eliminate the requirement to identify multiple carriers, and revised the proposed provisions to require in the IFR the submission of the identity of the carrier that is or will be carrying the article of food from the country from which the article is shipped to the United States. In doing so, FDA acknowledged the suggestion that the only pertinent carrier is the one arriving at the U.S. port. The final rule clarifies that the carrier is the carrier which is, or will be, carrying the article of food from the country from which the article is shipped to the United States to the port of arrival.

(Final rule) FDA and CBP have determined that identity of the country of the carrier is not necessary when the SCAC or IATA codes are not provided; the name alone of the carrier is sufficient for communication between the two agencies. However, FDA and CBP have determined that the license plate number of a privately owned vehicle as well as the State or Province that issued the license plate number is necessary for such communication.

While identity of the license plate number and State or Province that issued the license is needed to identify the carrier of the food at the port of arrival, it is more properly categorized as part of the identity of the carrier than as part of the identity of the planned shipment information. Therefore, the requirement for the submission of the license plate number (and State or Province that issued the license) for food arriving by privately owned vehicle has been moved to §

1.281(a)(16) and (c)(16). FDA has found that the identification of the privately owned vehicle as the carrier, when applicable, is such a critical factor in the identification of the article of food for examination and communication, that we have included this information in § 1.281(a)(16) and (c)(16) of the final rule.

Section 1.281(a)(16) and (c)(16) of the final rule requires the identity of the carrier by submission of the SCAC or IATA code of the carrier which is, or will be, carrying the article of food from the country from which the article is shipped to the United States to the port of arrival, or if these codes are not applicable, then the name of the carrier. If the carrier is a privately owned vehicle, the final rule requires the submission of the license plate number of the vehicle and the State or Province that issued the license plate number. Identification of the carrier is not required for an article of food that is imported or offered for import via international mail.

Identification of the carrier is necessary to enable FDA and CBP to identify the appropriate article of food for inspection or holding when the food arrives in the United States. FDA notes that a carrier typically is a different firm than the shipper. The broker or self-filer currently submits carrier information to ABI/ACS when entry is made, and it later is transmitted to OASIS.

16. Planned Shipment Information

In § 1.281(a)(17) and (c)(17), the IFR requires submission of planned shipment information as it exists when the prior notice is submitted. FDA recognized that some of this information may change after the prior notice has been submitted and addressed this in the IFR in § 1.282(a), which specifies when changes require resubmission to FDA.

Many comments addressed the planned shipment information. These comments are discussed in order of appearance of the specific data elements in the IFR and preceded by a discussion of general comments.

a. General comments. (Comments) One comment suggests that a complete list of ABI mandatory and optional data elements be immediately published via the CBP Administrative Message system. The comment asserted that some planned shipment information, such as the vessel carrier flag, is not necessary when the carrier code is submitted.

(Response) The “vessel carrier flag” is not part of the planned shipment information. For food arriving by ocean vessel, the vessel name and voyage number are part of the planned shipment information. The preamble to the final rule contains a table of information required at the end of this section (table 2 of this document). Each information requirement listed in the table 2 of this document is annotated to indicate when that information is required.

(Comments) One comment suggests an additional requirement for planned shipment information. The comment suggests that a number assigned through CBP’s PAPS be required and that the PAPS number could be added after the prior notice is submitted, but before the truck arrives at the border. The comment asserts that this amendment of a confirmed prior notice, would greatly decrease a truck’s waiting time at the border and aid in quickly clearing trucks through CBP.

(Response) PAPS is a CBP border cargo release mechanism that utilizes barcode technology to expedite the release of commercial shipments. FDA at this time has no plans to utilize PAPS in reviewing prior notices or otherwise administering the prior notice program, and therefore, FDA is not adding the PAPS number as an additional data element.

(Comments) One comment requests clarification as to whether the additional requirement for planned shipment information, as applicable (carrier, vessel name, voyage flight numbers and bill of lading number), will require a resubmission of prior notice when those details change due to transportation arrangements outside of the control of the supplier.

(Response) When we issued the IFR, we recognized that some of this information may change after the prior notice has been submitted, and addressed this in § 1.282(a) of the IFR, which specifies when changes require resubmission to FDA. If planned shipment information required in § 1.281(a)(17) changes after you receive notice that FDA has confirmed your prior notice submission for review, you are not required by the IFR to resubmit prior notice. The final rule retains this provision.

b. Airway bill number(s) and bill of lading number(s)--§ 1.281(a)(17)(i) and (c)(17)(i).

(Comments) One comment stated that FDA should simplify the data requirements 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 comment suggests that the waybill/bill of lading number be utilized as a single reference point because all shipments that are moved are repeatedly covered by this number.

(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.

(Final rule) The Airway Bill number(s) or Bill of Lading number(s) have been valuable information for identification, examination and communication; however, this information is generally not available to an individual submitter of an article of food that is arriving via express consignment operator or carrier. The express consignment operator or carrier tracking number is available to those individuals who send an article of food via express courier. Therefore, we have amended the final rule to allow the submission of the express consignment operator or carrier tracking number in lieu of the Airway Bill or Bill of Lading numbers when the article of food is arriving by express consignment operator or carrier and the submitter is not the express consignment operator or carrier.

Section 1.281(a)(17)(i) and (c)(17)(i) of the final rule requires submission of the Bill of Lading number(s) or the Airway Bill number(s), as applicable to the mode of transportation and when it exists. This information is not required for an article of food that is imported or offered for import via international mail or when carried by or otherwise accompanying an individual when entering the United States. For food arriving by express consignment operator or carrier when the submitter is not the express consignment operator or carrier, the tracking number may be submitted in lieu of the Bill of Lading or Airway Bill number.

c. Vessel name and voyage number--§ 1.281(a)(17)(ii) and (c)(17)(ii). (Comments) One comment asks the purpose of this requirement because the vessel name and voyage number are provided to other U.S. agencies, such as CBP and U.S. Coast Guard, at an even earlier stage than required for the prior notice.

(Response) The planned shipment information is necessary to ensure the effective enforcement of section 801(m) of the act. Submission of the vessel name and voyage number in prior notice associates that information with the article of food and enables FDA to effectively

communicate with CBP regarding examination of that article of food prior to arrival of that food. It is one of the means that FDA and CBP use to match the prior notice review to the food when it arrives at the port; e.g., what conveyance is carrying the article of food. The final rule will continue to require the vessel name and voyage number for food arriving by ocean vessel. As we discussed in the preamble to the IFR, while we are dedicated to increasing information sharing capabilities with other agencies, it is generally difficult to have the required information readily accessible if we need to coordinate with other agencies or governments to obtain from them the information necessary to respond to bioterrorism incidents or other food-related emergencies (68 FR 58974 at 58992).

(Final rule) Section 1.281(a)(17)(ii) and (c)(17)(ii) of the final rule requires submission of the vessel name and voyage number for food arriving by ocean vessel, when they exist.

d. Flight number--§ 1.281(a)(17)(iii) and (c)(17)(iii). (Comments) There were no comments received on this issue.

(Final rule) The final rule requires the flight number for food arriving by air carrier. The flight number has been valuable information for identification, examination and communication; however, this information is generally not available to an individual submitter of an article of food that is arriving via express consignment operator or carrier. The express consignment operator or carrier tracking number is available to those individuals who send an article of food via express consignment operator or carrier. Therefore, § 1.281(a)(17)(iii) and (c)(17)(iii) of the IFR have been amended to allow the submission of the express consignment operator or carrier tracking number in lieu of the flight number when the article of food is arriving by express consignment operator or carrier and the submitter is not the express consignment operator or carrier.

e. Trip number--§ 1.281(a)(17)(iv) and (c)(17)(iv). (Comments) Several comments request clarification of the definition of trip numbers. One comment reasons that the load tender numbers or manifest numbers should be used as trip numbers for food arriving by truck because loads are tendered to carriers with these numbers, and the carrier uses the numbers for billing reference. Another comment reasons that trip number appears to refer to a number that relates to the particular trip or journey rather than the vehicle. Another comment asserts that the trip number should identify the conveyance, everything onboard a trailer or container entering the United States. One comment recommends elimination of the mandatory requirement for trip number.

(Response) FDA disagrees. Land carriers use the "Trip" number to signify a train number, bus route number, and/or a truck route number. This number normally designates a repetitive route between two locations (e.g., Washington, DC to New York, NY) and may signify the specific truck, bus, or train route (e.g., Train # 138 or Bus # 4411). This information is necessary for communication between FDA and CBP, and thus, the final rule continues to require a trip number for food arriving by truck, bus, or rail.

(Final rule) Section 1.281(a)(17)(iv) and (c)(17)(iv) of the final rule requires submission of the trip number for food arriving by truck, bus, or rail, as applicable to the mode of transportation and when it exists. This information is not required for an article of food that is imported or offered for import via international mail.

f. Container number(s)--§ 1.281(a)(17)(v) and (c)(17)(v). (Comments) One comment suggests that FDA should allow for multiple container submissions on one prior notice.

(Response) Multiple container numbers can be submitted for one prior notice on screen via PNSI submission or through use of multiple qualifiers for the Affirmation of Compliance code for container number via ABI/ACS submission.

(Final rule) Section 1.281(a)(17)(v) and (c)(17)(v) of the final rule requires the identification of container numbers for food arriving as containerized cargo by water, air, or land, as applicable to the mode of transportation and when it exists. This information is not required for an article of food that is imported or offered for import via international mail or when carried by or otherwise accompanying an individual when entering the United States.

g. Car number--§ 1.281(a)(17)(vi) and (c)(17)(vi). (Comments) No comments were received on this issue.

(Final rule) The final rule retains the provisions of the IFR and requires submission of the identity of the car number for food arriving by rail, when it exists. This information is not required for an article of food that is imported or offered for import via international mail or when carried by or otherwise accompanying an individual when entering the United States.

h. License plate number and State or Province--§ 1.281(a)(17)(vii) and (c)(17)(vii).

(Comments) No comments were received on this issue.

(Final rule) FDA has determined that while identity of the license plate number and State or Province that issued the license is needed to identify the carrier of the food at the port of arrival, it is more properly categorized as part of the identity of the carrier than as part of the identity of the planned shipment information. Therefore, the requirement for the submission of the license plate number (and State or Province that issued the license) for food arriving by privately owned vehicle has been moved to § 1.281(a)(16) and (c)(16). The final rule requires the submission of the license plate number of the vehicle and the State or Province that issued the

license plate number, if the carrier is a privately owned vehicle. By including the identification of the privately owned vehicle as a carrier information requirement, when applicable, you must resubmit the prior notice in accordance with this subpart (see § 1.282) if the privately owned vehicle information changes after the prior notice has been confirmed by FDA for review.

Identification of the license plate number and State or Province that issued the license is not required for an article of food that is imported or offered for import via international mail.

i. Harmonized tariff schedule (HTS) codes--§ 1.281(a)(17)(viii) and (c)(17)(viii).

(Comments) One comment suggests the use of the HTS codes in lieu of FDA product codes and asserts that the HTS codes provide all the information that the FDA would need for prior notice.

(Response) The HTS codes often are not sufficient to specifically identify a product for FDA decisionmaking. For example, in many cases, the tariff code does not describe how the product was processed (e.g., commercially sterile or shelf-stable) or how the product is packaged, which is indicated in the Process Indicator Code (PIC) element of FDA's product code. Several products that FDA considers different from each other (because these differences affect the potential safety of the food) may be combined under one HTS code. Therefore, the HTS codes do not provide all the information that is required to identify the food.

Additionally, at the time that FDA and CBP issued the IFR, we believed that the HTS code was needed for communication between FDA and CBP and that the identification of the HTS would assist CBP in the efficient processing of prior notice through ACS. We also thought that, for prior notices submitted through the FDA's PNSI, the HTS numbers were needed to ensure that the data collected from the CBP entry when it is transmitted through ABI/ACS could be matched to prior notice. We have found that the HTS code is neither critical for communication with CBP nor for identification of the food for examination purposes.

Accordingly, we have removed the requirement to submit the HTS code as a part of prior notice planned shipment information.

(Comments) One comment suggests that FDA and CBP upgrade the flags associated with HTS numbers. The comment also states that prior notice cannot be submitted through ABI/ACS if the HTS code does not have a FDA flag. One comment states that FDA should not rely solely upon HTS flags to implement the prior notice requirements.

(Response) FDA agrees and monitors and updates the HTS flags. Guidance about the HTS flags is posted at <http://www.cfsan.fda.gov/~dms/htsguid3.html>. Prior notice can be submitted on any product because of intended use, regardless of the HTS flag. Not having a FDA flag associated with the HTS code does not prevent submission of prior notice via ABI/ACS or PNSI.

(Final rule) Section 1.281(a)(17) and (c)(17) of the final rule requires submission of the following planned shipment information, as applicable, based on the mode of transportation:

- Bill of lading number(s), Airway bill number(s), or express consignment operator or carrier tracking number when the article of food is arriving by express consignment operator or carrier and the submitter is not the express consignment operator or carrier (not applicable to food carried by or otherwise accompanying an individual);
- For food arriving by ocean vessel, vessel name and voyage number;
- For food arriving by air carrier, flight number or the express consignment operator or carrier tracking number when the article of food is arriving by express consignment operator or carrier and the submitter is not the express operator or carrier;

- For food arriving by truck, bus, or rail, the trip number;
- For food arriving as containerized cargo by water, air, or land, the container number(s) (not applicable to food carried by or otherwise accompanying an individual); and
- For food arriving by rail, car number (not applicable to food carried by or otherwise accompanying an individual).

We also added the phrase “to the mode of transportation and when it exists” after “as applicable” in the opening sentence of § 1.281(a)(17) and (c)(17) to clarify that the data elements under planned shipment information are applicable by mode of transportation and when the data element exists. For example, rail car number, container number, and train trip number may be applicable for rail shipments, and vessel name, voyage number, and container number may be applicable for food arriving by ocean vessel.

The final rule does not require that prior notice be cancelled and resubmitted if this planned shipment information changes after FDA has confirmed the prior notice for review. A prior notice will not be inadequate if any of the planned shipment information changes between the confirmation of prior notice and the time of arrival.

j. Refused articles. (Comments) One comment requests clarification of the process for resubmission if a prior notice is refused for reasons other than failure to satisfy prior notice requirements. The comment asks once the failure is rectified, should companies use the PNSI or ABI/ACS to resubmit the load for clearance?

(Response) A food may be refused under 801(m) of the act only if it is imported or offered for import with inadequate prior notice; i.e., no prior notice, untimely prior notice, or inaccurate prior notice. To resolve a refusal, prior notice or a revised prior notice must be

submitted via PNSI until such time as ACS or its successor system can accommodate such transactions.

The following table 2 summarizes the information required under § 1.281(a), (b), and (c):

TABLE 2.--PRIOR NOTICE INFORMATION REQUIRED BY CATEGORY

| Information | Transshipment | Carried By or Accompanying an Individual | Food Not in Natural State | Food in Natural State | Mail | After Section 801(m) of the Act Refusal |
|---------------------------------------|--------------------------|------------------------------------------|---------------------------|--------------------------|-------------|-----------------------------------------|
| §1.281 paragraph(s) | (a) and (c) | (a) | (a) | (a) | (b) | (c) |
| Submitter | Y | Y | Y | Y | Y | Y |
| Transmitter | Y | Y | Y | Y | Y | Y |
| Entry type | Y | Y | Y | Y | Y | Y |
| Entry identifier | Y | Y | Y | Y | N | Y |
| FDA product code | Y | Y | Y | Y | Y | Y |
| Common, usual, or market name | Y | Y | Y | Y | Y | Y |
| Estimated quantity | Y | Y | Y | Y | Y | Actual |
| Lot/Code # | Y | Y | Y | N | Y | Y |
| Manufacturer | Y | Y | Y | N | Y | Y |
| Grower, if known | Y | Y | N | Y | Y | Y |
| Country of production | Y | Y | Y | Y | Y | Y |
| Shipper | Y | Y | Y | Y | Y | Y |
| Country from which article is shipped | Y | Y | Y | Y | Y | Y |
| Port of arrival | Anticipated ¹ | Anticipated ¹ | Anticipated ¹ | Anticipated ¹ | N | Actual ¹ |
| Date of arrival | Anticipated ¹ | Anticipated ¹ | Anticipated ¹ | Anticipated ¹ | N | Actual |
| Time of arrival | Anticipated ¹ | Anticipated ¹ | Anticipated ¹ | Anticipated ¹ | N | N |
| Date of mailing | N | N | N | N | Anticipated | N |
| Importer | N | Y | Y | Y | N | Y |
| Owner | N | Y | Y | Y | N | Y |
| Ultimate consignee | N | Y | Y | Y | N | Y |
| U.S. recipient | N | N | N | N | Y | N |
| Mode of transport | Y | Y | Y | Y | N | Y |
| Carrier | Y | Y | Y | Y | N | Y |
| Bill of lading/airbill | Planned ¹ | N | Planned ¹ | Planned ¹ | N | Actual ¹ |
| Vessel/Voyage | Planned | Planned | Planned | Planned | N | Actual |
| Flight # | Planned ¹ | Planned ¹ | Planned ¹ | Planned ¹ | N | Actual ¹ |
| Trip # | Planned | Planned | Planned | Planned | N | Actual |
| Container # | Planned | N | Planned | Planned | N | Actual |
| Car # | Planned | N | Planned | Planned | N | Actual |
| Hold information | N | N | N | N | N | Y |

¹ If the article of food is arriving by express consignment carrier or operator, and the submitter and/or transmitter is not the express consignment operator or carrier, and the prior notice is submitted via the FDA PNSI, the express consignment operator or carrier tracking number may be submitted in lieu of this information.

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

In § 1.282 (a)(1) of the IFR, if any of the information required in § 1.281(a) except the quantity information, the anticipated arrival information, or the planned shipment information, changes after FDA has confirmed the prior notice submission for review, you must resubmit prior notice. For food arriving by international mail, if any of the information required in § 1.281(b), except the anticipated date of mailing, changes after FDA has confirmed the prior notice submission for review, you must resubmit prior notice.

The IFR also states that the original prior notice should be cancelled in PNSI or if originally submitted via ABI/ACS, the entry should be deleted.

(Comments) Some comments request that FDA revisit the concepts outlined in §§ 1.289 through 1.294 of the proposed rule, which allowed amendments to be made to product identity, estimated quantity, and arrival information, without having to cancel the entry and resubmit the prior notice under a new entry. The comments contend that such amendments were acceptable and would not taint the adequacy of a prior notice or compromise food security, if the amendments are made within the applicable 2-, 4-, or 8-hour timeframes per mode of transportation at issue. The comments suggest that amendments allow for a degree of flexibility in the prior notice system and acknowledge a well-known fact in the industry that this type of information may change after prior notice has been submitted. Some comments suggest that allowing the submitter or filer to update or correct information provided in a prior notice will facilitate the steady flow of prior notice submissions, without jeopardizing the security and safety of the food supply.

(Response) Unlike the proposed rule, the IFR does not allow for amendments relating to the product identity. After considering the comments on whether the final rule should allow amendments, and based on our experience with the IFR, we believe the approach in the IFR is sound. The reduced timeframes in the IFR, which are continued in the final rule, provide very little leeway in the time FDA has to receive, review, and respond to the prior notice submissions. Moreover, the timeframes are based, in part, on not receiving amendments because allowing amendments would increase the review time. In addition, ACS cannot accommodate changes in prior notice submissions that have been confirmed by FDA for review because CBP also needs finality so it can complete its own screening of the entry. Therefore, to keep the timeframes as short as possible, we are not permitting changes to prior notice without restarting the clock.

Moreover, we believe that the prior notice information required by the final rule should be sufficiently fixed to be submitted within the timeframes. The final rule allows for estimates for some information--estimated quantity, anticipated arrival information, and planned shipment information--and changes to any of these data elements does not require that the prior notice be resubmitted.

(Comments) Some comments request that FDA create a mechanism to allow correction of errors in a manner that does not restart the prior notice clock. One comment requests the final rule provide for correction of errors within the timeframe of the 2-, 4-, or 8-hour deadline. The comments suggest that a streamlined process, possibly through electronic means, of making clerical corrections or correcting errors in timely filed prior notice should be a permanent feature of the integrated FDA-CBP process. Some comments contend that without the opportunity to correct the error post-submission, shippers may find their shipments frozen in an extended period of delay, which would frustrate the purpose of the FDA-CBP Integration Plan that is aimed at

reducing such timeframes. Comments also suggest this would create an unintended legislative loop between the two regulatory frameworks meant by the Integration Plan to be seamlessly and efficiently integrated.

Some comments object to the IFR's requirements because after the CBP entry or entry summary has been certified, there currently is no mechanism for making corrections, including corrections of simple clerical errors, without canceling the entry and submitting a new entry. Comments state that the requirement to cancel and resubmit a prior notice when submitted information changes or to correct a clerical error creates additional work in an already overburdened environment. According to the comments, in the air and truck environment where cargo is processed on weekends and at off-hour operations, CBP is unavailable to process these entry cancellations. The comments state that in such circumstances, cargo could be forced into refused status due to CBP's inability to act in a timely manner.

Similarly, other comments state that many imported articles of food are time sensitive and must be shipped in a temperature controlled environment. The comments note that clerical errors in the prior notice may not be corrected, and if an error is discovered after a CBP entry is certified, the entry must be cancelled. According to the comments, if CBP is not available to cancel the entry (e.g., the shipment arrives over the weekend), the delay may cause the shipment to be destroyed. The comments request that FDA and CBP find a way to address this problem, either by allowing clerical revisions after the entry has been certified, permitting entry deletions under certain circumstances, or ensuring CBP availability on a 24 hours/7 days a week/365 days a year schedule.

(Response) Because we reduced the timeframes for submitting prior notice in the IFR to the least amount of time that we need to meet our statutory responsibility to receive, review, and

respond to prior notice submissions, the IFR did not provide for amendments or updates. The timeframes in the final rule also provide the least amount of time we need to receive, review and respond to prior notice submissions and therefore, the final rule also does not provide for amendments or updates. The use of ABI/ACS precludes amendments and updates without 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. Changes to ABI/ACS submissions that have been electronically transmitted to FDA's OASIS and confirmed by FDA for review are not feasible because CBP also needs finality so it can complete its own screening of the entry.

Changes to confirmed prior notice submissions, other than those relating to estimated quantity, anticipated arrival information, and planned shipment information, must be processed by resubmission of prior notice unless the article of food will not be offered for import or imported into the United States. The responsibility is on submitters to provide accurate prior notice to FDA, and we encourage affected parties to take appropriate measures to verify entries for accuracy before sending. FDA notes that both ABI and PNSI systems allow for correction of errors that are revealed by the systems' validation process. In PNSI, a PN confirmation number will not be provided if it detects errors in the submitted data.

Moreover, FDA notes that if CBP is unavailable to cancel a prior notice, submitters can create and submit new replacement entries and prior notices using either ABI or a combination of ABI and PNSI even when the original entry has not yet been cancelled. However, the submitter should cancel the previously submitted inaccurate ABI entry (via request to CBP) at the first chance possible to avoid subsequent administrative and operational problems with entry release. This is a revision to the IFR in that § 1.282(c) of the final rule uses the correct term

“cancel” versus “delete” when describing what CBP should be requested to do in this case.

When an entry is “deleted” versus “cancelled” in ABI, the filer is able to re-use the original entry number. However, PNSI will reject a prior notice submission that attempts to re-use a previous entry number. Therefore, we revised the final rule to provide for cancellation of the entry, rather than deletion of an entry.

(Comments) Some comments request that FDA and CBP develop a process for reviewing amendments that do not affect the security of the cargo in less than the full eight hours, so that the shipments’ release from the port is not delayed unduly.

(Response) The requirements for amendments set forth in the proposed rule were eliminated from the IFR. This final rule provides that if required information (except estimated quantity, anticipated arrival information, including the anticipated date of mailing, and planned shipment information) changes after FDA has confirmed prior notice for review, the prior notice should be cancelled and a prior notice with the correct information must be submitted. The reduced timeframes in the IFR, which are continued in the final rule, provide very little leeway in the time FDA has to receive, review, and respond to the prior notice submissions. Moreover, the timeframes are based, in part, on not receiving amendments because allowing amendments would increase the review time. In addition, ACS cannot accommodate changes in prior notice submissions that have been confirmed by FDA for review because CBP also needs finality so it can complete its own screening of the entry. Because we are maintaining the IFR timeframes in the final rule, it is difficult to accommodate amendments.

(Comments) Some comments state that changes to prior notice should be required for material changes only. Materiality would need to be determined.

(Response) We agree. The final rule requires that, if certain required information changes after FDA has confirmed prior notice for review, the prior notice should be cancelled and a prior notice with the correct information must be submitted. Changes to other information (i.e., estimated quantity, anticipated arrival information, and planned shipment information) do not require the submitter to re-submit a revised prior notice.

(Comments) Some comments suggest that entry deletions, rather than cancellations, should be permitted for legitimate reasons.

(Response) FDA believes the comment misunderstands § 1.282(c) of the IFR because that provision states, “If you submitted the prior notice via ABI/ACS, you should cancel the prior notice via ACS by requesting that CBP delete the entry” (emphasis added). However, the final rule now recommends that if you cancelled a prior notice submitted via ABI/ACS, you should cancel the prior notice via ACS by requesting that CBP cancel, rather than delete, the entry (§ 1.282(c)). When an entry is “deleted” versus “cancelled” in ABI, the filer is able to re-use the original entry number. However, PNSI will reject a prior notice submission that attempts to re-use a previous entry number. Therefore, we revised the final rule to provide for cancellation of the entry, rather than deletion of an entry.

(Comments) One comment requested clarification regarding whether the additional requirement for planned shipment information as applicable (carrier, vessel name, voyage flight numbers, and bill of lading number) will necessitate a resubmission when those details change due to transportation arrangements outside the control of the supplier.

(Response) No. The final rule does not require resubmission of prior notice if the planned shipment information changes after prior notice has been submitted and confirmed for review by FDA.

(Comments) One comment notes that part of the process of completing a prior notice is to obtain a CBP entry number, which many firms use a customs broker to do. The comment states that this works well in most cases, but can create problems for products arriving by boat. The comment further states that of all the modes of transportation, boats are the most unpredictable and can arrive earlier or later than expected. Early arrivals pose a problem because of the 8 hour notice period and the relatively short timeframe in which a company learns of an impending early arrival. Given the fact that customs brokers may not work a 24-hour, 7-day per week schedule, prior notice shipments that arrive on the weekend, holiday, or after normal business hours will be filed late and could be subject to civil penalties. The comment recommends that the prior notice system allow custom entry numbers to be updated after the customs entry has been filed by the customs brokers and that any penalty considerations be deferred under these circumstances.

(Response) The type of updates recommended by this comment is not necessary because prior notice can be submitted without a customs entry number. In the situation described, where prior notice must be submitted before entry can be filed, prior notice may be submitted using PNSI without a CBP entry identifier (e.g., a CBP entry number). PNSI will provide a system-generated entry identifier. Once a customs broker is secured during normal business hours to file the entry, the prior notice confirmation number(s) can be given to the broker who can affiliate the prior notice(s) to the customs entry via the ABI submission.

(Comments) Some comments request clarification on what happens to the food if the information relating to product identity, estimated quantity, or anticipated arrival changes after prior notice is submitted.

(Response) The final rule requires that if required information (except estimated quantity, anticipated arrival information, including the anticipated date of mailing, and planned shipment information) changes after FDA has confirmed prior notice for review, the prior notice must be resubmitted. As we explained in the preamble to the IFR, "FDA proposed to allow changes to certain information in the prior notice after a prior notice was submitted. * * *. Some comments stated that if the timeframe for submitting prior notice was changed, i.e., shortened to 4 hours for land and air and 8 hours for water, then amendments and updates would not be necessary. * * * FDA agrees with the comments that state that if the deadline for submission of prior notice were reduced, amendments and updates would not be necessary. FDA has chosen timeframes that provide it with very little leeway in the time it has to 'receive, review and respond' to the prior notice submissions. Thus, we concluded that we could no longer permit changes to prior notice without restarting the clock. In addition, the use of ABI/ACS precludes amendments and updates: changes to ABI/ACS submissions that have been electronically transmitted to FDA's OASIS and confirmed by FDA for review are not feasible because CBP also needs finality so it can complete its own screening of the entry. Therefore, the interim final rule does not allow for changes to a prior notice after the transmitter has been notified that FDA has confirmed the prior notice for review." (68 FR 58974 at 59013 and 59014)

We retain this view and therefore, changes in product identity require resubmission of a prior notice with the correct information. We do not require resubmission of a prior notice if the estimated quantity, anticipated arrival information, including the anticipated date of mailing, and planned shipment information changes, because these data elements are not firm in the first place. Moreover, such changes would not alter FDA's ability to review the prior notice or to examine the food.

(Comments) Some comments request that FDA maintain the flexibility, as provided by the IFR, to provide anticipated port arrival information for date and time of arrival and point of crossing. The comments state that this flexibility is critical for minimizing trade disruption and note that times of arrival and entry locations often change and importers need the flexibility to accommodate these unanticipated changes without refile entry information.

(Response) Section 1.281(a)(11), which requires anticipated arrival information, has been revised in the final rule. The requirement to provide the identity of the border crossing within the anticipated port of arrival has been eliminated in the final rule. As with the IFR, in the final rule, changes in anticipated port of arrival, anticipated date of arrival, and anticipated time of arrival do not require cancellation and resubmission of the prior notice.

(Comments) Some comments suggest that the requirement that all prior notice data be transmitted via the PNSI portal after the prior notice time limitations or refusal will increase the load on this limited system. The comments state that the PNSI system capacity must be dramatically increased before the August 2004 full enforcement deadline in order to ensure that legitimate trade is not impacted due to a failure of the system.

(Response) FDA does not agree that post-refusal prior notice submissions have or will impact or overload PNSI. PNSI has operated effectively since the IFR took effect and has sufficient capacity for any increase in submissions after the effective date of this final rule. FDA has carefully monitored both PNSI and OASIS system usage and performance. No issues related to load on PNSI have been identified since the IFR took effect. Until such time as ACS or its successor system can accommodate such transactions, post-refusal prior notice must be submitted via PNSI (see § 1.280(a)(2)).

(Final Rule) Section 1.282 of the final rule requires that if required information (except estimated quantity, anticipated arrival information, including the anticipated date of mailing, and planned shipment information) changes after FDA has confirmed prior notice for review, the prior notice should be cancelled and a prior notice with the updated information must be submitted.

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

The IFR in § 1.283 identifies consequences and procedures for failure to provide adequate prior notice and describes the requirements and procedures for various situations.

The comments received will be discussed below in the order each issue appears in § 1.283 of the IFR, preceded by comments generally addressing consequences.

1. General Comments

(Comments) Some comments suggest that enforcement actions should be based on levels of culpability (e.g., negligent, grossly negligent, and fraudulent), number of infractions, and seriousness of infractions.

(Response) FDA and CBP take various considerations, such as the seriousness of the violation, into account when deciding whether to take an enforcement action in response to violations of the prior notice rule and, if so, what actions to take. For areas in which we have established enforcement policies for prior notice, these are contained in, and communicated to the public through a Compliance Policy Guide (CPG). Elsewhere in this issue of the FEDERAL REGISTER, we are announcing the availability of the Prior Notice Final Rule Draft CPG, which describes our proposed enforcement policies for the final rule.

(Comments) Some comments request clarification on the penalties for inadvertent errors, such as clerical errors, in the prior notice submission.

(Response) As described in the previous response, FDA and CBP take into account the nature of the violation in determining how to respond to prior notice violations. The validation process built into ABI and PNSI should assist in catching inadvertent errors, such as clerical errors, because the systems will not accept data with certain errors. This validation process then allows the submitter to correct errors before final submission of prior notice data.

(Comments) Some comments ask if there are any measures that importers should undertake to avoid delays at the port of entry.

(Response) FDA advises that most delays based on inaccurate and untimely submission of prior notice are avoidable and recommends that importers focus on measures to increase accurate and timely submissions of prior notice.

(Comments) Some comments state that the "Category 3" refusal and fine provision is excessive for a shipment showing up at the border in advance of the 2-hour timeframe elapsing and FDA should consider lowering the penalty for this type of offense. Other comments request clarification about what will happen to trucks that arrive too early, i.e., will they be turned away or will they be allowed to wait in the compound?

(Response) Section 1.283(a)(1)(iii) of the final rule provides that if an article of food arrives early (i.e., before the prior notice time has elapsed), its arrival will not be considered untimely if FDA already has reviewed the prior notice, determined its response to the prior notice, and advised CBP of that response. However, if FDA has not reviewed the prior notice submission and responded to CBP before the food arrives, the food is subject to refusal. As noted previously, in determining whether to refuse the food, assess a CBP civil monetary

penalty, or take other regulatory action, we will take into account the seriousness of the violation and other considerations. Trucks arriving before FDA has processed the prior notice will be handled as appropriate under the individual circumstances.

(Comments) Some comments state that the implementation plan for the prior notice rule must include a contingency plan to ensure that border traffic can still be cleared and does not come to a standstill as new systems are put in place and problems are resolved. Comments point out that it is essential for FDA and CBP to have appropriate mechanisms and procedures in place (such as referral to a secondary inspection, where appropriate) so that border congestion is not increased by the application of the rules.

Some comments request clarification on arrangements between FDA and CBP, the Canada Border Services Agency, and the bridge authorities to address issues surrounding refusal of entry due to missing or incomplete prior notice information. The comments indicate that the relevant agencies on both sides of the border should have a plan in place to deal with the inevitable problems posed by larger volumes of returning trucks to ensure that busy border crossings do not become a "no man's" land. Some comments indicate that local staff at busy border crossings, such as the Peace Bridge and Ambassador Bridge, have indicated that trucks will be turned back for missing/incomplete prior notice if secure storage cannot be arranged. Comments suggest that CBP could stamp a shipping document (such as the bill of lading) "Refused--BTA" or implement procedures that CBP had in place for refused trucks prior to the Bioterrorism Act.

Some comments suggest that carriers should be permitted a variety of options when and if they are advised that one or more products within a shipment have been refused due to a failure to have an adequate prior notice. According to the comments, these options may include,

permission to hold the cargo at the border while the proper information is submitted to the FDA and before mandatory notice of intended destination for delivery; returning the cargo to the exporting facility directly; holding the cargo at a designated carrier's closest facility; and/or holding the cargo at a designated FDA holding facility, not necessarily a general order bonded warehouse, near the port of entry.

(Response) FDA and CBP have not experienced any major disruptions in border traffic as a result of the implementation of the IFR in December 2003. The agencies also have not made any significant revisions to the IFR in this final rule that cause us to believe there will be major disruptions in trade once the provisions in this final rule take effect, particularly since we are providing a 180-day period between publication of this rule and the effective date of its provisions. This period of time should allow for full understanding by affected parties of the requirements of the final rule.

We also note that the automated validation process in ABI and PNSI will catch most missing and incomplete submissions before refusal because the systems will not accept submissions with certain errors or omissions. If refusal does occur, the carrier will have the option to segregate refused food from the rest of the shipment (§ 1.283(a)(3)), the option to export after refusal with CBP concurrence (§ 1.283(a)(5)), and the option to have refused food held at the port of entry, unless directed otherwise by CBP or FDA (see § 1.283(a)(1)).

(Comments) Some comments recommend establishing an electronic means to resolve the refused admission status.

(Response) Both the IFR and the final rule provide for a response to an 801(m) refusal to be provided to FDA by mail, e-mail, fax, or courier. FDA will respond in kind, as we have not experienced any problems as a result of this flexibility.

2. Inadequate Prior Notice (§ 1.283(a)(1))

(Comments) Several comments request that FDA notify the submitter, filer, importer, or ultimate consignee, either in lieu of or in addition to the carrier, about inadequacies in a prior notice submission that result in refusal of the food. The comments state that the carrier is not in a position to resolve the problem when the article of food is refused. The comments note that the carrier has temporary possession of the product, has minimal vested interest in the shipment, particularly if it is offloaded, and has little, if any, resources or incentive to resolve the refusal. However, according to the comments, the exporter, importer, or ultimate consignee has an ownership interest in the refused food and a strong economic incentive to resolve the refusal swiftly, or to export or destroy the refused food if the prior notice defects cannot be corrected. The comments state that delaying notification to the submitter, importer, and ultimate consignee, unduly hinders the resolution of the problem.

One comment specifies that the filer of the prior notice, who is in most cases the importer, supplier, owner of the merchandise, or a representative of one of these entities, should be notified directly, without any intermediate communication, so that the filer may promptly take corrective action and mitigate any possible adverse regulatory and commercial consequences. Some comments request that FDA or CBP notify the General Order Manager (GOM) when a shipment has been rejected or denied entry and also provide the rationale for that decision.

(Response) FDA disagrees. The IFR does not require FDA or CBP to provide notice about a refusal, and we continue to believe this is appropriate. As an operational matter, the carrier would have to be notified of the refusal. The carrier can then notify others, such as the entity that hired the carrier to transport the article of food, that there is a problem with the prior notice. It would be resource-intensive for FDA or CBP to assume responsibility for notifying

various other entities of the refusal. FDA notes that, although we collect the contact information for the submitter and transmitter, which we could use to contact parties about certain actions, including refusals, routinely notifying these and other parties about a refusal would take limited staff resources away from other functions, such as reviewing prior notices. FDA will try to notify other parties (e.g., submitter), in addition to the carrier, if feasible, and we often do contact these other parties as resources allow. FDA notes that for the future migration of ABI/ACS to the ITDS/ACE environment, FDA has requested the ability to provide electronic prior notice “refusal” messaging. This capability does not currently exist. If electronic prior notice refusal messaging is in place, it would significantly reduce the resources required to notify ITDS participants of these refusals.

(Comments) Some comments express concern that trucking companies that pick up FDA-regulated freight in Canada or Mexico bound for the United States cannot ascertain that the importer, shipper, or customs broker has filed the appropriate prior notice. The comments ask what form of proof FDA (or other border regulatory agencies) will consider acceptable in order to release the motor carrier from responsibility if the prior notice was not filed appropriately. The comments state that it is not clear whether FDA will supply an official document that the importer, shipper, or customs broker would issue to the motor carrier to assure the carrier that prior notice has been filed.

(Response) Under § 1.279(d) of the final rule, FDA notifies the submitter when the prior notice has been confirmed for review, with a message containing a prior notice confirmation number. Section 1.279(g) of the final rule requires 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.

To address the concern in the comments, carriers may consider, as a matter of business practice, requesting from their customers proof of confirmation of prior notice submission prior to transporting the food to the United States, even when there is no requirement to provide the confirmation number to CBP or FDA upon arrival.

(Comments) Some comments request clarification on whether information for FDA clearance will be allowed to be transmitted via ABI, PNSI or either, for a shipment of food that will be entered after the arrival of a vessel or an aircraft. Comments ask what error message will be entered after the arrival of a vessel or an aircraft. Comments ask what error message will be sent back to the transmitter for entry that is untimely filed, e.g., will the transmitter receive a refused admission status or some other error message? In addition, comments ask what the mechanism is for communicating with the carrier on the disposition of the prior notice. The comment states that carriers cannot view the FDA "may proceed" messages in CBP's AMS, and the ABI participant (usually the customs broker) is responsible for communicating freight holds to the various parties involved, including importers, container freight stations (CFS), and truckers.

(Response) FDA clarifies that if an article of food subject to prior notice requirements arrives in the United States and prior notice has not been received for review by FDA in the timeframes prescribed in the final rule, the food is subject to refusal under section 801(m) of the act, unless FDA already reviewed the prior notice, determined its response, and advised CBP of that response. See also the discussion above regarding communication of refusal status.

(Comments) One comment requests clarification as to how transmitters may confirm the validity and existence of registration numbers provided by the shippers, importers, and carriers. The comment states that the transmitter might bring in goods based on erroneous, but good faith information.

(Response) FDA will identify anomalies in the initial submission of registration numbers based on review of the information prior to confirmation of receipt of the prior notice, and will respond accordingly. If our subsequent review, after the prior notice is confirmed for review, reveals problems with a submitted registration number that causes the prior notice submission to be deemed inaccurate, the food is subject to refusal under section 801(m) of the act. Subsequent corrections to the submitted information can be provided by resubmitting corrected information in a post-refusal prior notice (see § 1.283(c)).

If our subsequent review reveals problems with the submitted registration number such that an article of food is from a foreign facility that is not registered under section 415 of the act and 21 CFR, part 1, subpart H, and is imported or offered for import into the United States, the food is subject to hold under section 801(l) of the act. To resolve a hold, the facility must register and obtain a registration number, and that number must be provided to FDA. This is covered under § 1.285(i) of the final rule.

As discussed in response to comments 157 and 158 in the preamble to the Registration of Food Facilities Interim Final Rule (68 FR 58894 at 58931, October 10, 2003), section 305 of the Bioterrorism Act states that FDA's list of registered facilities and registration documents FDA receives under the rule are not subject to disclosure under FOIA. Furthermore, section 305 of the Bioterrorism Act provides that any information derived from the list of facilities or registration documents that would disclose the identity or location of a specific registered person is not subject to disclosure under FOIA. This does not preclude the registered facility from disclosing its registration number, such as to the submitter or others with whom it has a business relationship.

(Comments) Some comments request that FDA clarify the penalties for inadequate prior notice. One comment asks about the consequences when foods are accidentally shipped without meeting the prior notice requirements, i.e. can they be transshipped?

(Response) Prior notice is required for food imported or offered for import into the United States, including shipments intended for transshipment. If adequate prior notice is not provided, the food is subject to refusal. Refused food must be held, in accordance with the provisions of § 1.283(a), unless CBP concurrence is obtained for export and the food is immediately exported from the port of arrival under CBP supervision. An article of food that has been refused is considered general order merchandise and can only be moved under appropriate custodial bond unless immediately exported under CBP supervision. If the food is held at a secure facility outside of the port, FDA must be notified of the location of the secure facility before the food is moved there. Post-refusal prior notice can be submitted as provided by § 1.283(c).

We also note that CBP may seize goods imported contrary to law, assess civil monetary penalties, including those under 19 U.S.C. 1595a(b) against every person who directs, assists, financially or otherwise, or is in any way concerned in the importation of any merchandise contrary to law, and refer violations for criminal investigation and prosecution. Section 1.284 of the final rule lists other consequences for failure to submit adequate prior notice. For example, under 21 U.S.C. 335a, FDA can seek debarment of any person who has been convicted of a felony relating to importation of food into the United States or any person who has engaged in a pattern of importing or offering for import adulterated food that presents a threat of serious adverse health consequences or death to humans or animals.

(Comments) Some comments ask whether an entry of food would be subject to detention if the product code does not precisely reflect the nature of the product.

(Response) The final rule requires the submission of accurate information that is submitted in the prior notice, including the product code, which is required in § 1.281 (a)(5)(i), (b)(4)(i), and (c)(5)(i) of the final rule. If the product code does not accurately identify the food, the food is subject to refusal. Section 1.283(a)(1)(ii) of the final rule states that if prior notice has been submitted and confirmed by FDA for review, but upon review of the notice or examination of the article of food, the notice is determined to be inaccurate, the food is subject to refusal of admission under section 801(m)(1) of the act.

3. Status and Movement of Refused Food (§ 1.283(a)(2))

(Comments) Some comments request that FDA clarify the process for food that is refused and later deemed to be admissible.

(Response) Section 1.283 of the final rule identifies the consequences and procedures for food that is refused because of inadequate prior notice. If the refused food is not immediately exported with CBP concurrence, it is considered general order merchandise and must be held until adequate prior notice is submitted and FDA has notified CBP and the transmitter that the food is no longer refused because of inadequate prior notice. If in response to a request for FDA review, FDA determines that the article is not subject to the prior notice requirements or that the prior notice submission is complete and accurate, it will notify the requester, the transmitter, and CBP that the food is no longer subject to refusal under section 801(m)(1) of the act. A determination that an article of food is no longer refused under section 801(m)(1) of the act is different than, and may come before, determinations of admissibility under other provisions of the act or other U.S. laws. Moreover, a determination that an article of food is no longer refused

under section 801(m)(1) does not mean that it will be granted admission under other provisions of the act or other U.S. laws (§ 1.283(g)). Further information regarding the process may be found in the preamble to the IFR (68 FR 58974 at 59016 through 59022).

(Comments) Some comments state that the holding period for prior notice should be no longer than the original required prior notice timeframe. The comments contend that exceeding this time period does not increase the safety to the public and may cause a bottleneck for all freight movements if thousands of shipments are held at their port of arrival. Comments suggest that, before the holding period is fully implemented, FDA should determine the percentage of shipments that are still not in conformity with the prior notice rule and determine the potential for harming the movement of all freight into and out of the United States when prior notice is fully implemented.

(Response) Section 1.283(a)(2) of the final rule states that refused food will be considered general order merchandise. In the first instance, it is not within our control how long it will take the parties associated with the article of food being held to satisfy the prior notice requirements. Moreover, CBP regulations address the length of time an imported product will be held in General Order (G.O.) Status (19 CFR part 127). Section 1.283(a)(1) of the final rule states that refused food that is not immediately exported must be held at the port of entry unless directed by CBP or FDA. Accordingly, the final rule does not require refused food to be held at the port of arrival unless so directed by CBP or FDA. In § 1.283(c)(3), we state that FDA will try to review and respond to post-refusal prior notice submissions within the prior notice timeframes.

(Comments) Some comments request that FDA establish procedures for handling refused merchandise. The comments contend that secure storage facilities and cargo movement

procedures have not been established for refused merchandise. According to the comments, there is no mechanism to handle refused refrigerated or frozen shipments. The comments state that perishable food that is held or is not properly stored may no longer be commercially viable when it is released or sold at auction. Comments also state that highly perishable shipments that are held past their commercially viable time period and small shipments that have little commercial value will quickly fill any warehouse, including any G.O. warehouse, with no one to claim them. Other comments request that FDA and CBP develop a joint operational plan for handling refused merchandise with input from the importing and shipping industries. Another comment states that directions on executing CBP 6043 Permit to Transfer or CBP 7512 "Restricted in-bond" is needed to avoid major congestion.

(Response) Section 1.283(a)(2)(i) of the final rule provides that food refused under section 801(m)(1) of the act has "General Order" status. Under CBP laws and regulations, general order merchandise must generally be held in a general order warehouse (19 CFR 127.1). CBP regulations also empower the port director, if merchandise requires specialized storage facilities that are unavailable in a bonded facility, to direct the storage of the merchandise by the carrier or by any other appropriate means (see 19 CFR 4.37(f), 122.50(f), or 123.10(f)). Additionally, fruit and other perishables may be held by the port director in a bonded cold-storage warehouse for a reasonable period, if it is probable that entry will be made at an early date (19 CFR 127.28(c)).

FDA and CBP believe that general order storage qualifies as secure facilities for purposes of the Bioterrorism Act, as it is subject to the requirements set forth at 19 CFR part 19. In particular, 19 CFR 19.9 contains controls that will ensure that refused food will be adequately

controlled while in storage and will not be released from general order storage without CBP authorization.

FDA also emphasizes that refusal under section 801(m) of the act occurs when no prior notice or inadequate or untimely prior notice is submitted, as required under the Bioterrorism Act for articles of food imported or offered for import into the United States. Costs and other consequences described by the comments due to refusal for inadequate prior notice should be avoided when adequate prior notice is submitted to FDA. The final rule also outlines procedures for satisfying the prior notice requirements after food has been refused and procedures for requesting an FDA review of the refusal.

(Comments) One comment requests that FDA establish a clear definition of “perishable” shipments. The comment states that destroying or selling frozen, refrigerated, and fresh merchandise held at a secure facility after 3 days, for inadequate prior notice, is unreasonable and an excessive financial burden on international trade.

(Response) FDA does not agree that it is necessary or pertinent to establish a definition of “perishable” for purposes of implementing the prior notice requirements of the Bioterrorism Act, which requires FDA to receive prior notice of food imported or offered for import into the United States. Financial burdens associated with merchandise directed to a secure facility because of inadequate, untimely or no prior notice generally can be avoided by ensuring FDA receives adequate prior notice in accordance with this final rule.

(Comments) Some comments request that FDA consider the “port of entry” to be the port where legal entry is accomplished. The comments state that these ports have facilities for proper food storage, as well as the CBP and FDA processes and personnel to deal with any irregularities. The comments point out that international shipments are not legally “entered” with

CBP at the port of arrival, but instead are moved under bond to a subsequent port where CBP entry is made. Further, shipments are not released at the port of entry until clearance is obtained from CBP, and carriers are under a strict obligation to retain control of shipments from the port of arrival to the legal entry port. The comments note that under the IFR, shipments of food will not be permitted to be moved from the port of first arrival to the port of legal entry if prior notice is not provided or is inadequate. According to the comments, express carriers may be required to unload and reload entire planes in order to find one or two shipments. The comments state that this is especially problematic because proper facilities for the storage of food may not be available at the ports of arrival. Comments further note that express consignment operators have invested millions of dollars to construct and operate dedicated sorting facilities that use state of the art automation and scanning equipment. These facilities are far better suited to identifying and detaining food shipments of concern to FDA than the ramps or conventional air freight handling facilities commonly found at the ports of arrival. Other comments state that there are no cold storage facilities currently available in San Diego/Otay Mesa. The comments contend that the Mexican authorities will not permit such shipments to be returned to Mexico.

(Response) The IFR and the final rule at § 1.283(a)(1) require that food refused due to inadequate prior notice food must be held within the port of arrival only if directed by CBP or FDA, and that otherwise refused food must be held within the port of entry.

As we discussed in the preamble to the IFR, we defined “port of arrival” and “port of entry” to provide flexibility to ensure that “food that has been refused may move to the port of destination where, for example the consumption or warehouse entry will be filed, unless directed by CBP or FDA. Generally, we do not intend to hold shipments at the border unless our

assessment of the situation leads us to believe it is warranted; e.g., the food may present a serious risk to public health or that the prior notice violation is egregious.” (See 68 FR 58974 at 58988.)

(Comments) One comment requests that FDA notify public food storage warehouses when a shipment is being held, is not accepted for entry, or when such shipments are released. The comment points out that the warehouses receive shipments via multiple transport methods, store them for multiple customers, and should be officially informed of the status of the shipments, rather than relying on information from the owners of the articles of food.

(Response) Under § 1.283(a)(2), refused food shall not be entered and shall not be delivered to the importer, owner, or consignee. As discussed previously, FDA does not believe it should modify the rule to require notice of the refusal to any specific entity or entities. The entity moving the food to a warehouse can notify the warehouse of the food’s status, and the warehouse can likewise ask or require that it be provided this information before accepting the food for storage.

(Comments) Some comments state that the requirement in § 1.283(a)(2)(ii) for carriers to notify FDA regarding delivery of refused shipments within 24 hours of arrival and then to make delivery immediately imposes an unreasonable burden on carriers.

(Response) We have changed the requirement to notify FDA of the location where the food has been or will be moved from within 24 hours of refusal to before the food is moved to that location. FDA needs this information before the food is moved to verify that the facility where the food is to be held is a secure facility. Moreover, because refused food shall not be delivered to the importer, owner, or ultimate consignee, before the food is moved, FDA needs to verify that the secure facility is not owned by any of these parties.

For clarity and consistency, we also are changing the phrase "designated location" to "secure facility" in § 1.283(a)(2)(ii) and throughout the final rule. In addition, § 1.283(a)(2)(ii) of the IFR states that refused food must be moved under appropriate custodial bond. We have 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 also clarifies that the refused food may be held at the port of entry or at a secure facility.

(Comments) Some comments request clarification on whether "refused goods" will have to be exported or destroyed.

(Response) Articles of food that have been refused under section 801(m) of the act because of inadequate prior notice must be held until prior notice requirements have been satisfied, unless the food is immediately exported with CBP concurrence from the port of arrival. The decision to export the refused food is not the responsibility of FDA or CBP. If no prior notice submission or request for FDA review is submitted in a timely fashion after a food is refused, the food will be dealt with as set forth in CBP regulations relating to general order merchandise. It may only be sold for export or destroyed as agreed to by CBP and FDA.

(Comments) One comment requests clarification on the process for designating a "secure facility" after a shipment of food is refused admission status. The comment points out that the CF3461 entry document currently designates a CBP exam site in box 29 and requests clarification on whether refused goods will be sent automatically to the designated CBP exam site or if arrangements can be made to designate another facility.

(Response) FDA clarifies that a refusal under section 801(a) of the act, relating to admissibility, differs from a refusal under section 801(m) of the act, relating to prior notice. A food refused under section 801(m) of the act must be held within the port of entry for the article

of food unless directed to another location by CBP or FDA. If CBP or FDA directs the food to be delivered to a secure facility, this will not necessarily be the CBP exam site designated in box 29 of the CF3461 entry document.

(Comments) Some comments ask if FDA will publish a list of approved "secure facilities" by port so that transmitters can designate these facilities.

(Response) Early in our prior notice experience, FDA had indicated that we would publish a list of secure facilities. However, our experience has shown us that it is not practicable to maintain such a list since the secure status of facilities changes very rapidly. While we will not maintain such a list, FDA will verify whether a facility is secure on a case-by-case basis.

(Comments) Some comments request that FDA and CBP jointly issue a guidance document explaining in greater detail how they intend to hold and store articles of food, particularly perishable food, refused admission into the United States. One comment requests that FDA clarify the process for food that is held and later deemed to be admissible.

(Response) FDA agrees and, as resources permit, will publish a guidance document that will set out procedures for food refused for failure to meet prior notice requirements.

(Comments) Some comments state that there are an insufficient number of general order warehouses to store the food articles that have been refused for noncompliance with these regulations.

(Response) FDA disagrees. Under CBP laws and regulations, general order merchandise must generally be held in a general order warehouse (19 CFR 127.1). However, in ports where there is no bonded warehouse authorized to accept general order merchandise, CBP regulations also empower the port director to direct the storage of the merchandise by the carrier or by any other appropriate means (see 19 CFR 4.37(f), 122.50(f), or 123.10(f)). In addition, our

experience has not shown that there are an insufficient number of general order warehouses to store food that has been refused under prior notice.

(Comments) Some comments state that FDA must delay full enforcement of the prior notice regulations until it has done all that is necessary to equip the U.S. ports to handle refused perishable goods.

(Response) FDA believes that the ports are equipped to handle refused perishable goods. Since the IFR took effect, we have not been aware of problems relating to perishable goods not being properly maintained while being held at the ports.

(Comments) Some comments ask whether public storage warehouses will be stuck with unsaleable food items or whether they will be compelled to re-export at their own expense if the owner abandons a shipment that is refused entry because of inadequate prior notice. Comments indicate that a warehouse loses its lien abilities if a refused shipment is not allowed in interstate/intrastate trade and is re-exported. Thus, according to the comments, if the owner of the food does not pay storage and handling for the product, the warehouse has no collateral to compel payment. Comments also state that even if it does remain at the warehouse and the owner declines payment, the product has been refused entry so it cannot be sold to allow the warehouse to recoup its charges.

(Response) Under the final rule, food refused under section 801(m) of the act is considered to be general order merchandise and generally must be held at a general order warehouse. If the refused food is not immediately exported and if no prior notice is submitted or resubmitted and no request for FDA review of the refusal is submitted, then the food will be dealt with as set forth in CBP regulations relating to general order merchandise (19 CFR part

127), except that, unless otherwise agreed to by CBP and FDA, the article may only be sold for export or destroyed (§ 1.283(a)(6)).

We made a minor change to the final rule by changing the last phrase of § 1.283(a)(6) from “* * * except that the article may only be sold for export or destroyed as agreed to by CBP and FDA” to “* * * except that, unless otherwise agreed to by CBP and FDA, the article may only be sold for export or destroyed.” This change was needed because concurrence from FDA is not needed whenever a refused article of food is sold for export or destroyed, and no prior notice is submitted or resubmitted and no request for FDA review is submitted. We are adding the phrase “unless otherwise agreed to by CBP and FDA” to allow for the improbable (but not impossible) scenario when a refused prior notice shipment would need to be transferred to another agency for examination or investigation; in these cases, we would want concurrence from both FDA and CBP.

(Comments) Some comments request that FDA revise the requirement to store refused merchandise at local port facilities. One comment indicates that this provision of the IFR does not make sense and does not provide any measure of security or safety to the food supply. The comment points out that, before the IFR, shipments were allowed to be held at the importer's premises and suggested that this practice should be allowed to continue. According to the comment, ports and land borders do not have sufficient storage capacity to handle the possibly overwhelming demand for space that will be needed when the prior notice regulations are implemented.

(Response) FDA disagrees. Section 801(m)(2)(B) of the act specifically requires that food refused under section 801(m) be held and not delivered to the importer, owner, or consignee. The IFR and the final rule require that refused food must be held within the port of

entry for the article unless directed to another location by CBP or FDA. Therefore, an importer's premises, as suggested by the comment, would not be appropriate since the Bioterrorism Act specifically requires that the refused food not be delivered to the importer, owner, or consignee. Nor would such a location be adequate because it also may not be secure.

(Comments) Some comments object because shipments of food for which prior notice has not been provided will not be permitted to be moved to the port of entry. According to the comments, the operator will be required to off-load these shipments and detain them at the port of arrival until the prior notice is provided.

(Response) FDA disagrees. The IFR and the final rule require that refused food must be held within the port of entry for the article unless directed to another location by CBP or FDA. Thus, refused food may be permitted to move to the port of entry; such food is not required to be held at the port of arrival.

(Comments) Some comments express concern about the time it takes for FDA to release food offered for import into the United States, and request that FDA examine its inspection procedures and reduce the time to clear and release the food. The comments indicate that some shipments of food have been held at the port of entry for periods ranging from 2 weeks to 2 months, which has a serious economic impact on importers of perishable foods. The comments point out that there are already additional costs associated with the IFR, such as fees charged by custom brokers to file the prior notice. The comments further state that the delays are adding more costs that importers must bear, including the cost to store the food during this period, additional freight charges, and costs incurred due to spoilage of perishable products.

(Response) We know of no instance where a food has been held at any port facility or secure location for an extended period of time as described in the comment (2 weeks to 2

months) due to FDA's review of a prior notice submission or due to FDA's refusal of food for failure to provide adequate prior notice. Perhaps the comment actually is referring to delays caused by FDA's admissibility review under section 801(a) of the act. Nevertheless, FDA will make every effort to minimize the time necessary to perform prior notice assessments to minimize delays in releasing shipments.

4. Segregation of Refused Foods (§ 1.283(a)(3))

(Comments) Some comments state that in an "LTL" (less-than-truckload) environment, where an average trailer contains about 40 shipments, there is a potentially serious impact on several parties when prior notice is not filed in a timely fashion for one of the articles of food. The comments point out that the motor carrier's potential loss of productivity from having equipment tied up when an article of food has been denied entry or is being held has a serious negative impact on the profitability of cross-border trucking operators. According to the comments, this kind of down time has a serious negative impact on truck drivers' compensation, when they are paid based on miles driven, and greatly reduces the number of allowable hours a driver is allowed to operate under Federal Motor Carrier Safety regulations. The comments also indicate that holding a trailer at a port of entry affects not only the motor carrier's operations, but also all of the shippers, importers, and consignees whose goods are on board. Some comments request that FDA require importers to provide motor carriers with proof that prior notice was transmitted to FDA. The comments state that currently FDA and CBP only suggest that motor carriers require proof of prior notice filing from customers, but this type of arrangement is not required by law or regulation. According to the comments, because FDA system's acknowledgement of receipt of a prior notice does not mean that the information received is correct or complete, carriers are still left vulnerable to carrying goods that could be turned back

at the border. The comments indicate that this type of action by FDA would tie up a carrier's equipment, negatively affect driver wages, and have a serious effect on carrier productivity.

(Response) Financial burdens associated with refused food because of inadequate or no prior notice generally can be avoided by ensuring FDA receives adequate prior notice in accordance with this final rule. For example, while the final rule requires only that the prior notice confirmation number accompany any food for which the prior notice was submitted through PNSI when the article arrives in the United States, it does not preclude the carrier from requiring proof of confirmation of prior notice submission prior to transporting the food to the United States when prior notice is submitted through ABI/ACS. Moreover, according to § 1.283(a)(3) of the final rule, segregation may take place to separate food that has not been placed under hold from food refused for inadequate prior notice.

(Comments) Some comments request clarification on who is responsible for the physical segregation of the refused food from the rest of the shipment: The carrier, FDA or CBP, customs broker, or importer. Comments also ask whether FDA or CBP officials will always supervise the segregation.

(Response) The IFR at § 1.283(a)(3) states that segregation may take place to separate food that has not been placed under hold from food refused for inadequate prior notice. The final rule clarifies this paragraph by adding that other merchandise not subject to prior notice requirements may be segregated from refused food.

The segregation may be done by any person as long as the refused food is held as required and not delivered to the importer, owner, or consignee. Neither FDA nor CBP is responsible for segregation. However, the IFR and final rule state that FDA or CBP may

supervise the segregation. If FDA or CBP determine that supervision is necessary, segregation must not take place without supervision.

(Comments) Some comments indicate that carriers should have the option of unloading refused articles of food so they can deliver the rest of their load without being detained any longer than necessary. The comments point out that carriers do not have title or financial interest in the goods they transport and they cannot provide information to provide or correct an inadequate prior notice.

(Response) Carriers already have the option to segregate food so that they can deliver the rest of their load. As discussed previously, the IFR and the final rule at § 1.283(a)(3) state that segregation may take place to separate food that has not been placed under hold from food refused for inadequate prior notice.

5. Costs (§ 1.283(a)(4))

(Comments) Some comments ask who is responsible for costs associated with FDA verification of a shipment that is initially refused and then it is later determined that the shipment's documentation fulfills all requirements and complies with regulations; i.e., the shipment was improperly refused.

(Response) Section 1.283(a)(4) of the final rule provides that neither FDA nor CBP will be responsible for transportation, storage, or other expenses resulting from refusal.

6. Export After Refusal (§ 1.283(a)(5))

(Comments) Some comments request clarification on procedures for exporting fresh vegetables after refusal. The comments indicate that some ports of arrival do not have cold storage facilities.

(Response) The procedures for exporting fresh vegetables after a refusal under section 801(m) of the act are no different than other exports, with the following qualifications: Food refused under section 801(m) must be immediately exported from the port of arrival with CBP concurrence and under CBP supervision.

7. Post-Refusal Prior Notice Submissions (§ 1.283(c))

In § 1.283(c)(2) of the final rule, FDA revised the text to read “the prior notice should be canceled” instead of “you should cancel” to indicate that the cancellation of the prior notice can be done by CBP, upon request by the filer, if originally submitted in ABI/ACS or by the transmitter if originally submitted in PNSI.

(Comments) Some comments object because the current ABI system cannot accept prior notice after the articles of food arrive in the United States. Instead, filers must use the PNSI system. The comments suggest there is no valid reason for this limitation and request modifications to allow filers to use the ABI system for submitting prior notice, even after cargo has arrived in the United States. Other comments request removal of edits for date sensitive prior notice in ABI and PNSI. Some comments point out that if prior notice is transmitted after the articles of food arrive, the filer must enter an incorrect anticipated date of arrival, which is on or after the actual date of arrival. According to the comments, this skews FDA information, prevents FDA from determining whether prior notice was filed timely, and gets the filer in the habit of submitting false information. The comments also ask that if prior notice is submitted in this manner, how FDA can determine if the date was filed timely or not? The comments also state that because ABI will not accept prior notice on articles of food that have already arrived, this leads to the more time consuming filing of prior notice in PNSI and also leads to a corruption of the correct data.

(Response) Prior notice submitted after the food has arrived in the United States is a post-refusal submission. Under § 1.280(a)(2) of the IFR, post-refusal submission of prior notice must be completed via PNSI. The final rule retains this provision, but re-worded the text to state that post-refusal submissions must be submitted in PNSI until such time as ACS or its successor system can accommodate such a transaction. Post-refusal information requirements are found at § 1.281(c). Among other data elements, a post-refusal submission requires the location and address where the article of refused food will be or is being held, the date the article has arrived or will arrive at that location, and identification of a contact at that location (§ 1.281(c)(18)). The final rule now also requires the date the article of food arrived at the port of arrival.

Post-refusal submissions cannot be submitted via ABI/ACS because CBP's system cannot be modified at this time to accept information about the location where the article of refused food will be or is being held and the actual date of arrival of the article of refused food. Amending ABI/ACS 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.

PNSI programming changes should address the concern raised in the comment about "submitting false information." These same concerns should not arise under the final rule since the final rule requires the actual date of arrival for post-refusal submissions.

FDA made a minor change in the text of § 1.283(a)(6) by replacing the phrase, "in a timely fashion," with the phrase, "in accordance with paragraph (d) of this section," to clarify that the timeliness of a request for FDA review is found at paragraph (d). We made a similar change in § 1.285(g).

8. FDA Review After Refusal (§ 1.283(d))

(Comments) One comment requests that the final regulations make it clear that the request for the review and/or the participation in the review can be conducted by any of the parties named in § 1.283(d) of the IFR or by a designated representative, such as a customs broker, freight forwarder, or attorney.

(Response) Section 1.283(d)(2) of the final rule provides that the carrier, submitter, importer, owner, or ultimate consignee may submit a written request asking FDA to review whether the article of food is subject to the requirements of this subpart under § 1.277. FDA has added carrier in the final rule since the carrier is often the entity notified of the refusal. Although not explicitly stated in the rule, a designated representative of any of the parties listed (carrier, submitter, importer, owner, and ultimate consignee) may act on behalf of that party.

Furthermore, FDA revised § 1.283(d)(1) to state that the request for FDA review may include whether the information submitted in a prior notice is complete, in addition to accurate. (In the IFR, we also cited § 1.276(b)(5), but we deleted it in the final rule because it is redundant.) FDA revised § 1.283(d)(5) to be consistent with the changes made to § 1.283(d)(1). In § 1.283(d)(3), FDA 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 to ensure that requests are expeditiously received and directed to the appropriate staff.

9. International Mail (§ 1.283(e))

(Comments) Some comments request clarification on the disposition of mail for which prior notice is required, but is not provided. Comments also ask about the U.S. Postal Service's responsibilities for mail lacking prior notice.

(Response) In the case of food arriving by international mail, if prior notice is inadequate or if the prior notice confirmation number is not affixed, the article will be held by CBP for 72 hours for FDA inspection and disposition. If the article is refused and there is a return address, the parcel may be returned to the sender. If there is no return address or the food in the shipment appears to present a hazard, FDA may dispose of or destroy the parcel at its expense. If FDA does not respond within 72 hours of the CBP hold, CBP may return the parcel back to the sender or, if there is no return address, destroy the parcel, at FDA expense. Under the prior notice final rule, only FDA and CBP have responsibilities for the destruction or return of refused foods that arrive via international mail.

FDA revised § 1.283(e) and § 1.285(k) in the final rule to change the word “stamped ‘No Prior Notice—FDA Refused’” to “marked ‘No Prior Notice—FDA Refused’” to more accurately describe the marking that is placed on international mail packages arriving with inadequate prior notice or without the prior notice confirmation number affixed as required. In certain cases, the package cannot be stamped and a label/sticker is placed on the package.

We also 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.

10. Prohibitions on Delivery and Transfer (§ 1.283(f))

(Comments) Some comments ask whether CBP will put a manifest "hold" on food cargo until the prior notice confirmation is received. The comments state that, at the present time, cargo can be moved inland on an IT or T&E entry without FDA review. The comments ask if

FDA will remind the transmitters that products should remain intact until a “may proceed” message is received. The comments further ask if ocean carriers will be advised of the FDA status of the articles of food when the shipment involves “doors moves” beyond 50 miles from the port of entry.

(Response) Food arriving as an IT or T&E entry is subject to FDA review of prior notice before it arrives in the United States. Food that arrives with no prior notice is subject to refusal and must be held within the port of entry for the article unless directed to another location by CBP or FDA. Food that is refused under section 801(m) of the act is considered G.O. merchandise and cannot be entered or delivered to the importer, owner, or consignee.

For clarity, FDA revised § 1.283(f)(2) of the final rule to state that an article of food refused under section 801(m)(1) of the act may not be transferred by any person from the port or other designated secure facility.

11. Relationship to Other Admissibility Decisions (§ 1.283(g))

(Comments) Some comments request that FDA integrate the section 801(m) and the section 801(a) clearance processes and develop mechanisms to expedite the release of imported food for sale and use in domestic commerce. One comment states that currently numerous shipments that are offered for import are cleared for section 801(m), but are held pending section 801(a) review. The comments indicate that little is gained if shipments with adequate prior notice under section 801(m) are permitted to move promptly across the borders of the United States, only to encounter delays arising from the release process under section 801(a). The comments further note that in many cases, the shipments held for section 801(a) review are eventually released without another further examination or sampling. The comments suggest that a concurrent section 801(a) and section 801(m) review would eliminate rework, decrease

unnecessary holds on shipments, and decrease the burden on both the importing community and FDA.

Another comment also suggests that FDA integrate the prior notice information collection system with the existing OASIS (section 801(a) of the act) information management system as fully as possible. The comment states that these systems currently function separately, essentially creating two sequential FDA reviews. The comment believes that by merging these systems and resources, food security would be enhanced and productivity for FDA and the industry will be improved. In addition, the comment states that such a merger would be a natural extension of the ongoing integration efforts with CBP.

(Response) FDA does not agree that doing the OASIS review under section 801(a) of the act concurrently with the prior notice review under section 801(m) of act would reduce the burden on the industry or FDA. Under section 801(m), prior notice for imported food shipments must be provided to FDA before the arrival, and an article of food is subject to refusal of admission if adequate prior notice has not been provided. Section 801(m) also provides that refused food must be held until adequate notice is given and may not be delivered to the importer, owner, or consignee. Thus, the refusal standard under section 801(m) is based on whether the requisite information has been provided in a timely fashion.

The refusal standard in section 801(a) of the act is based on, among other things, whether the article appears to be adulterated or misbranded. Admissibility decisions under section 801(a) may be made after entry has been made. Thus, if prior notice is adequate, requests for further information, examination, or sampling of the food that is necessary to determine admissibility under section 801(a) may occur. The article of food need not be held at the port for FDA to accomplish its section 801(a) review.

Because the section 801(m) review must occur prior to arrival, concurrent section 801(a) and section 801(m) reviews also would have to occur prior to arrival. FDA also notes that section 801(a) reviews typically take longer to complete than section 801(m) reviews. FDA believes such a concurrent process would be inefficient and impractical and would likely increase congestion at the ports of arrival. Thus, FDA generally intends to continue with its current practice of reviewing prior notice prior to arrival to decide whether to inspect the food at the time of arrival, based on information that suggests that the food is a potential significant risk to public health, and to allow shipments to proceed beyond the point of arrival to conduct section 801(a) reviews.

(Comments) One comment asks FDA to clarify expectations at the port regarding “may proceed” decisions. The comment notes that the IFR indicates that “the system will transmit a message back through OASIS to ABI/ACS interface for CBP that the article of food may be conditionally released.” The comments continue to state that the IFR indicates that staff operating “24 hours a day, seven days a week” will review at the port of arrival or closest examination site. The comment notes that this implies decisions were to be made at the port of entry. However, companies have reported that since December 12, 2003, conditional release messages have not consistently been received at entry. The comment asks that FDA clarify when this message should be received and the implications for companies that enter the United States within the “release.”

(Response) The IFR states, “If the FDA system does not indicate that further evaluation of or action on the notice or article of food is necessary for prior notice purposes, the system will transmit a message back through the OASIS to ABI/ACS interface for CBP that the article of food may be conditionally released under section 801(b) of the act.” However, if additional

evaluation of the prior notice information is necessary, FDA headquarters staff, operating 24 hours a day, 7 days a week, will review and assess the information and may initiate an examination or other action by FDA or CBP of the article of food at the port of arrival or elsewhere, or in the case of rail shipments, within the confines of the closest appropriate examination site.” (68 FR 58974 at 58976) The IFR clearly states that the conditional release message is sent from FDA to CBP, not to any other person. This is to ensure that CBP staff will know when the food arrives if prior notice has been satisfied and that no further examination by FDA is necessary. This conditional release does not provide information about FDA’s section 801(a) admissibility decision. Further, the IFR clearly states that FDA headquarters staff operates 24 hours a day, 7 days a week and will review the prior notice and make the decision regarding further action on the prior notice submission. FDA and CBP do not intend to change these procedures for implementation of the final rule.

(Comments) One comment encourages FDA to consider low risk status to expedite its section 801(a) deliberations.

(Response) FDA does use a risk based approach when making prior notice and admissibility decisions. FDA screening under section 801(a) is separate from the subject of the final rule, FDA’s screening under section 801(m) of the act. Therefore, this comment is outside the scope of the final rule.

(Final rule) Section 1.283 of the final rule describes the consequences for an article of food that is imported or offered for import with inadequate prior notice. The final rule sets out procedures for resolving the inadequacy as well as for the movement and status of the refused food.

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

Section 1.284 of the IFR provides that failure of a person who imports or offers for import an article of food to submit prior notice is a prohibited act under section 301(ee) of the act (21 U.S.C. 331(ee)) and sets out the civil, criminal, and debarment actions that the United States may bring against persons who are responsible for the commission of a prohibited act.

(Comments) One comment states that many of the mistakes made during the initial implementation of the prior notice IFR can be attributed to difficulties with both government and industry computer systems. The comment indicates that such mistakes should not be part of an importer's record.

(Response) FDA acknowledges that some mistakes in prior notice submissions may have occurred because changes were needed in PNSI and CBP's ABI/ACS or because industry needed to develop appropriate software to facilitate the submission of prior notice. During the initial implementation of the IFR that extended for more than 8 months after the IFR took effect, FDA and CBP exercised enforcement discretion to accommodate that situation. During this period, the two agencies focused their resources on education to achieve compliance with the prior notice requirements, escalating imposition of civil monetary penalties, and ultimately refusal of shipments. This final rule will take effect 180 days after today's publication date to allow affected parties time to understand the requirements that differ from those in the IFR, and make appropriate changes, including changes that may be needed to filers' software. In enforcing prior notice, we will continue to take into account the circumstances, such as whether a violation is due to mistakes that can be attributed to difficulties in government and industry computer systems during initial implementation.

(Comments) Some comments request clarification on the penalties that apply for food that arrives without proper prior notice. Some specifically request clarification of civil monetary penalties and an explanation of the mechanism and criteria for application of these penalties. One comment notes that, in the absence of clearly defined procedures for assessing penalties, the current policy of liquidated damages would apply, which has always been unacceptable with the community and sureties.

(Response) CBP, in consultation with FDA, may assess civil monetary penalties under 19 U.S.C. 1595a(b) against any person who directs, assists, financially or otherwise, or is in any way concerned in the importation of any merchandise contrary to law. During the early implementation phase, FDA recommended to CBP that civil monetary penalties (CMPs) be assessed only to those parties who failed to submit prior notice. The parties were notified via e-mail regarding their failure to submit prior notice before FDA recommended CMPs. As of May 2008, CBP has pursued CMPs on a total of 29 PNC related cases. Any CMPs that CBP brings are subject to the administrative proceedings described in 19 U.S.C. 1618 and 19 CFR part 171. Furthermore, liquidated damages would not apply in the case of prior notice violations because no bond obligations would vest under the basic importation bond.

(Comments) Some comments note that there are few options available in the current penalty structure to assist FDA in enforcing compliance other than civil and criminal charges. Comments suggest that some form of monetary consequences, in lieu of civil and criminal charges, should be available to allow FDA more flexibility in application.

(Response) Section 1.284 of the final rule provides consequences of failing to comply with the requirements for submitting prior notice. These are the primary enforcement options, ~~aside from refusal of the food, available to FDA under the Federal Food, Drug, and Cosmetic~~

Act. In addition, CBP can seize goods imported contrary to law, assess civil monetary penalties or take other enforcement action, including referral to U.S. Immigration and Customs Enforcement (ICE), as provided for under its laws in lieu of or in addition to refusal of the food or other civil and criminal penalties.

(Comments) Some comments suggest that failure to provide prior notice in a timely fashion should result in refused entry and the movement of the food to a secure facility where the prior notice can be secured. The comments state that failure to enter U.S. commerce should be considered a sufficient deterrent and that monetary penalties would be counterproductive. The comments suggest that this arrangement would avoid instances where businesses find themselves unable to trade or constantly in situations of being in violation, and consequently subject to criminal action.

(Response) FDA does not agree that refusal and movement of the food to a secure facility will provide a sufficient deterrent in all cases. CBP may assess civil monetary penalties under 19 U.S.c. 1595a(b) and will, in consultation with FDA, continue to assess those penalties when warranted. FDA may further use the civil, criminal, and debarment provisions provided by the Bioterrorism Act. These statutory penalties are used only when warranted, and to date have been used relatively infrequently.

(Comments) One comment notes that importers receive conflicting information as to the enforcement guidelines at individual crossing points and/or from individual FDA and CBP enforcement officers. The comment recommends extension of the full enforcement date, which would allow FDA and CBP to upgrade their current training efforts with the officers at all ports of entry to ensure uniform and consistent enforcement of the IFR.

(Response) FDA and CBP will continue to coordinate staff training and industry outreach activities to ensure consistent enforcement of the final rule. FDA believes that the effective date of 180 days after publication of the final rule provides sufficient time to communicate and implement changes to the final rule. As we establish enforcement policies, these will be made publicly available through our compliance policy guides. These policies and other information about the final rule may be found through links on FDA's Web site at <http://www.fda.gov>. FDA notes that the communication issues experienced when the prior notice IFR initially took effect have been addressed and we generally have found the prior notice process to be proceeding smoothly.

(Comments) Some comments state that serious inconsistencies in interpretation or application of the prior notice requirements at multiple ports have caused confusion, delayed shipments, and increased shipment costs. Examples provided by the comments include: the shifting percentage of shipments that are physically held at the port due to incomplete or inaccurate prior notice submissions during the initial phases of enforcement, varying information regarding whether the carrier must be in possession of the actual prior notice confirmation number at the time of arrival regardless of whether the submission was made via an ABI transmission, conflicting information as to whether submissions of bonded freight will be allowed through the ABI system, and failure to notify importers of specific errors pertaining to their submissions. Some comments request that FDA establish a national office with authority to resolve various field and port interpretations and actions. Comments note the importance of a timely resolution to disputes because of the potential financial impact to commerce if food shipments are detained needlessly.

(Response) The initial source for resolving all perceived conflicts is the final rule, and related information, including the responses to comments in this preamble, the Prior Notice Final Rule CPG, and the Prior Notice of Imported Food Questions and Answers, which may be found through links on FDA's Web site at <http://www.fda.gov>. FDA's PNC, which directs all prior notice activities, has been operating since the prior notice IFR took effect on December 12, 2003. The PNC is available 24 hours a day, 7 days a week, and 365 days a year to answer questions and resolve, as appropriate, operational concerns. The PNC can be reached at 866-521-2297 for calls originating in the United States and 703-621-7728 for calls originating from outside the United States. In addition, FDA notes that based on the current PNC call/inquiry volume levels as compared to those experienced during the initial 18 months of implementation, repetitive prior notice submitters have now been experiencing fewer difficulties in submitting prior notice.

(Comments) One comment requests that FDA outline what actions will be taken against a company that is not complying with prior notice requirements, but has committed the error only by acting on incorrect advice from an FDA representative. The comment wants to know what recourse is available to industry when a company faces large fines due to inaccurate FDA guidance.

(Response) The PNC is responsible for resolution of these actions, on a case-by-case basis. The advice that a submitter may have received from an agency representative is considered when determining whether an enforcement action is warranted. FDA notes that under the proposed enforcement policy in the Prior Notice Final Rule Draft CPG, we intend to take into consideration the circumstances surrounding a violation, including the seriousness of the violation and flagrant and repeat violations.

(Comments) One foreign government agency requests access to the quantity and identity of the industries that are not complying with the prior notice IFR so that they could help bring these industries into compliance. The comment suggests creating a mechanism to notify foreign governments of any noncompliance related to the Bioterrorism Act to enable them to provide a faster and more efficient response.

(Response) FDA has established mechanisms for working cooperatively with foreign government regulatory authorities on issues of mutual concern, including matters relating to compliance with the prior notice regulations. When requested and as resources allow, FDA/PNC personnel have continued to participate in briefings for foreign governments and organizations and at industry trade meetings. These have included presentations to European Community visitors to the United States, joint FDA-Canadian Food Inspection Agency import meetings, and other foreign government and industry outreach events widely attended by both industry and other government agencies, e.g., WESCCON (Western Cargo Conference). FDA continues to work with foreign governments to develop more efficient and effective communications. In addition, information about compliance with prior notice requirements is posted at <http://www.cfsan.fda.gov/-pn/pnsum.html>.

(Comments) Some comments request that FDA provide a sufficient period of time for implementation of the final rule so that affected parties can prepare for any changes in the rule.

(Response) FDA agrees and is providing 180 days after publication of the final rule, which should be sufficient time for implementing changes necessary to comply with the final rule.

(Comments) One comment states that FDA and CBP categorize some articles of food differently; i.e., some articles that are "drugs" for FDA purposes are classified by CBP as

"foods." The comment indicates that such products should not be denied entry or assessed monetary penalties and suggests that the final rule provide for immediate release and cancellation of monetary penalties for such articles that are not "food," as defined by the FDA.

(Response) FDA does not agree that a change in the final rule would alleviate the concern expressed by the comment. The scope of the final rule is stated explicitly in § 1.277. Situations involving discrepancies between FDA and CBP classification of an imported article as a food or drug are best resolved on a case-by-case basis as they arise. However, because FDA and CBP have worked closely to identify and resolve such issues, the agencies believe that such situations will be rare. In cases of doubt, the submitter should contact the PNC to determine whether a product is an article of food subject to prior notice requirements.

FDA uses a list of HTS codes to indicate which products FDA believes prior notice is or may be required under the prior notice regulations. FDA has provided this list to CBP so that CBP can "flag" the HTS codes in its entry systems to screen for foods for which prior notice to FDA is required and to ensure that, as appropriate, prior notice has been provided. FDA publishes this list to inform the food industry which HTS codes have been "flagged" in CBP entry systems with prior notice indicators. Guidance about the HTS flags is posted at <http://www.cfsan.fda.gov/~dmslhtsguid3.html>.

(Comments) One comment suggests that FDA consider the importer's circumstances when denying entry or assessing penalties. The comment states that, although it is reasonable to expect a company whose principal business is importing food to abide by regulations applicable to food imports, companies that rarely import food products will likely have greater difficulty in complying with the requirements. The comment further states that although these companies

be required to comply before their entries are released, blanket denials of entry or assessments of monetary penalties are not appropriate.

(Response) Elsewhere in this issue of the FEDERAL REGISTER, we are announcing our Prior Notice Final Rule Draft CPG which describes our policies for enforcing prior notice.

Under the CPG, we are proposing to take consideration of the circumstances surrounding a violation, including the seriousness of the violation and flagrant and repeat violations.

(Final rule) Section 1.284 of the final rule states that the importing or offering for import into the United States of an article of food in violation of the requirements of section 801 (m) of the act, including the requirements of this subpart, is a prohibited act under section 301(ee) of the act and sets out the civil, criminal, and debarment actions that the United States may bring against persons who are responsible for the commission of a prohibited act.

L. 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)

Section 1.285 of the IFR outlines the consequences for food arriving at the port of arrival from facilities that are not registered as required under section 415 of the act and 21 CFR part I, subpart H. These are similar to provisions in the IFR for handling food that is refused for inadequate prior notice. The IFR states that if an article of food from a foreign manufacturer that is not registered as required under section 415 of the act and subpart H is imported or offered for import into the United States, the food is subject to being held at the port under section 801 (l) of the act and refusal under section 801 (m) of the act and § 1.283 for failure to provide adequate prior notice. Under the IFR, the failure to provide the correct registration number of the foreign manufacturer, if registration is required under section 415 of the act and 21 CFR part 1, subpart H, renders the identity of that facility incomplete for purposes of prior notice.

(Comments) Several comments state that FDA should increase inspections of imported food when they arrive at the port, rather than denying admission based on lack of the manufacturer's registration number.

(Response) If the prior notice does not include a registration number, it can instead include the full address of the manufacturer and the reason why the registration number is not provided. In this situation, the article of food will not be refused admission solely because of the lack of the manufacturer's registration number. We agree with the comments it is appropriate to consider the fact that the registration number is not provided in determining whether FDA should inspect the food, either upon arrival or as part of the admissions process.

While an article of food will not be refused admission solely because of the lack of the manufacturer's registration number, the food is nonetheless subject to being held under section 801 (1) of the act if the manufacturer has not registered under section 415 of the act. It may take FDA more time to determine the registration status of the manufacturer if the name and full address, but not the registration number, is provided as part of prior notice. Thus, if the registration number is not provided, this may delay the food at the border until this verification is completed.

(Comments) Some comments state that, although the prior notice regulations clearly indicate that the manufacturer's registration number is required on the prior notice, even for U.S. Goods Returned, they do not expressly indicate that refusal will result when the registration number is not provided. Rather, according to the comments, § 1.285(a) of the regulations only indicates that articles of food arriving from an unregistered foreign facility will be subject to refusal, as will articles of food arriving with an inaccurate registration number in the prior notice. In more general terms, under § 1.283(a)(1)(ii), articles of food arriving with an "inaccurate" prior

notice are subject to the same possibility of refusal upon arrival. The comments state that the language of the regulations does not guarantee refusal, but provides for flexibility and discretionary enforcement. Comments suggest that FDA should not refuse entries for which the importer does not know and cannot determine the registration number.

(Response) As discussed in the previous response, if the prior notice does not include a registration number, it can instead include the full address of the manufacturer and the reason why the registration number is not provided. In this situation, the article of food will not be refused admission solely because of the lack of the manufacturer's registration number, although the food is nonetheless subject to being held under section 801 (l) of the act if the manufacturer has not registered under section 415 of the act.

Because this is a change from the IFR, in the final rule we have deleted the text in § 1.285(a) that states that failure to provide the manufacturer's registration number renders the identity of the facility incomplete for purposes of prior notice. We have also clarified the text in § 1.285(b) by removing the phrase "imported or offered for import from a foreign facility that is not registered as required under section 415 of the act" because it is redundant.

As part of our effort to develop policies for enforcing prior notice and section 801 (l) of the act, we are publishing the Prior Notice Final Rule Draft CPG, announced elsewhere in this issue of the FEDERAL REGISTER.

(Final rule) Section 1.285 of the final rule describes the consequences and processes for food imported or offered for import in the United States that is from a facility that is not registered under section 415 of the act and 21 CFR part I, subpart H. The food is subject to being held and cannot be delivered to any importer, owner, or consignee.

~~FDA also made other minor changes in this section.~~

- We revised the requirement in § 1.285(c)(2) to notify FDA of the location where the food has been or will be moved from within 24 hours of refusal to before the food is moved to the hold location. FDA needs this information before the food is moved to verify that the facility where the food is to be held is a secure facility. Moreover, because refused food shall not be delivered to the importer, owner, or ultimate consignee, before the food is moved, FDA needs to verify that the hold location is not owned by any of these parties. In addition, § 1.285(c)(2) of the IFR states that food under hold must be moved under appropriate custodial bond. We have 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 also clarifies that the refused food may be held at the port of entry or at a secure facility.
- We revised § 1.285(g) for clarity by adding the word, "number," after the word, "registration." We also changed the last phrase of § 1.285(g) from "* * * except that the article may only be sold for export or destroyed as agreed to by CBP and FDA" to "* * * except that, unless otherwise agreed to by CBP and FDA, the article may only be sold for export or destroyed." Similar to § 1.283(a)(6), this change was needed because concurrence from CBP and FDA is not needed whenever an article of food placed under hold under section 801 (l) of the act is sold for export or destroyed, and no registration number or request for FDA review is submitted. We are adding the phrase "unless otherwise agreed to by CBP and FDA" to allow for the improbable (but not impossible) scenario when such a shipment would need to be transferred to

another agency for examination or investigation; in these cases, we would want concurrence from both FDA and **esp**.

- In § 1.285(h), we added the phrase, "not for personal use," after the phrase, "food carried by or otherwise accompanying an individual arriving in the United States," because if it is for personal use, then it is not subject to prior notice as provided by § 1.277(b)(I).
- We deleted references and provisions in § 1.285(i) and (l) relating to refusals, because the process for resolving a prior notice submission for an article of food from a facility that is not registered as required is based on holds under section 801 (l) of the act and not refusals under section 801(m) (see discussion above for § 1.285(a)). Under § 1.285(i)(2), we are allowing submission of the notification resolving the hold by fax and e-mail only, and deleting the option to submit the notification by mail and express courier. We also made other minor revisions to this § 1.285 to simplify the text.
- We revised § 1.285(j)(2) of the final rule to allow the carrier to submit a request for review after hold. Under § 1.285(j)(3), we revised the final rule to allow submission of the request for review after hold by fax and e-mail only, and deleted the option to submit the notification by mail and express courier.

M. Outreach and Enforcement

As discussed in the IFR, FDA directed outreach to both domestic and international stakeholders after publication of the IFR (68 FR 58974). Our outreach activities included many methods of communication:

- Dissemination of materials to guide affected domestic and international food facilities through the new processes established to implement prior notice requirements;
- Numerous domestic and international outreach meetings to the food industry, trade organizations, and State and foreign government regulators;
- A series of videoconferences and a satellite downlink video broadcast to more than 1,000 sites around the world;
- Materials provided for and events targeted to the media;
- Presentations by FDA officials and exhibits at professional and trade conferences and meetings to inform industry and State and local government representatives of the new requirements;
- Presentations by USDA's Foreign Agricultural Service (FAS) and U.S. embassy officials who disseminated materials and answered questions in various countries;
- Cooperative arrangements with CBP and other Federal agencies to ensure that information on the interim final regulations and their requirements is disseminated to affected companies and individuals; and
- Issuance of several guidance documents (all available on the Internet) that explain the prior notice requirements, including, "Prior Notice of Imported Food: Questions and Answers," "What You Need to Know About Prior Notice of Imported Food Shipments," and numerous Web-based tutorials for PNSI. Many of these guidance documents are available in foreign languages; e.g., Arabic, French, Hindi, Japanese, Malay, Portuguese, and Spanish.

Specifics regarding each of these activities are included on FDA's Web site. In addition, FDA also provided training in new or revised procedures for its field personnel, as well as CBP field personnel. FDA included an initial transition period in the December 2003 prior notice CPG for more than 8 months, during which the agencies emphasized education to achieve compliance, rather than refusal of articles of food with inadequate prior notice.

Shortly after publication of the IFR, FDA began disseminating at U.S. ports flyers and posters summarizing the new requirements and informing representatives of affected entities how to provide prior notice to FDA. We also provided (and continue to provide) online assistance and the FDA Help Desk to deal with technical issues involving PNSI after the IFR became effective.

When FDA reopened the comment period on the IFR in the FEDERAL REGISTER of April 14, 2004, under discussion of Flexible Alternatives in question 7, we asked: "Should FDA offer a prior notice submission training program for submitters and transmitters, including brokers, to ensure the accuracy of the data being submitted?" Many comments address various issues concerning outreach and enforcement. Discussion of these issues by subject follows, proceeded by a discussion of general issues.

1. General Outreach and Enforcement Issues

(Comments) Several comments acknowledge that the outreach activities conducted by FDA and CBP were of tremendous assistance to affected persons with the implementation of the PNSI and encourage continued communication between the trade community and FDA and CBP. Several other comments state that FDA and CBP's outreach efforts were ineffective and encourage continued efforts toward education and outreach.

(Response) FDA received praise from the Small Business Administration for our efforts to address regulatory flexibility and the impact on small business of the interim final rule. FDA and CBP will continue outreach efforts to affected industry and other governments, as resources allow. These efforts will focus on changes to and implementation of the final rule. The PNC also will continue to answer questions and provide technical assistance upon request, and FDA and CBP will issue and update guidance as policies change or need clarification.

12. Prior Notice Submission Training Program From Flexible Alternative Question 7

(Comments) Many comments believe that a training program will improve the accuracy of the data being submitted under the regulations and that a training program would resolve many of the other problems being encountered with the present rules. One comment suggests that, following a detailed analysis of compliance issues, FDA should target its training to specific problems and their solutions, and to entities new to the process. One comment suggests that FDA offer a training program for brokers and other transmitters and submitters. Other comments recommend that specific outreach and training should be conducted for each mode of transportation. Another comment cautions that the FDA and CBP should have resources to implement an educational campaign before initiating another training and outreach program.

(Response) FDA and CBP will conduct training focused on changes between the final rule and the IFR. Depending on resources, the education and outreach may take the form of public meetings, Web-based interactive training, or posting on our Web sites of guidance and other outreach materials. As resources permit, we also may translate our guidance and other outreach materials into other languages.

3. Requests for Additional Outreach

(Comments) There were many comments that request additional outreach and training, as well as some comments that suggest specific outreach programs, such as:

- Providing an expanded program that would educate and train all stakeholders, including substantially more and varied educational programs before the full enforcement of the IFR, and escalating training efforts in the area of shipper and carrier education and compliance;
- Establishing an effective mechanism for disseminating answers to specific questions to affected persons;
- Providing enforcement guidance that addresses specific enforcement issues, such as enforcement of the food facility registration requirements at the time of prior notice submission and describing enforcement procedures in detail;
- Providing guidelines on the procedures to submit prior notice either via FDA's PNSI or CBP's ABI, such as instructions on cancellation or change of a prior notice and descriptions on what is meant by identifying goods by the common, usual or market name;
- Explaining procedures of the rule in foreign languages and establishing point of contacts in foreign countries;
- Publicizing the rule to individual Americans who will travel abroad, and making compliance with it a simple, practicable, and straight forward process;
- Providing a Web-based tutorial;
- Using CBP's ABI Administrative Messages to announce changes in PNSI;

- Establishing an FDA and CBP agency-industry working group and/or a more formal advisory committee with representatives of various industry groups;
- Improving staffing on the "hotline" and/or creation of an exclusive Help Line staffed with individuals with the requisite technical expertise and the ability to resolve operational problems as they arise;
- Creating dedicated e-mail addresses within FDA to which specific questions can be addressed and/or specific e-mail addresses for different technical and operations areas;
- Providing prompt information to submitters regarding inadequacies or inaccuracies in prior notice, including shipment level feedback to the filer; and
- Holding public meetings before the final rule takes effect to ensure that all affected parties understand the rule and can be heard.

(Response) We will provide outreach and training on the final rule as resources permit.

At a minimum, we will provide guidance and instructions on the process for filing prior notice on our Web site. This guidance, along with detailed instructions on the use of PNSI, including step-by-step help, is available at <http://www.cfsan.fda.gov/~furl/helpf.html>.

We agree with the recommendation to establish an effective mechanism for disseminating answers to specific questions to industry, and have issued guidance documents for each of the rules we have issued to implement the authorities in the Bioterrorism Act that provide our response to the frequently asked questions (FAQs), including the prior notice IFR. We anticipate doing the same for this final rule. These guidance documents are designed to help affected parties comply with the legal requirements established by the various rules. We intend to issue additional guidance as new questions arise and as resources permit.

In terms of providing enforcement guidance, in December 2003, FDA and CBP issued a CPG that stated that, until August 12, 2004, the two agencies generally would utilize communication and education strategies with escalating imposition of civil monetary penalties rather than refusal of shipments. The two agencies revised the CPG in June 2004, August 2004 (August 16, 2004, 69 FR 50389), November 2004, March 2005, and November 2005 (November 14, 2005, 70 FR 69160), as our enforcement policies changed and evolved. Published elsewhere in this issue of the FEDERAL REGISTER is a notice of availability for the Prior Notice Final Rule Draft CPG, which describes FDA's and CBP's proposed policies for enforcing this final rule. A copy of the CPG may be found at <http://www.fda.gov/ora> under "Compliance References."

Generally, FDA enforcement procedures regarding imports are provided in FDA's Regulatory Procedures Manual, Chapter 9. This guidance is posted at <http://www.fda.gov/ora/complianceref/rpmnew2/ch9/default.htm>.

FDA agrees, in part, with the recommendation about providing user guidelines and has provided guidance and instructions on the process for filing prior notice. This guidance, along with detailed instructions on the use of the PNSI, including step-by-step help, is available at <http://www.cfsan.fda.gov/-furls/helpf.html>. Instructions for contacting FDA with questions about prior notice are also available at that Web site.

FDA cannot provide specific instructions on the use of ABI software to file prior notice, as that software is developed and made available through private vendors. Users should contact their vendor for specific instructions on the use of their ABI software. CBP does regularly issue to filers ABI Administrative Messages which provide instruction and guidance regarding submission of prior notice through *ABI/ACS*.

As part of our outreach efforts for the prior notice IFR, we issued a number of documents explaining the requirements of the IFR and/or PNSI and provided them on our Web site in English and one or more other languages, including:

- FDA Industry Systems, Index of Help Pages at <http://www.cfsan.fda.gov/~furl/helpl.html>) (also available in Spanish);
- HELP: Getting Started: Create New Account Quick Start Guide) (also available in Spanish);
- OUTREACH: Overview of Prior Notice Interim Final Rule (Slide Presentation) (also available in Arabic, French, Malay and Spanish);
- Booklet: What You Need to Know About Prior Notice of Imported Food Shipments (also available in French and Spanish); and
- Fact Sheet on the Interim Final Rule - Prior Notice of Imported Food Shipments (also available in French, Malay, Polish, Portuguese, Spanish, Arabic, Chinese, Hindi, and Japanese).

We also have an "FDA Food and Cosmetic International Foreign Language Documents and Videos," which is a list of all food (and cosmetic) documents that have been translated and the languages in which they are available on our Web site at <http://www.cfsan.fda.gov/~mow/internat.html>. Many of the documents describing prior notice requirements and guidance have been translated into foreign languages.

FDA does not currently maintain staff in foreign countries. However, FDA has developed the Beyond our Borders initiative, which includes plans to build an on-the-ground presence for FDA in Asia, Europe, Latin America, and the Middle East. In March of 2008, we received approval from the U.S. Department of State to establish eight full time permanent FDA

positions at U.S. diplomatic posts in the People's Republic of China, pending authorization from the Chinese government. Furthermore, CBP, U.S. Department of State, and USDA Food Agricultural Service staff are located at U.S. Embassies in many foreign countries. These U.S. government entities frequently provided assistance to foreign stakeholders, including foreign government officials and private companies, in understanding the requirements of various U.S. regulations, including those provided in our Bioterrorism Act regulations. We will routinely update these U.S. officials abroad about changes to and implementation of this prior notice final rule.

As resources permit, we also will continue to translate guidance documents and system instructions into other languages.

FDA agrees with the comment requesting publicizing the rule to individual Americans who will travel abroad, and making compliance with it a simple, practicable, and straight forward process. CBP Publication # 0000-0512, revised January 13, 2005, Know Before You Go--Regulations for U.S. Residents, is posted at <http://www.cbp.gov/xp/cgov/travel/vacation/kbyg/>. This publication is the primary CBP guidance document concerning import regulations targeted to travelers and contains information about the prior notice final rule's requirements for importation of food. In addition to providing information about prior notice requirements, the publication also provides a link to FDA's Web site at <http://www.fda.gov/oc/bioterrorisrn/bioact.html>.

FDA also agrees with the comment that requests us to provide a Web-based tutorial. Since October 2003, FDA has provided a PNSI tutorial in the form of step-by-step help on its Web site (<http://www.cfsan.fda.gov/~furl/helpf.html>). FDA welcomes any additional

comments or suggestions on how to improve the help information; these can be submitted to the PNC using the phone number or provided on that Web page.

FDA and CBP agree that operational issues impacting ABI filers should be announced using Administrative Messages, and intend to continue to use that system, as we have routinely done since December 2003. When appropriate, information about the PNSI system will also be announced both on the FDA Web site and through CBP's Administrative Messages.

CBP also has established avenues of communication with trade working groups and ensures FDA's participation when the subject for discussion is prior notice. FDA does not plan to establish a formal advisory committee to address prior notice.

FDA agrees with the comment to improve help desk staffing, as resources permit. Our Web site contains a tutorial on how to submit a registration for a facility subject to the requirements at 21 CFR part 1, subpart H. In addition, the PNC staff can answer questions about how to submit prior notice. Questions regarding clarification of the rule that are not addressed in this preamble or existing publications should be submitted to FDA at industry@fda.hhs.gov. We will generally not provide an individual response to these questions, but will answer them in Question and Answer Guidance Documents so the information will be broadly available.

FDA has included features in PNSI to inform submitters of many types of inadequacies in the information provided, such as missing required fields. FDA also has coordinated with CBP to provide prompt messaging back to users when Prior Notice is filed through ACS. FDA notes that certain inaccuracies cannot be identified electronically, but could be detected in an intensive prior notice review (e.g., the packaging of an actual shipment (12 oz cans of tuna fish) does not match the prior notice data submitted for that shipment (e.g., 6 oz cans of tuna fish)).

With respect to holding public meetings to provide an opportunity for parties to voice their opinions on the IFR, FDA and CBP published the IFR on October 10, 2003, and opened the comment period through December 24, 2003. We reopened the comment period from April 14, 2004, through July 13, 2004. We reviewed 320 timely comments that raised multiple issues, and have considered those comments as we developed this final rule. We also held numerous outreach meetings both domestically and abroad--in person and by video conferencing--to explain the requirements of the IFR to affected parties and answer questions of clarification to ensure all were able to provide meaningful comment to FDA and CBP. The comment period was the time for all parties to be heard on the provisions of the IFR. While the agencies welcome discussion and wanted to ensure that all stakeholders understand their obligations under the statute and the IFR, the comment period ended July 13, 2004, and the agencies did not consider comments submitted outside of the open comment periods.

(Comments) Several comments recommend that FDA provide feedback to the industry detailing areas of noncompliance and compliance. One foreign government stated its willingness to work with FDA to increase the level of industry compliance within their country through outreach and education activities. It requests that FDA provide it on a timely basis detailed information concerning noncompliance by their industry. Another comment suggests that FDA could post on its Web site a description of the types of errors most commonly observed filed prior notices.

(Response) We agree, and have been posting on our Web site summary information about submission of prior notice, including data on the types of errors. See <http://www.cfsan.fda.gov/-pn/pnsum.html>. We stated that this information will also be analyzed to help FDA take appropriate enforcement action when necessary. FDA presented the Summary

Information in two categories: (1) General interest--Information about the number and types of prior notices that are being submitted, and which systems are being used to submit them; and (2) Specific requirements--Information about submission of the required information. We provided an initial posting of the summary information and two subsequent updates. The August 2004 update included some summary information from December 2003 through April 2004 and some snapshots of activity in July 2004, along with information on specific information requirements such as registration number and carrier information.

We also posted information summarizing the number of facilities registered pursuant to 21 CFR part 1, subpart H at: <http://www.cfsan.fda.gov/~furl/ffregsum.html>. This summary includes a breakdown of the number of registered facilities by country and U.S. State.

4. Enforcement Timeframe

(Comments) Many comments state that because FDA and CBP have not informed prior notice submitters of specific deficiencies in their submissions, FDA must extend the enforcement date of the rule to allow more time to communicate errors and allow adequate time to fix them. One comment suggests that the agencies should develop and implement a notice-specific informational system that provides detailed feedback to submitters when a prior notice is deemed to be noncompliant. Another comment states that exporters should be advised of noncompliant shipments in order to take corrective action prior to the shift to full enforcement. One comment believes that part of the phase-in period should include a feedback program to let brokers know which importers and corresponding transactions are handled with inadequate or no prior notice. The comment states that this program should be developed in conjunction with the industry to define measurements (history profile and/or transactional), and determine what the notification process should be. One comment encourages FDA to expeditiously publish a notice that it

intends to continue outreach and delay enforcement of the regulation so that the business community may have a greater opportunity for education, training, and continued dialogue with the agencies. Other comments recommend a delay in the final phase of enforcement until all systems are fully operational.

(Response) FDA disagrees. The obligation to comply with applicable regulations is on the parties subject to a regulation as specified therein; FDA does not have an obligation to inform all prior notice submitters of specific deficiencies in their submissions before beginning enforcement of a rule. FDA and CBP, however, were cognizant of the potential effect the prior notice IFR could have on trade and thus, after publication of the IFR, FDA published guidance that included a transition period during which we emphasized education to achieve compliance, rather than general refusal of noncompliant shipments (the December 2003 Prior Notice Interim Final Rule CPG) (68 FR 69708). In addition, during the prior notice transition periods from April 2004 through April 2005, we provided compliance summaries that informed submitters, and those who transmit on their behalf, of the major areas of deficiencies with respect to missing data elements. These represented the general deficiencies we were seeing in prior notice submissions during the educational transition period (see <http://www.cfsan.fda.gov/~pn/pnsum.html>). The compliance summaries also generally described the deficiencies in prior notices that are *not* confirmed for review (e.g., failure to provide a valid registration number). However, we do not plan to communicate submission deficiencies to other than the submitter and transmitter. FDA believes that the effective date of 180 days after publication of the final rule provides sufficient time for the business community to become familiar with all the provisions of the final rule. Moreover, we plan to conduct outreach after publication of the final rule to affected industry and other governments, as resources allow.

These efforts will focus on changes to the final rule. Given the delayed effective date, the fact that the changes in the final rule are not very extensive, and the public's experience in complying with the IFR, FDA believes there is no need for a phased-in enforcement approach similar to what was done for the IFR.

(Comments) One comment states that if FDA discovers that a large number of problems are experienced during the grace period between publication of this final rule and the effective date, FDA should consider extending the effective date, especially for first time offenders.

(Response) FDA believes that the 180 day delay in effective date is adequate for affected parties to become familiar with all the provisions in the Prior Notice Final Rule. While we do not anticipate extending the effective date past 180 days, we intend to take into account the circumstances of the violation in enforcing the final rule.

5. Enforcement Penalties

(Comments) One comment requests that the agencies publish procedures that clearly define what types of penalties will be issued for failure to comply under § 1.284 and to whom they will be issued.

(Response) Sections 1.283 and 1.284 of the final rule describe the consequences for failing to submit adequate prior notice or otherwise failing to comply with the final rule. We believe these adequately describe the types of penalties. The Prior Notice Final Rule Draft CPG describes our proposed enforcement policies, and states, for example, that we intend to focus our resources on more serious violations and repeat or flagrant violations.

Civil monetary penalties, which are issued by CBP, may also be assessed in response to a prior notice violation. CBP has posted a variety of publications that explain both the administrative process for fines, penalties, forfeitures, and liquidated damages, such as: "What

Every Member of the Trade Community Should Know About: Customs Administrative Enforcement Process: Fines, Penalties, Forfeitures and Liquidated Damages," which is posted at: http://www.cbp.gov/linkhandler/cgov/trade/legal/informed_compliance_pubs/icp052.ctt/icp052.pdf, and "What Every Member of the Trade Community Should Know About: Mitigation Guidelines: Fines, Penalties, Forfeitures and Liquidated Damages," which is posted at http://www.cbp.gov/linkhandler/cgov/trade/legal/informed_compliance_pubs/icp069.ctt/icp069.pdf. (FDA has verified the Web site addresses, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the FEDERAL REGISTER.)

N. The Joint FDA-CBP Plan for Increasing Integration and Assessing the Coordination of Prior Notice Timeframes

We stated in the preamble to the IFR (68 FR 58974 at 58995) that FDA and CBP would publish a plan, including an implementation schedule, to achieve the goal of a uniform, integrated system and to coordinate prior notice timeframes 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," all while fulfilling the Bioterrorism Act mandates. For this reason, as well as to obtain comments on other aspects of the rule, we issued an IFR, with an opportunity for public comment for 75 days: Moreover, to ensure that those who comment on this IFR would have had the benefit of actual experience with the systems, timeframes, and data elements, FDA also stated it intended to reopen the comment period for an additional 30 days to coincide with the issuance of the plan by FDA and CBP relating to timeframes. We extended this comment period twice on April 14, 2004, and May 18, 2004, thereby providing an opportunity for affected persons to comment for 165 days.

In April 2004, *FDA* and CBP announced the Joint Food and Drug Administration-Customs and Border Protection Plan for Increasing Integration and Assessing the Coordination of Prior Notice Timeframes (the Plan).

The comments addressing the Plan are discussed in the following paragraphs. Comments addressing our assessment of reducing the prior notice timeframes are found earlier in section III.F "Must prior notice be submitted to *FDA*?" (§ 1.279)) of this document. We respond to the other questions (e.g., special programs and flexible alternatives) raised in our April 14th reopening of the comment period in sections III.D ("What is the Scope of this subpart?" (§ 1.277)) and III.M (Outreach and Enforcement) of this document.

1. Increased Integration

FDA and CBP have increased their integration and are continuing to do so in the following ways:

- Co-location of all *FDA* Prior Notice staff with CBP's targeting staff;
- Further refinement to *FDA*'s targeting rule sets in CBP's targeting system, coupled with additional training in targeting techniques;
- Continued targeting support from CBP and other Federal law enforcement analysts; and
- Enhancement of communications and cooperation with CBP to facilitate information exchange and to ensure expeditious access and examination of food shipments *FDA* has decided to inspect upon arrival.

(Comments) One comment suggests that *FDA* should consider performing the OASIS review concurrently with the "*FDA* BTA review" to eliminate duplicative work and burdens on both the importing community and *FDA*. Another comment suggests that *FDA* coordinate the

prior notice procedure with FDA's "Intact Notice" so that FDA can avail itself of the opportunity to identify in advance shipments for inspection, sampling or detention, or permit the shipment to pass and be delivered without delay.

(Response) FDA disagrees. As we previously explained in an earlier response in section I1LJ.1] of this document, FDA does not agree that doing the OASIS review under section 80] (a) of the act concurrently with the prior notice review under section 80] (m) of act would be beneficial to industry or FDA. Because the section 80] (m) review must occur prior to arrival, concurrent section 80] (a) and section 80] (m) reviews also would have to occur prior to arrival. FDA believes such a concurrent process would be inefficient and impractical and would likely increase congestion at the ports of arrival.

(Comments) Comments state that co-locating FDA PNC staff with CBP's targeting staff is a positive step because the two agencies' personnel are both accountable for the risk analysis process, and thus, both agencies' personnel can easily interact and share information, leading to increased efficiencies and integration of the risk analysis process.

(Response) FDA agrees and has co-located the PNC with CBP's targeting staff.

(Comments) Comments strongly support further refinement of FDA's targeting rule sets in order to maintain and improve the risk analysis system to flag specific shipments for security concerns. Comments further support the continuing plan to target shipments for which little is known, while maintaining expedited processing for those shipments and importers that are well known and have provided FDA and CBP with the means by which they can assure general compliance. These comments also argue that products subject to FDA's prior notice requirements should be eligible for **full** expedited processing and information transmission benefits allowed with C-TPAT, FAST, and any other similar programs established in the future.

One comment specifically encourages FDA and CBP to incorporate the current information contained within these programs and allow for the removal of the maximum number of flags within the risk analysis system for those companies that demonstrate their compliance by participation in these additional security programs.

(Response) FDA agrees that refining our targeting rule sets helps to improve both agencies' risk analysis systems. As we discussed previously, FDA has decided not to consider any special programs, such as C-TPAT and FAST, in implementing the prior notice rule.

(Comments) All the comments favor initiatives to provide additional training of FDA staff in targeting techniques that will increase the efficiency and effectiveness of the border crossing systems. One comment particularly notes that additional training should be targeted towards those individuals and issues that will provide measurable additional value to the prompt and efficient release of compliant cargo.

(Response) Any effective targeting technique allows for the identification of food likely to be at risk for adulteration based on a scientific risk assessment. Targeted training will be provided, as resources permit.

(Comments) Comments support enhanced communications and cooperation with CBP to facilitate information exchange and ensure fast access to foods that are subject to prior notice holds. Comments state that this will be critical to the food industry, as any delays will translate into added costs and inefficiencies to their current supply chain. One comment encourages FDA and CBP to integrate technologies used for implementing the Bioterrorism Act with NEXUS, US VISIT, FAST, C-TPAT, and other programs at the border.

(Response) FDA agrees that exchanging information between the agencies is important to evaluation of and response to food safety and security challenges.

(Comments) One comment encourages FDA and CBP to work with their Canadian counterparts to ensure that information is shared and technologies are working in parallel to make crossing the border seamless, efficient, and safe.

(Response) FDA agrees that exchange of information between its international counterparts, when feasible, is critical to evaluation and response to food safety and security challenges.

(Comments) One comment notes that FDA recently announced the signing of an MOU with CBP to commission CBP officers in ports and other locations to conduct investigations and examinations of imported foods on behalf of FDA. The comment questions whether this would have any consequences on the selections for controls by CBP officials stationed in EU ports.

(Response) Investigation and examination of food as a result of prior notice is conducted upon or after arrival of the food in the United States. Therefore, the MOU should not have any consequences on CBP operations at EU ports.

2. General Comments on the Plan

The Plan as announced in April 2004 and revised in November 2004 outlines the following:

- From November 1, 2004, to January 3, 2005, we plan to assess existing procedures and staffing needed to receive, review, and respond to the prior notices submitted in accordance with the Prior Notice IFR (i.e., 2 hours before arrival by land by road; 4 hours before arrival by air or by land by rail; and 8 hours before arrival by water).
- From January 4, 2005, to February 3, 2005, we intend to 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 (e.g., 1 hour/30 minutes before arrival by land by road; 2 hours before arrival by land by rail; and by "wheels up" for flights originating in North and Central America, South America (north of the Equator only), the Caribbean, and Bermuda; otherwise 4 hours before arrival by air).

- From February 4, 2005, to May 3, 2005, we plan to implement necessary changes and make appropriate adjustments to ensure we could receive, review, and respond to all prior notice submissions with reduced timeframes.

Under the Bioterrorism Act, any timeframe must be sufficient to receive, review, and respond to prior notice submissions, as set out in section 801 (m)(2)(A) of the act (21 U.S.c. 801 (m)(2)(A)). The agencies 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.

(Comments) Numerous comments concur with the proposed joint FDA-CBP plan for increasing integration of both agencies' activities, as this would eliminate the requirement for importers to maintain two different timeframes for submission of data. One comment concurs with the joint plan and states that it would minimize procedures and costs for firms. One comment states that it was confident that, with proper planning and development, additional integration of the security processes and the differing timeframes can be coordinated through the actions outlined in the published joint plan.

(Response) FDA agrees that increased integration of activities, including timeframes when appropriate and feasible, would be advantageous, provided FDA still is able to meet its

statutory obligation to receive, review, and respond to prior notice. As discussed previously (see section 111.F, *When must prior notice be submitted to FDA?* (§ 1.279)), FDA conducted an assessment of FDA response times with reduced timeframes and determined that if it changed the prior notice timeframes to be consistent with those of CBP'S advance electronic information rule, the agency would not have adequate time to receive, review, and respond to the prior notices. Moreover, commerce actually would be adversely impacted by shorter prior notice timeframes for submission, because this would 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. 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 or arrival without the benefit of a complete review. Accordingly, FDA has retained the timeframes in the IFR.

(Comments) One comment requests that FDA explain why the maritime transportation timeframe was not considered in the joint plan.

(Response) FDA did not include the maritime transportation timeframe because the CBP advance electronic information timeframe for cargo arriving by water is 24 hours, which is significantly greater than the time established by the prior notice IFR for this mode of transportation (8 hours before arrival).

(Comments) One comment suggests that assessment of the resources encompass all potential resources available at the port, including those of the Department of Homeland Security (DHS) in order to make better use of DHS resources at the border. Another comment states that any assessment taken up during this timeframe must take into account the problems inherent in the current systems, as well as the fact that not all submissions will be properly prepared or

followed up on, as this could potentially translate into current practices or staffing appearing to be inadequate when, in fact, they may not be.

Another comment asserts that some border crossings were not designed for today's traffic volumes or the post 9-11 environment and recommends that these physical resources be included in the assessment of existing procedures. This comment also encourages CBP to audit staffing levels at border crossings to determine if additional staff is needed.

(Response) FDA agrees that any assessment must take into account the availability of all resources, including those resources of agencies with which we maintain MOU or other agreements covering inspection and sample collection, which can, or should, be devoted to the receipt, review, and response of prior notice. Accordingly, DHS resources are used in implementing this rule, as described elsewhere in this preamble.

(Comments) Two comments noted that they are experiencing significant delays on shipments that cross the border on Fridays due to FDA's limited hours on that day. The comments are concerned about uncertainty regarding transit times and that customers' date-sensitive orders will not be received on time. Another comment noted that waiting times due to traffic volume has increased at the bridge at Detroit because of the inability to move prior notice shipments through the tunnel. The comment states that these delays have made it very difficult to deliver to U.S. facilities that do not operate 24 hours and that these delays will continue to cost exporters and importers and may cause U.S. processing facilities to have unplanned downtime due to a lack of raw material. Another comment notes that different FDA locations ask for more information than the Bioterrorism regulations or systems can process, thereby holding up shipments that move freely at other border crossing locations.

(Response) Prior notice is submitted electronically through *ABI/ACS* or PNSI. There is no ability for individual ports to require different information as part of the prior notice submission process. The PNC directs all prior notice activities for FDA and ensures consistent review of submitted prior notices. If industry is having difficulties with a specific port, they should contact the PNC to have the issues resolved. FDA believes it is likely that the concerns raised in the comments relate to admissibility decisions being made under section 801 (a) of the act, which is a separate review than the one made under section 801(m) of the act, as described previously.

(Comments) One comment states that FDA personnel should be assigned to all arrival ports, particularly those where high risk shipments may arrive.

(Response) FDA does not have the personnel to cover all possible ports of arrival. Accordingly, under the authority of section 314 of the Bioterrorism Act, FDA and CBP signed an MOU in December 2003 that allowed FDA to commission thousands of CBP officers in ports and other locations to conduct, on FDA's behalf, investigations and examinations of imported foods. This FDA-CBP collaboration significantly strengthens the implementation of the Bioterrorism Act to assure the security of imported foods. The MOU enables FDA to work more efficiently with CBP and builds upon FDA's and CBP's long history of close cooperation. Additionally, the MOU enhances the two agencies' teamwork in training, day-to-day operations, and information sharing. As part of the MOU, FDA and CBP provide specialized training for the commissioned CBP employees who will 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. (See <http://www.fda.gov/oc/bioterrorism/moucustoms.html>.)

(Comments) One comment states that there were connection problems with FDA's computer system, perhaps as a result of submission overloads to the system, with session "timeouts" occurring. The comment notes that it is crucial that an infrastructure with the capacity to deal with the information being required by FDA be in place in order for stakeholders to meet the requirements of prior notice.

(Response) As discussed in section JII.G, *How must you submit the prior notice?* (§ 1.280), FDA has carefully monitored both PNSI and OASIS system usage and performance since prior notice was implemented in December 2003. During this period, no issues related to load on these systems have been identified. Both systems have experienced occasional outages (including planned down times for maintenance and upgrades). During these outages, messages between the CBP and FDA systems are held in a queue, resulting in a backlog. Initially, we did experience some difficulties when trying to clear the queue after returning to normal operations, but these issues have been resolved. 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 the production system and to test for performance as the system is upgraded and enhanced.

(Comments) One comment suggests that FDA and CBP take the integrated timeframes further and require only one notification that should meet both FDA and CBP requirements and prevent confusion and delays in the case of a bioterrorism event.

(Response) FDA disagrees. The Bioterrorism Act and the Trade Act have different statutory requirements. In implementing these laws, the agencies require different information and use different targeting and screening tools. FDA and CBP have discussed interfacing with AMS (the module of ACS through which carriers, port authorities, or service bureaus transmit

electronically the cargo declaration portion of the inward foreign manifest to CBP) 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 asserts that it is redundant for FDA to repeat a feasibility analysis of submission timeframes because CBP has clearly addressed those issues. Another comment proposes that FDA accelerate the schedule for implementing the joint plan, and make this evaluation with CBP as quickly as possible. One comment supports the plan and suggested that any short term assessment take into account the problems involved with the current systems. Another comment expresses concern that full enforcement of the IFR will be in effect during the proposed review period and that consequently, industry will be placed in the difficult position of trying to comply with timeframe requirements that are not synchronized. Another comment suggests that other reasons for noncompliance, such as the need for additional discretion on data and education, be included in the evaluation.

In response to the agencies' statement that the evaluation of timeframes will depend on the level of compliance industry achieves during the assessment, one comment asserts that it is not appropriate for the agencies to place the burden of compliance entirely on the trade. The comment further states that the trade's ability to provide the information required also depends on the systems working properly, the efficiencies of the government personnel involved, the educational outreach levels and the feedback individual importers receive in relation to their

current processes. These are areas that are controlled and managed by the agencies, so they also must be considered when assessing the probability of reducing timeframes. One comment expresses concern that the implementation schedule of the Plan may be delayed due to industry noncompliance with the IFR. Another comment asserts that this lack of communication from the agencies to submitters regarding errors could negatively impact the assessment of compliance of the trade and subsequently, the agencies' decisions regarding the trade's future ability to provide a high level of compliance.

(Response) FDA disagrees. The obligation to comply with applicable regulations is on the parties subject to a regulation as specified therein; FDA does not have an obligation to inform all prior notice submitters of specific deficiencies in their submissions before beginning enforcement of a rule. Nonetheless, after publication of the IFR, FDA published guidance that included a transition period during which we emphasized education to achieve compliance, rather than general refusal of noncompliant shipments (the December 2003 Prior Notice Interim Final Rule CPG) (68 FR 69708). In addition, we have provided compliance summaries that inform submitters, and those who transmit on their behalf, of the major areas of deficiencies, in general, that we were seeing in prior notice submissions during this educational transition period (see <http://www.cfsan.fda.gov/-pn/pnsum.html>), and generally advise the submitter of deficiencies in prior notices that are not confirmed for review (e.g., failure to provide a valid registration number). Moreover, FDA and CBP believe that the level of compliance was sufficiently high during the assessment period. The assessment period began almost a year after the IFR went into effect. During that time, we resolved initial problems with the government's prior notice systems and processes. Our extensive outreach and focus on education instead of refusals and other enforcement actions helped ensure that industry submission rates were at or

near 100 percent for most prior notice information by November 2004. In certain circumstances, such as with the manufacturer's registration number, FDA and CBP continued to provide flexible enforcement. With these measures, prior notice was operating smoothly during the assessment period.

(Comments) One comment fully supports this process and encourages FDA to provide for any changes that may be needed to allow the timing reductions that are critical to economic prosperity. The comment suggests that once the program has been operational for a time, and the systems glitches worked out from past experience, the assessment would translate into a faster processing time.

(Response) As stated previously, the prior notice timeframes must ensure that we have sufficient time to receive, review, and respond to the prior notice.

(Comments) Several comments encourage both agencies to ensure that they allow for the proper communications with the trade prior to planning for or implementing any changes as a result of the previously mentioned assessments, so that the interests of all parties involved can be assessed and the best changes can be implemented. One comment requests that sufficient resources be allocated by FDA and CBP to implement the Plan.

(Response) The IFR included an extended public comment period, and comments were received and reviewed during the development of this final rule. We also held numerous outreach meetings both domestically and abroad--in person and by video conferencing--to explain the requirements of the IFR to affected parties and answer questions of clarification to ensure all were able to provide meaningful comment to FDA and CBP. The final rule will not take effect until 180 days following publication. The agencies plan additional outreach and guidance during that 180-day period.

(Comments) Some comments request that FDA issue a final prior notice rule only after there has been a period of full enforcement followed by an additional comment period. These comments argue that both FDA and industry need the benefit of experience with active and full enforcement before fine-tuning the prior notice regulation into a final rule. Comments suggest

FDA reopen the comment period for 60 days after full enforcement has been in place for 90 to 180 days or for at least 6 months. In the interim, the comments recommend that the rule should be maintained as an IFR for a longer period of time with phased implementation, as one comment suggests, while developing the final rule.

(Response) FDA reopened the comment period for a total period of almost 6 months to allow parties an opportunity to provide meaningful comment based on their experiences in complying with the IFR. FDA also extended the initial eight-month transition period from August 2004 to November 2004 for several of the data elements that our review indicated had higher error submission rates while continuing educational outreach activities. The implementation date for this final rule is 180 days after publication. The IFR remains in effect until the time the final rule takes effect. No comment period is associated with the publication of the final rule.

(Comments) One comment urges the FDA to build into the final rule the capability to administratively amend the prior notice provisions quickly, if needed. The comment notes that this would be particularly important for imports from any country with which the FDA has reached a bilateral arrangement. This arrangement would serve as the basis for having different (e.g., more efficient, effective, or risk based) prior notice requirements. The comment further notes that this ability to administratively amend the rule would be important so that FDA could

adjust procedures quickly and efficiently to reflect actual reductions in risks through such arrangements.

(Response) FDA disagrees. The Bioterrorism Act requires that FDA receive prior notice for every article of food imported or offered for import into the United States. There are no exceptions based on the country of production or the country from which the article of food is shipped.

To the extent that FDA and CBP believe that changes in our policies related to enforcing this final rule are needed, we will announce those as revisions to the Prior Notice Final Rule Compliance Policy Guide, a draft of which we are announcing elsewhere in this issue of the FEDERAL REGISTER.

IV. Analysis of Economic Impacts

A. Final Regulatory Impact Analysis

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.c. 601-612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104-4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this final rule is not a significant regulatory action under the Executive order.

The Regulatory Flexibility Act (RFA) requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. The requirements of this final rule have not changed significantly from the IFR, although there are changes, such as those relating to the identity of the manufacturer. Because of these changes, FDA has determined that

this final rule may have a significant economic impact on a substantial number of small entities. Under the requirements of the RFA, and as explained in section IV.B of this document, FDA has analyzed the economic impacts of this rule on small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing "any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in anyone year." The current threshold after adjustment for inflation is \$130 million, using the most current (2007) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this final to result in any 1-year expenditure that would meet or exceed this amount as compared to the IFR.

In this regulatory impact analysis for the prior notice final rule we: (1) Respond to comments on the economic analysis of the IFR, (2) revise the economic analysis of the IFR using new data, (3) present an economic analysis of the leading alternative to the IFR using new data, and (4) explain the marginal benefits and costs of the final rule itself, relative to the IFR.

1. Need for Regulation

Section 307 of the Bioterrorism Act of 2002 requires prior notice of all food imported or offered for import into the United States. Before the prior notice requirement was instituted in 2003, there were no security assessments made specifically on imported food products, and all such shipments were allowed to move into the United States prior to FDA being notified of their existence, which legally could have occurred up to 15 days after the food had arrived in the United States and been moved to its final destination. Requiring prior notice of imported foods allows FDA to target food that may pose a significant risk to public health and inspect it upon

arrival. The prior notice submission requirement protects the Nation's food supply against actual or threatened terrorist acts and other food-related emergencies. It helps ensure that imported food shipments that appear to pose a significant threat to public health are stopped at the border upon arrival before they are allowed to move into the United States. This final rule replaces the IFR that is already in effect.

2. Final Rule Coverage

This final rule applies to all food for humans and other animals that is imported or offered for import into the United States for use, storage, or distribution in the United States, including food for gifts and trade and quality assurance or 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.

This final 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; food that was made by an individual in his or her personal residence and sent by that individual as a personal gift to an individual in the United States; or food that is imported then exported without leaving the port of arrival until export.

This final rule also does not apply to 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.); or 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.).

Finally, prior notice is not required for articles of food subject to Art. 27(3) of The Vienna Convention on Diplomatic Relations (J 961), i.e., shipped as baggage or cargo constituting the diplomatic bag.

As required by the Bioterrorism Act, prior notice submissions must provide the identity of the article, manufacturer, shipper, and grower (if known), the FDA Country of Production, the country from which the article is shipped, and the anticipated port of arrival. In addition, the notification must provide the identity of the person who submits and transmits the prior notice, the importer, the owner, the consignee, the carrier, the CBP entry identifier, the anticipated time and date of arrival, anticipated shipment information, and, if the food has been refused admission and required to be held, the location where it is held. For food shipments arriving in the United States through international mail, notification of the import must be sent before the article is mailed. Only the prior notice information that is relevant to that type of shipment must be submitted for articles of food arriving by international mail.

3. Comments on the Interim Final Regulatory Impact Analysis

(Comment) The extra work of completing prior notices because each separate food line in an entry needs a prior notice has forced brokers to raise their fees to clients and forced manufacturers to raise their prices to U.S. consumers.

(Response) FDA agrees this is a possible impact of the rulemaking, and noted in the IFR regulatory impact analysis that the costs of prior notice would likely be partially passed on to consumers in the form of higher retail prices for some foods (68 FR 58974 at 59024).

(Comment) One comment states that smaller U.S. importers cannot afford the additional costs charged by a broker to submit the FDA information via the ABI system. As a result, they are having their foreign suppliers submit prior notice. Some small companies estimate that,

including Web site disruptions, 80 packages would take 40 to 80 hours for prior notice. The comment believes that this is totally unmanageable.

(Response) We account for increase in broker costs due to prior notice in our analysis; the comment estimate of the time it takes to complete prior notice is accurately reflected in the IFR and final rule analysis. FDA expects importers to modify their business practices to find the most cost effective way to deal with prior notice requirements. In this case, the small importer can avoid higher broker fees by having the foreign supplier submit the prior notice. Another alternative would be for the small importer to submit prior notice themselves through PNSI. We would expect small firms would comply in whichever manner is most cost effective. It is also possible some of the costs of prior notice could be passed on to consumers in the form of higher retail prices for some foods; in this case the small importer would not feel the complete impact of the higher broker submission costs.

(Comment) The costs of the IFR were underestimated because some types of imported fruits and vegetables were not included in the "loss of freshness, loss in value" calculation.

(Response) Some fruits and vegetables are regulated by USDA's APHIS regulations (certain types of citrus, tomatoes, avocados, and other products) and already have to be inspected or checked at the port of entry regardless of the prior notice regulation. For importers of these fruits and vegetables, the requirement to have certain documentation available at the port of entry and coordinating times to be at the port of entry is not new. Thus, persons importing fruits and vegetables subject to APHIS' requirements are not included in the "loss of freshness" calculation as these costs of doing business are already taken into account when scheduling importation of the produce. FDA believes we have accounted for every other type of possible instance where a fruit or vegetable regulated under this rulemaking could experience a loss in freshness or value.

Several fresh produce importers commented on the IFR that they considered prior notice redundant as their produce shipments already have to be inspected at the port of entry by USDA. These comments further support the exclusion of some fruits and vegetables from the "loss of freshness" cost calculations presented here and in the IFR's regulatory impact analysis.

(Comment) The cost to complete a prior notice to send food by mail, for companies that ship low volumes of inexpensive food products, is higher than the value of the product being shipped and therefore shipping to the United States may be discontinued.

(Response) FDA stated in the analysis of the IFR that the costs of completing prior notice submissions may be partially passed along to the consumer in the form of higher retail prices for some foods (68 FR 58974 at 59024). FDA's IFR analysis also acknowledged the possibility that companies in the business of sending small shipments of food to private individuals in the United States may stop shipping to U.S. addresses (68 FR 58974 at 59067).

(Comment) A number of postal services take issue with the requiring of filing prior notice for personal food items. The comments state that the labor-intensive process of mailing personal food items will cause a decrease in the items being shipped, thus decreasing the business of the mail system.

(Response) When the cost of shipping increases, the number of items shipped is indeed likely to decrease. Although some of the reduction in postal revenues would represent a dead-weight loss, it is primarily a transfer, not a social cost and therefore is not included in the cost estimates for this analysis.

(Comment) Several comments express concern about their continued ability to import fine wine because although they can obtain the name and address of the site-specific manufacturer of the wine, obtaining the manufacturers' (i.e., the wineries') registration numbers

for these products often is difficult to those not in the winery's direct distribution chain. The comments state that smaller importers, wholesalers, retailers, restaurants, clubs or hotels will be negatively affected by not having the registration number for the manufacturer of the fine wine. The comments further state that the prior notice rule will negatively impact small producers by reducing the number of potential representatives and sales venues as secondary fine wine market importers disappear.

(Response) FDA does not believe that the fine wine industry will be negatively affected by the prior notice final rule. The final rule at § 1.281(a)(6) requires the identity of the manufacturer as follows: 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 (hereafter "the identity of the manufacturer"). Even if a wine importer, retailer, or wholesaler cannot obtain the registration number (e.g., the winery refuses to disclose its registration number because the importer, retailer, or wholesaler is outside the winery's distribution chain), the prior notice can include the name and full address of the winery, which comments stated is obtainable. We do not include additional costs to fine wine manufacturers or importers in this final rule analysis; however, we do refine the estimate of the difference between the IFR requirements and this final rule modification.

(Comment) Smaller importers that buy from brokers and wholesalers because they are too small to buy directly from larger food manufacturers will be put out of business. These smaller importers allege that they will not be able to provide the manufacturers' registration numbers on their prior notices as required by the final rule. The comments argue that the registration number requirement interferes with small businesses' rights to free trade because now only larger businesses that deal with the manufacturers directly, rather than buying through

brokers and wholesalers, will be able to obtain the manufacturer's information that is required for prior notice.

(Response) The final rule provides an alternative for submitters to provide the identity of the manufacturer when the manufacturer's registration number is not obtainable. Under the final rule, submitters may provide the name and full address of the site-specific manufacturing facility along with a reason as to why the registration number was not used in the prior notice.

(Comment) While most comments state that the name and address of the manufacturer could be submitted in prior notice, one comment states that re-sellers will not normally supply the name of their supplier or the name of the manufacturer of a particular product to their customers. The comment asserts that supplying the name of the manufacturer would allow that customer to circumvent the re-seller and attempt to make direct contact with the supplier or manufacturer, thus taking business away from the re-seller. Another comment states, however, that smaller importers buy from brokers and wholesalers specifically because they are too small to buy directly from larger manufacturers and other corporations, as large entities typically would not find it cost-effective to deal with smaller importers.

(Response) Depending on the business atmosphere, FDA believes that it is likely that many resellers will be willing to supply the name and the address of the manufacturers of the products they sell. Unlike the manufacturer's registration number, which many may view as confidential business information that is to be disclosed only on a "need to know" basis, the name and full address of a facility is public information that not only is typically in phone books and on the Internet, but it also often is provided on documents typically exchanged between buyers and sellers (e.g., receipts, purchase orders, and bills of lading). The issues discussed in

~~these comments are addressed further in Options 1 and 3.~~

4. Regulatory Options Considered

In the analysis of the IFR, FDA analyzed 12 options. The 12 options focused on varying timeframes for prior notice submission and prior notice submission by transport type. The options regarding shorter submission timeframes by transport type are similar to the options presented in this analysis; we do not analyze those options with longer minimum submission timeframes (e.g. 8 hours, 12 hours) or options that do not vary prior notice submission timeframe by transport type again here, although this final rule analysis updates the analysis of the chosen IFR option. The costs and benefits of all twelve options analyzed for the prior notice IFR can be found in the FEDERAL REGISTER of October 10,2003 (68 FR 58974 at 59025),.

This final regulatory impact analysis emphasizes the differences between the IFR and final rule, and compares new options against the IFR. Each option covers all food subject to the final rule that is imported or offered for import into the United States; the mode of transportation for the food is specifically addressed in options where minimum prior notice time constrains importation.

Option 1 (IFR). The minimum prior notice time will be 2 hours for articles of food arriving by land by road, 4 hours for articles of food arriving by land by rail and by air, and 8 hours for articles of food arriving by water, with electronic submission of information. Most changes in prior notice information require resubmission of corrected or new information.⁶

Option 2. This option includes all components of Option I, but would reduce the minimum prior notice time for food arriving by land by road to 1 hour for general entries and 30

⁶ You do not have to resubmit your prior notice if there are changes in: (1) The estimated quantity of product, (2) the anticipated arrival information, (3) the planned shipment information, or (4) the anticipated date of mailing for shipments by mail.

minutes for FAST⁷ participants, reduce minimum prior notice time for food arriving by land by rail to 2 hours, and reduce the minimum prior notice time for food arriving by air on flights originating in North and Central America, South America (north of the equator only), the Caribbean, and Bermuda to "wheels-up". This option would integrate FDA's prior notice timeframes with the timeframes required by CBP's Advance Manifest Rule.

Option 3 (Final Rule). This option includes all components of Option 1, except the final rule now allows, when the submitter is unable to determine the registration number of the manufacturer, the site-specific facility name and full address instead of the facility's, name, partial address, and registration number.

Option I: Minimum prior notice time is 2 hours for articles of food arriving by land by road, 4 hours for articles of food arriving by land by rail and by air, and 8 hours for articles of food arriving by water; information is submitted electronically, most changes in information require resubmission.

This option is already in place as the IFR and will be compared against other options for assessing costs and benefits of the changes between the IFR and final rule.

a. Option I--Prior Notice IFR. In the economic analysis of the IFR we calculated the number of entities that would submit prior notice and the costs to those entities of: Learning prior notice, computer acquisition, information coordination, submitting prior notice, creating the

⁷ The Free and Secure Trade (FAST) program is a Border Accord Initiative between the United States, Mexico, and Canada designed to ensure security and safety of imported and exported products. Eligibility for the FAST program requires participants (carrier, drivers, importers, and southern port of entry manufacturers) to submit an application, agreement, and security profile depending on their role in the Customs and Trade Partnership Against Terrorism (C-TPAT) and FAST programs. The FAST program allows known low risk participants to receive expedited CBP entry processing. (Ref. 2)

PNSJ, not being able to use CBP's BRASS⁸ system, and loss of value to fresh produce that waits longer at the port of arrival than before prior notice was required.

i. Number of entities affected. Prior Notice for an article of food may be submitted by any person with knowledge of the required information, e.g., a foreign food manufacturer, a food exporter or importer, a consignee. The flexibility of the identity of the prior notice submitter makes it difficult to get a precise count of the number of unique people or firms who submit at least one prior notice annually. In the IFR we estimated, based on FDA OASIS data from 2001, that there were 77,427 unique people or firms who submitted prior notice. To update the number of prior notice submitters in the final rule we use two sources of data: U.S. Census data and data from OASIS.

First we use U.S. Census data by North American Industry Classification System (NAICS) codes. Six-digit NAICS codes for Industry, 42-Food Wholesalers, indicates that there are 68,651 U.S. businesses registered under this code. We use this information because, in general, establishments importing products into the United States are classified in Wholesale Trade (Ref. 3) (<http://www.naics.com>). Thus the number of U.S. businesses engaged in the wholesale food industry could likely be the number of persons who submit prior notice for the goods they receive. Table 3 of this document shows a breakdown of business by six-digit NAICS code for food wholesalers.

| NAICS Codes for Wholesale Trade Related to Food From the NAICS Association' 6 digit | | Numbers of U.S. Businesses |
|----------------------------------------------------------------------------------------|-----------------------------------------------------------------|----------------------------|
| NAICS Code | | |
| 424210 | Drugs and Druggists' Sundries Merchant Wholesalers ² | 8,288 |
| 424410 | General Line Grocery Merchant Wholesalers | 8,061 |
| 424420 | Packaged Frozen Food Merchant Wholesalers | 1,250 |
| 424430 | Dairy Product (except Dried or Canned) Merchant Wholesalers | 2,195 |

⁸ Border Release Advance Screening and Selectivity (BRASS) is a CBP program that allows expedited arrival processing for high-volume, repetitive shipments that have been judged by CBP to be low risk.

| | | |
|----------------------------|------------------------------------------------------------|--------|
| 424440 | Poultry and Poultry Product Merchant Wholesalers | 899 |
| 424450 | Confectionery Merchant Wholesalers | 3,202 |
| 424460 | Fish and Seafood Merchant Wholesalers | 4,157 |
| 424470 | Meat and Meat Product Merchant Wholesalers | 3,299 |
| 424480 | Fresh Fruit and Vegetable Merchant Wholesalers | 5,494 |
| 424490 | Other Grocery and Related Products Merchant Wholesalers | 14,763 |
| 424510 | Grain and Field Bean Merchant Wholesalers | 5,217 |
| 424520 | Livestock Merchant Wholesalers | 5,106 |
| 424590 | Other Farm Product Raw Material Merchant Wholesalers | 2,158 |
| 424810 | Beer and Ale Merchant Wholesalers | 2,181 |
| 424820 | Wine and Distilled Alcoholic Beverage Merchant Wholesalers | 2,381 |
| Total Number of Businesses | | 68,651 |

1 Source of original data: NAICS Association, September 29, 2008, available online at <http://www.naics.com/naics42.htm>.

2 This category is included to capture wholesale merchants of botanicals, herbs, and vitamins.

Next, using OASIS data, we are able to estimate that there were 123,063 unique manufacturers and 25,929 unique importers of food in FY 2007. Combining the OASIS data with the Census data we estimate that the number of prior notice submitters annually ranges from 68,000 to 149,000. We use the average of this range, 108,500, as the number of entities likely affected by having to submit prior notice.

ii. Costs to entities. We update the cost calculations to the new number of entities affected for learning prior notice, buying computers, and information coordination. We do not update the costs of FDA information technology here. Table 4 of this document shows these cost calculations; for a complete discussion of how these costs were calculated refer to the preamble in the prior notice IFR (68 FR 58974 at 59025).

Table 4 -- ~~Cost~~ Calculations for Learning PN, Information Technology, Information Coordination, and FDA System Costs

| Cost to Learn About the Prior Notice Requirements | | |
|-----------------------------------------------------------------|--------------|----------------------------------|
| | Manager cost | Admin. Worker cost (two workers) |
| Number of firms | 108,500 | 108,500 |
| rate per hour for manager and admin. worker including overhead) | \$56.74 | \$25.10 |
| 1-day learning seminar | 8 hours | 8 hours |
| First year one time learning costs | \$49,250,320 | \$21,786,800 |
| Total first year learning costs for learning | | \$71,037,000 |

| | |
|----------------------------------------------------------------------------------------------------------|--------------------|
| Annual learning costs for new entrants | \$7,103,700 |
| Facilities and Responsible Parties Without Initial Internet Access | |
| Number of facilities | 4,340 |
| Computer equipment cost per facility | \$2,000 |
| Annual cost of Internet access (\$20 per month x 12) | \$240 |
| Search costs for equipment and access (\$25.10 x 8 hours) | \$201 |
| Total first year one time cost of electronic transmitting capacity | \$10,593,940 |
| Annual one time cost of electronic transmitting capacity for firms entering industry in subsequent years | \$1,059,394 |
| Information Gathering and Coordination Costs | |
| Number of firms submitting notices | 108,500 |
| Administrative worker wage rate (doubled to include overhead) | \$25.10 |
| Time to coordinate existing accounts | 16 hours |
| First year cost of coordination of information on current accounts | \$43,573,600 |
| Annual cost of coordination of information on new accounts | \$4,357,360 |
| FDA Prior Notice System Costs | |
| Infrastructure design and implementation | \$7,400,000 |
| Contractor services | \$5,100,000 |
| FDA PN system interface cost | \$12,500,000 |
| CBP ABVACS system modification costs | \$500,000 |
| Total prior notice system cost | \$13,000,000 |

We also have new data on the number of prior notices submitted based on 2007 data collected by FDA's PNC. Therefore, we do update, for the IFR and all other options, the costs of submitting prior notices, the costs of not being able to use CBP's BRASS system, and the lost value of fresh produce and seafood.

Also, due to an oversight in the calculation of the costs for the IFR, FDA did not calculate the costs to importers of providing the imported product's manufacturer registration number and full facility address on prior notice. We correct that oversight here.

b. Updated annual costs to submit prior notice. FDA's PNC received 9,804,050 prior notices for FY 2007, which is about 3 million more prior notices than we estimated in the analysis of the IFR. The difference in number of submissions is in part due to an increase in the number of prior notices submitted for each imported food entry. In the IFR analysis, we

estimated that there were about 2.6 lines (prior notices) submitted for each food shipment.⁹ New OASIS shipment data show that for 2007, the average number of lines per entry for food, food related, infant food, and food additive industry codes is 3.6 lines per entry.

We use these new data on entry lines to estimate that FDA receives 9,804,050 prior notices per year, which translates into approximately 2.7 million imported food entries (based on 3.6 lines per entry¹⁰) annually. Table 5 of this document shows that the annual costs to complete a prior notice will be \$202.5 million instead of the \$187.5 million estimated in the IFR.

TABLE 5.--COST TO COMPLETE A PRIOR NOTICE BY IMPORT ENTRY (MUST BE ELECTRONIC)

| | |
|-------------------------------------------------------------------------------|---------------|
| Broker cost per entry to submit prior notice | \$75 |
| Entry total based on 9.8 million lines | 2,700,000 |
| Total annual costs of all prior notices, including updates to the information | \$202,500,000 |

c. Updated costs to BRASS users. Under the prior notice rule, no food product shipments imported into the United States are eligible to take advantage of CBP's BRASS system. We update the number of entries that used the BRASS system in FY 2002 (242,000) to estimate the number of imported food entries that would have used the BRASS system in FY 2007 (305,000) if it would have been available to them. Table 6 of this document shows that the updated costs to BRASS users are \$61 million annually; the previous estimate was about \$48 million annually.

⁹ As explained in more detail in the economic analysis of the interim final rule, OASIS data indicate there are typically more than two different articles of food per import entry; e.g., 100 cases of canned tuna and 50 cases of canned peaches in the same shipment. A prior notice must be filed for each of the *lines* in an entry.
¹⁰ This is likely a slight overestimate of prior notices per entry because food-related items (such as eating utensils) are not subject to prior notice.

TABLE 6.--UPDATED ADDITIONAL COSTS FOR BRASS USERS

| | |
|---------------------------------------------------------------------|---------------------|
| <u>Additional Submission Costs</u> | |
| Total Cost per import | \$75 |
| FY2002 BRASS line total for FDA-regulated products | 1,098,054 |
| BRASS yearly entry total (3.6 lines per entry) | 305,015 |
| <u>Additional annual costs of submissions for BRASS users</u> | <u>\$22,876,125</u> |
| <u>Border Wait Time</u> | |
| Cost per half hour | \$125 |
| BRASS yearly entry total | 305,015 |
| Additional annual border wait costs for former BRASS users | \$38,126,875 |
| <u>Total Annual additional food importing costs for BRASS users</u> | <u>\$61,003,000</u> |

d. Updated costs to submit prior notice by mode of transport.

i. 2-hour minimum prior notice time for food arriving by land by road. Prior notices for perishable articles of food from Canada and Mexico that arrive in the United States by land by road must be submitted at least 2 hours before the food arrives in the United States. In the analysis of the IFR, we assumed that this minimum submission time should eliminate the probability of having to resubmit prior notice (due to proximity to the U.S. port of entry) for all but 5 percent of those perishable products imported from Canada and Mexico.

Data from the FDA PNC for 2007 indicate that 85 percent of the articles of food arriving from Canada enter the United States by land by road; and approximately 94 percent of the articles of food arriving from Mexico enter the United States by land by road.¹¹ Using these updated estimates, we calculate the proportion of the total retail value of highly perishable produce and seafood from Canada and Mexico that arrive in the United States by land by road. We then calculate the lost product value for the 5 percent of highly perishable produce and seafood from Canada and Mexico for which importers may have to resubmit the prior notice when the minimum submission time is 2 hours. Table 7 of this document shows the revised

¹¹ The mode of transportation field in prior notice is user defined; thus, the person submitting the prior notice is responsible for informing FDA by what mode of transport the food will enter the United States. As mode of transport is user defined, there is a possibility of error.

estimated loss in value caused by the cancelled and resubmitted prior notice information for the 5 percent of imported Mexican and Canadian perishable seafood and produce affected.

We do not include the lost value for perishable seafood and produce imported from Central America because perishable products from Central America are most likely to arrive by air into the United States. We also do not include the cost of additional truck time with this option because the minimum prior notice time for articles of food arriving by vehicle is only 2 hours.

TABLE 7.--LOSS IN VALUE CAUSED BY RESUBMITTED PRIOR NOTICE UNDER OPTION I FOR ARTICLES OF FOOD ARRIVING BY LAND BY ROAD (2-HOUR MINIMUM NOTICE REQUIREMENT)

| Perishable Produce | Dollars |
|----------------------------------------------------|-----------------|
| 200 I Imported Mexican produce total retail value | \$3,458,525,000 |
| 94% of total retail value for Mexican produce | \$3,251,014,000 |
| 1.2% Reduction in value for 5% of Mexican produce | \$1,951,000 |
| 200 I Imported Canadian produce total retail value | \$401,826,000 |
| 85% of total retail value for Canadian produce | \$341,552,000 |
| 1.2% Reduction in value for 5% of Canadian produce | \$205,000 |
| Total lost value for produce | \$2,156,000 |
| Perishable Seafood | Dollars |
| 200 I Imported Mexican seafood total retail value | \$112,277,000 |
| 94% of total retail value for Mexican seafood | \$105,540,000 |
| 4.2% Reduction in value for 5% of Mexican seafood | \$222,000 |
| 200 I Imported Canadian seafood total retail value | \$1,863,218,000 |
| 85% of total retail value for Canadian seafood | \$1,583,735,000 |
| 4.2% Reduction in value for 5% of Canadian seafood | \$3,326,000 |
| Total lost value for seafood | \$3,548,000 |

ii. 4-hour minimum prior notice time for food arriving by land by rail and by air. The hour minimum submission time for prior notice applies to articles of food imported or offered for import by land by rail and by air. A 4-hour minimum prior notice time for railroads and airplanes could constrain products arriving from the countries bordering the United States. Data

from the PNC for 2007 show that about 4 percent of the articles of food arriving from Canada were imported into the United States by land by rail and only about 2 percent of the articles of food arriving from Mexico were imported into the United States by land by rail. Similarly, about 8 percent of the articles of food arriving from Canada were imported into the United States by air, while only about 3 percent of the articles of food arriving from Mexico were imported into the United States by air.

To estimate potential lost value for produce imported from Canada and Mexico by rail and air, we adjust the total retail value of highly perishable produce and seafood from Canada and Mexico to account for the 12 percent from Canada and the 5 percent from Mexico that are imported by land by rail or by air. Table 5 of this document shows the articles of food arriving by rail and air from Canada and Mexico that may have to resubmit prior notice when the minimum prior notice timeframe is 4 hours before arrival in the United States.

For Central American and Caribbean countries, most, if not all, of their perishable products are imported to the United States by air. Table 8 of this document shows the loss of value for the estimated 20 percent of air shipments from Central America for which prior notice needs to be resubmitted under Option 1.¹²

¹² The estimated 20 percent cancellation and resubmission rate for prior notices when the minimum submission time is 4 hours is used in the IFR analysis. (See 68 FR 58974 at 59045.)

TABLE 8.--Loss IN VALUE CAUSED BY RESUBMITTED PRIOR NOTICE UNDER OPTION I FOR SHIPMENTS ARRIVING BY AIR AND BY LAND BY RAIL (4-HOUR MINIMUM NOTICE REQUIREMENT)

| Perishable Produce | Dollars |
|---------------------------------------------------------------------------|-----------------|
| 200 I Imported Mexican produce total retail value | \$3,458,525,000 |
| 5% of total retail value for Mexican produce | \$172,926,000 |
| 2.4% reduction in value for 20% of Mexican produce | \$830,000 |
| 200 J Imported Canadian produce total retail value | \$401,826,000 |
| 12% of total retail value for Canadian produce | \$48,219,000 |
| 2.4% reduction in value for 20% of Canadian produce | \$231,000 |
| 2.4% reduction in value for 20% of Central American and Caribbean produce | \$1,044,000 |
| Total lost value for produce | \$2,105,000 |
| Perishable Seafood | Dollars |
| 200 I Imported Mexican seafood total retail value | \$112,277,000 |
| 5% of total retail value for Mexican seafood | \$5,614,000 |
| 8.3% reduction in value for 20% of Mexican seafood | \$93,000 |
| 200 I Imported Canadian seafood total retail value | \$1,863,218,000 |
| 12% of total retail value for Canadian seafood | \$204,954,000 |
| 8.3% Reduction in value for 20% of Canadian seafood | \$3,712,000 |
| 200 I Imported Central American and Caribbean seafood total retail value | \$251,796,000 |
| 8.3% Reduction in value for 20% of Central American and Caribbean seafood | \$4,180,000 |
| Total lost value for seafood | \$7,985,000 |

e. Updated IFR costs to include the costs of manufacturer name, registration number and partial address on prior notice. Section 1.281(a)(6), (b)(5), and (c)(6) of the IFR requires that prior notice for an article of food that is no longer in its natural state include the name and address of the manufacturer and the registration number assigned to the facility that is associated with the article of food.¹³ This IFR requirement has not been fully enforced by FDA, as described in ePG Sec. 110.310; however, it is a requirement of the rule and therefore we

¹³ The interim final rule further states that 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. The interim final rule also provides that if the article of food is sent by an individual as a personal gift (i.e., for nonbusiness reasons) to an individual in the United States, he or she may provide the name and address of the firm that appears on the label under § 101.5 instead of the name, address, and registration number of the manufacturer. If a registration number is provided, city and country may be provided instead of the full address.

evaluate it as a cost of the IFR. We correct an oversight in the calculation of the costs of the IFR by including the costs of submitting the food manufacturer registration number and facility address on prior notice here.

f. How some importers will be affected. The November 2004 revision of the IFR CPG stated that if the manufacturer's registration number was not given on the prior notice, the submitter should select the appropriate reason identifying why the manufacturer's registration number and/or name and address was not provided. The reason codes provided by PNSI and ABIACS were:

- A--facility is out of business
 - B--facility is a private residence
 - C--facility is a restaurant
 - D--facility is a retail food establishment
 - E--facility is a nonprocessing fishing vessel
 - F--Facility is nonbottled water collection and distribution establishment
 - G--Individual gift-label name/address
 - H--Grower-satisfies fann exemption
 - I--Samples-quality assurance, research or analysis purposes only
 - J--D.S. manufacturing facility that is not required to register
 - K--Unable to detennine the registration number of the manufacturer
 - L--Unable to determine identity of manufacturer-providing identity of manufacturer's headquarters
 - M--Unable to determine identity of manufacturer or headquarters-providing invoicing firm's identity
-

- O--Gift pack for nonbusiness purposes-providing single prior notice and identity of packer

Prior notices submitted without manufacturer registration numbers but using reason codes A through F, H, and J would be compliant with IFR requirements because the manufacturer would be exempt from being registered according to the Registration of Food Facilities rule (21 CFR part I, subpart H). Prior notices submitted without manufacturer registration numbers but using reason code G would be compliant with IFR requirements because the prior notice IFR allows that if an article of food is sent by an individual as a personal gift (i.e., for nonbusiness reasons) to an individual in the United States, the submitter may provide the name and address of the firm that appears on the label instead of the name, address, and registration number of the manufacturer. A prior notice submitted without the manufacturer name, address, and/or registration number but using reason code I, K through M, or O would not be compliant with IFR requirements. However, FDA's enforcement policy was that it should typically consider not taking any regulatory action for prior notice violations in these cases.

We can use information from the PNC on the CPG code reasons given for FY 2007 to determine how many submitters had trouble providing the manufacturer registration number and facility address as is required by the IFR (submitters who used reason codes I, K through M, and O).

The PNC was able to determine that about 92.5 percent of prior notices contained the manufacturer's name, address, and registration number as required by the IFR. Table 9 of this document shows that about 2.9 percent of prior notice submissions (2.91 percent) for 2007 used reason codes I, K, L, M, and O.

TABLE 9.--No MANUFACTURER REGISTRATION NUMBER ON PRIOR NOTICE, REASON CODE COUNT FOR
FY 2007

| Reason Code | Description | PN Lines Count | % of Total Lines |
|-------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|----------------|------------------|
| Total prior notice submissions for fiscal year 2007 | | 9,804,050 | |
| A | Facility is out of business | 43,479 | 0.44% |
| B | Facility is a private residence | 30,801 | 0.31% |
| C | Facility is a restaurant | 5,146 | 0.05% |
| D | Facility is a retail food establishment | 47,705 | 0.49% |
| E | Facility is a nonprocessing fishing vessel | 2,488 | 0.03% |
| F | Facility is a nonprocessing drinking water collection and distribution establishment | 1,417 | 0.01% |
| G | Individual gift label name/address in lieu of registration number | 36,808 | 0.38% |
| H | Grower satisfies farm exemption | 267,369 | 2.73% |
| I | Samples--quality assurance, research or analysis purposes only | 55,374 | 0.56% |
| j | U.S. manufacturing facility that is not required to register | 15,142 | 0.15% |
| K | Unable to determine the registration number of the manufacturer | 166,647 | 1.70% |
| L | Unable to determine identity of the manufacturer--providing identity of manufacturer's headquarters | 15,674 | 0.16% |
| M | Unable to determine identity of manufacturer or headquarters providing invoicing firms identity | 15,839 | 0.16% |
| 0 | Gift pack for nonbusiness purposes--providing single prior notice and identity of packer | 32,371 | 0.33% |
| Total times a reason code was given (includes submission for PNSI and <i>ABI/ACS</i>) for fiscal year 2007 | | 637,153 | 7.51% |

FDA posits that larger entities (e.g., medium to large importers) that deal directly with foreign manufacturers will not be impacted by this IFR requirement (are not part of the 2.91 percent) as they will be able to obtain the manufacturers' registration numbers and facility addresses for the products they are importing. Therefore, it is mostly the small U.S. retailers or individuals that buy from other wholesalers or retailers in foreign countries that may have a problem obtaining the registration number, city, and country of the actual food manufacturing facility.

Using data from the U.S. Census Bureau, FDA was able to determine that for 2006, about \$64.8 billion foods, feeds, and beverages were imported into the United States. Some of this value of imported food could be affected by the IFR requirement that the registration number,

city, and country of the manufacturer be provided on prior notice; to assess how this imported value may be affected, we present best and worst case scenarios.

In our best case scenario, few imported foods would be affected by manufacturer registration number, name and partial address being required on prior notice. For our best case scenario we subtract the full import value of the potentially "unaffected" categories listed in table 10 of this document from \$64.8 billion, the total value of food, feeds, and beverages imported into the United States in 2006 (Ref. 4). In essence, we subtract out those food categories that are likely comprised of foods that are still in their natural state such that a manufacturer is not required for the prior notice (e.g., green coffee). This is our "best case" scenario because not all foods imported from the categories below will come from facilities that are not required to be registered (i.e., vegetables could be farm commodities or could be processed). The remaining imported foods value, about \$29 billion, represents the value of alcoholic beverages, bakery products, non-agricultural, and "other" imported foods, which are products from facilities more likely to be subject to the food facility registration requirements.

About 2.91 percent of the prior notice submissions for FY 2007 indicated that the importer could not provide the name, address, and/or registration number of the actual manufacturing facility. While we do not know the value of imported foods for each of the prior notice submissions in the 2.91 percent affected, in the absence of better information, for our best case scenario we reduce the value of imported foods affected to \$843 million, or 2.91 percent of \$29 billion. For the worst case scenario, we apply the 2.91 percent of import lines for 2007 that could not provide the registration number, city, and country of the actual manufacturer to the entire value of FDA-regulated imported food shipments, \$59 billion, giving us a possible \$1.7

billion in imported foods value that could be affected by the prior notice IFR requiring the name, registration number, and partial address of the manufacturing facility on most prior notices.

The estimated \$843 million to \$1.7 billion in imported food affected by the facility name, registration number, and partial address requirement for prior notice is an overestimate of the imported value likely affected for two reasons. First, the 2.91 percent of prior notice submissions that could not supply the information required by the IFR are most likely goods imported by small or very small U.S. retailers or individuals. These goods are likely purchased for import not through the manufacturer but through middlemen, thus the importers often do not have access to, or knowledge of, the manufacturer registration number and facility address. These small U.S. retailers or individuals would not be importing large quantities of food; therefore, the value of their imported shipments should be small, much smaller in total than the \$843 million to \$1.7 billion estimate.

Second, we expect that most of those persons importing without knowledge of the manufacturing facility's registration number or address will adjust business practices, and perhaps their supply chain, to other entities in the supply chain that will provide them with this information for prior notice submissions. For the persons who can adjust business practices, the value of the food imported will be affected by prior notice, but not lost, because importation of those products not cease. However, some of these businesses will find that the costs associated with changing business practices to supply the necessary information on prior notice will cause importing food products into the United States to no longer be profitable. These persons will cease importing and the value of these imported goods that is lost will be a cost of the rule. Thus we must adjust our value of imported food affected by the manufacturer identity

requirement to reflect that: (1) Most importers will adjust business practices to continue importing and (2) some importers will cease doing so.

To account for the businesses that cease importing food into the United States, we estimate that 3 percent of the possible \$843 million to \$1.7 billion of imported food value is lost. We do this because according to the Small Business Administration, about 3 percent of small businesses closed between 2003 and 2007 (Ref 5). We estimate this value to be \$25 million to about \$52 million.

To account for the businesses that change importing practices, we estimate that 3,157 prior notice submitters (2.91 percent of the estimated 108,500 submitters) will spend 80 hours adjusting their supply chain.¹⁴ As with table 4 of this document, we use the manager wage rate, including overhead, of \$56.74 per hour.

Taking the midpoint of the lost value due to cessation of importation (\$38.5 million) plus the costs to the 3,157 firms to change business practices, we estimate that the cost of the manufacturer identity requirement in the IFR to be about \$52.8 million.

¹⁴ These costs are costs incurred beyond the information gathering and coordination costs presented in table 4 of this document.

TABLE 10 --IMPORTS OF GOODS BY END USE CATEGORY AND COMMODITY (2006 SEASONALLY ADJUSTED DATA)

| | Best Case Scenario (Millions) | Worst Case Scenario (Millions) |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|-----------------------------------|
| Foods, feeds, and beverages (FFB) total) | \$64,782 | \$64,782 |
| Categories of imported food products subtracted | | |
| Meat products | \$5,611 | \$5,611 |
| Fish and shellfish | \$9,867 | |
| Vegetables | \$4,943 | |
| Cane and beet sugar | \$1,121 | |
| Cocoa beans | \$520 | |
| Tea, spices, etc. | \$715 | |
| Food oils, oilseeds | \$1,999 | |
| Feedstuff and food grains | \$1,577 | |
| Fruits, frozen juices | \$5,503 | |
| Nuts | \$856 | |
| Green coffee | \$2,035 | |
| Dairy products and eggs | \$1,070 | |
| Remaining value of imports that may be affected by the IFR identity of the manufacturer requirement | \$28,965 | \$59,171 |
| Imported value reduced further to represent that 2.91% of prior notice submissions could not provide registration number and site-specific information on prior notice for fiscal year 2007 | \$843 | \$1,722 |
| 3 percent of imported food value lost through cessation of importation into U.S. | \$25.3 to \$51.7 million | |
| Costs that reflect change in business practices for 3,157 submitters (80 hours x \$56.74 per hour) | \$14.3 million | |
| Total Value Affected | \$52.8 million | |

¹ Source of original data. U.S. Census Bureau, U.S. Bureau of Economic Analysis, US DOC News, November 9, 2007, pages 12 and 15, available online at <http://www.bea.gov/newsreleases/international/trade/2007/pdf/trad0907.pdf>. (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.)

Table 11 of this document presents a summary of the revised estimated costs associated with Option 1, including the marginal costs to importers who may be affected by the IFR requirement that a facility's name, registration number and partial address be provided on prior notice. Also included in the summary table 11 of this document are the discounted present value of the costs at the OMB-recommended discount rates of 3 and 7 percent.

TABLE II.--SUMMARY OF UPDATED COSTS FOR OPTION J-- IFR

| | (In Thousands of Dollars) |
|----------------------------------------------------------------------------------------|---------------------------|
| Learning costs | \$71,037 |
| Coordination costs | \$43,574 |
| Computer acquisition costs | \$10,594 |
| FDA prior notice <u>system</u> cost | \$13,000 |
| Annual costs to fill out prior notice screens | \$202,500 |
| Additional costs for BRASS users | \$61,003 |
| Lost value for produce | \$4,261 |
| Lost value for seafood | \$11,533 |
| Cost for truck time | \$0 |
| Costs of manufacturer registration number and full facility address <u>requirement</u> | \$52,800 |
| <u>first year</u> costs for <u>Option 1</u> | \$470,302 |
| Annual costs after first year ¹ | \$293,118 |
| PV of costs at 7% for 20 years | \$3,270,884 |
| PV of costs at 3% for 20 years | \$4,532,872 |

¹Annual costs include the start-up costs of prior notice to the estimated 10 percent of new businesses that enter the market each year.

g. Benefits of Option 1. FDA's prior notice system provides us with enhanced knowledge of what articles of food are being imported or offered for import into the United States. Requiring prior notice of imported food shipments and defining the required data information improves our ability to detect accidental and deliberate contamination of food and to deter deliberate contamination.

Before prior notice was required, FDA received almost no advance notice information about food products entering the United States from foreign sources, or the location of the food's anticipated port of arrival. With the information required by prior notice, FDA does know what articles of food are being imported or offered for import before they arrive at the port. In the event of a credible threat for a specific product or a specific manufacturer or processor, for example, FDA will be able to mobilize and assist in the detention and removal of products that may pose a serious health threat to humans or animals.

FDA's PNC reviews prior notices and assesses the risk related to imported food shipments. Personnel at the PNC decide on a case-by-case basis whether the article of food needs

to be held for examination upon arrival at the port. Having notice of an article of food imported or offered for import into the United States before it reaches a U.S. port allows FDA personnel to be ready at any time to respond to shipments that appear to pose a significant health risk to humans or animals.

h. Cost benefit summary table. Table 12 presents the costs of Options I annualized over 20 years.

TABLE 12.--UPDATED COST BENEFIT SUMMARY TABLE FOR OPTION I

| | Annualized Costs Over 20 Years at 7% Discount Rate (Millions) | Annualized Costs Over 20 Years at 3% Discount Rate (Millions) |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------|---------------------------------------------------------------------|
| Option 1--2 hour prior notice for vehicle, 4 hour for rail and air, 8 hour for vessels (IFR) | \$304 | \$301 |
| Benefits--FDA will know what articles of food are being imported or offered for import, before they arrive at the port. In the event of a threat of significant public health risk to humans or animals, FDA and CBP will be able to mobilize and assist each other in the detention and removal of those products. | | |

Option 2 (A and B): Minimum prior notice time frame would be 1 hour before arrival for articles of food arriving by land by road or 30 minutes for FAST participants, 2 hours before arrival for articles of food arriving by land by rail, "wheels-up" for flights originating in North and Central America, South America (north of the equator only), the Caribbean, and Bermuda; 4 hours for all other flights, and 8 hours before arrival for vessels; information would be submitted electronically, most changes in information would require resubmission

This option coordinates FDA minimum prior notice times with those of CBP for imports arriving by land by road, by land by rail, and by air.¹⁵ For this option's timeframes we present two scenarios: (1) The costs and benefits of Option 2 when FDA's PNC is staffed at its current

¹⁵ We do not examine or integrate timeframes for products arriving by water. Persons that use vessels to import their products are usually dealing with merchandise that is not highly perishable in nature and thus less time-sensitive. FDA did not receive comments requesting the coordination of FDA and CBP timeframes for food arriving by water. FDA's current minimum prior notice timeframe for notification of food being imported by water is 8 hours before arrival; CBP's current minimum prior notice timeframe for articles being imported by water is 24 hours before arrival.

level and must review and respond to prior notices received within the minimum timeframe required and (2) the costs and benefits of Option 2 when the PNC has increased its staff to review and respond to prior notices received within the minimum timeframe required.

Option 2A: PNC is Staffed at its Current Level and Must Review and Respond to Prior Notices Within the Minimum Timeframe Required

a. Costs of Option 2A.

i. 1-hour or 30 minute minimum prior notice time for food arriving by land by road. A significant portion (approximately 31 percent) of the prior notices reviewed by the PNC on a daily basis is for articles of food that arrive in the United States by land by road. The PNC conducts a more intensive security review on at least 225 to 250 prior notices per day. Of these prior notices that are flagged as potentially high-risk and require a more intensive security review, about 77 (31 percent of 250) are for articles of food arriving by land by road. Complicating matters further is that prior notice submissions and expiration times are not evenly distributed over an 8-hour shift or 24-hour day; an overwhelming majority of prior notice submissions arrive during a certain 12-hour time period.

The PNC has estimated using 2007 data that most prior notices submitted for land border entries took between 30 and **110** minutes to review. This range indicates that if the prior notice minimum submission time frames were reduced from 2 hours to 1 hour, approximately 27 percent of those high risk prior notices for articles of food arriving by land by road that are selected for a more intensive review would exceed the minimum prior notice timeframe and would have to be delayed at the port of arrival while the PNC completes its review and risk assessment, as discussed earlier in this document.

If the minimum prior notice submission time for articles of food arriving by land by road is shortened to 30 minutes, the intensive security reviews (described previously) on approximately 69 percent of the high-risk targeted land border prior notices would not be completed within the prior notice timeframe. Again, as a result of the shorter timeframe, it would be necessary for the PNC to delay the movement of these shipments at the port of arrival in order to complete their review and risk assessment.

The synopsis stated in the previous paragraph implies that the PNC likely will not be able to review and respond to all prior notices received for articles of food arriving by land by road within the minimum time if the minimum prior notice submission time for articles of food arriving by land by road is either 1 hour or 30 minutes. The loss of value to fresh produce and seafood calculated in table 8 of this document reflects that some articles of food (about 27 to 69 percent of high risk prior notices) will be held at the port of arrival past the 30 minutes or 1 hour minimum prior notice submission time frame while the PNC completes its review.

In table 13 of this document, we first calculate the lost value to fresh produce and seafood as if FDA had the additional staff necessary to receive, review, and respond to prior notices within the minimum prior notice submission time¹⁶ and then increase those costs (in terms of lost value to perishable produce and seafood arriving in the United States by land by road by 48 percent--the average of 27 and 69 percent) to account for the fact that some of these articles of food will be held up at the port pending prior notice review completion given the current PNC staffing level.

¹⁶ We use the same probability of resubmission structure established in the analysis of the IFR (68 FR 58974 at 59025). This minimum submission time should eliminate the probability of having to resubmit prior notice for all but 2.5 percent of those perishable products imported from Canada and Mexico by land by road.

We note that we base this analysis on the typical (average) prior notice review time.

Given that most prior notices for land border entries took between 30 and **110** minutes to review, the typical article of food arriving by land by road should not have to wait longer than 2 hours to enter; which is equivalent to the time that articles of food arriving by land by road will have to wait to enter the United States under Option 1. However, no matter what the minimum prior notice submission timeframes are, there will always be some articles of food whose review will take longer than the minimum allotted prior notice review timeframes.

TABLE 13.--Loss IN VALUE CAUSED BY RESUBMITTED PRIOR NOTICE UNDER OPTION 2A FOR SHIPMENTS ARRIVING BY LAND BY ROAD (1-HOUR OR 30-MINUTE MINIMUM NOTICE REQUIREMENT)

| Perishable Produce | Dollars |
|----------------------------------------------------------------------------|-----------------|
| 200I Imported Mexican produce total retail value | \$3,458,525,000 |
| 94% of total retail value for Mexican produce | \$3,251,014,000 |
| 0.6% Reduction in value for 2.5% of Mexican produce | \$488,000 |
| 48% Increase in lost value due wait time past minimum submission timeframe | \$234,000 |
| Total lost value for Mexican produce | \$722,000 |
| 200I Imported Canadian produce total retail value | \$401,826,000 |
| 85% of total retail value for Canadian produce | \$341,552,000 |
| 0.6% Reduction in value for 2.5% of Canadian produce | \$51,000 |
| 48% Increase in lost value due wait time past minimum submission timeframe | \$24,000 |
| Total lost value for Canadian produce | \$75,000 |
| Total lost value for produce | \$797,000 |
| Perishable Seafood | Dollars |
| 200I Imported Mexican seafood total retail value | \$112,277,000 |
| 94% of total retail value for Mexican seafood | \$105,540,000 |
| 2.1% Reduction in value for 2.5% of Mexican seafood | \$55,000 |
| 48% Increase in lost value due wait time past minimum submission timeframe | \$26,000 |
| Total lost value for Mexican seafood | \$81,000 |
| 200I Imported Canadian seafood total retail value | \$1,863,218,000 |
| 85% of total retail value for Canadian seafood | \$1,583,735,000 |
| 2.1% Reduction in value for 2.5% of Canadian seafood | \$831,000 |
| 48% Increase in lost value due wait time past minimum submission timeframe | \$399,000 |
| Total lost value for Canadian seafood | \$1,230,000 |
| Total lost value for seafood | \$1,311,000 |

ii. 2-hour minimum prior notice time for food arriving by land by rail and "wheels-up" or 4-hour minimum prior notice time by air. The 2-hour minimum submission time for food imported by land by rail should reduce the probability of having to resubmit prior notice for virtually all articles of food imported from Canada and Mexico by rail. However, with current

staffing levels at the PNC, the possibility exists that some articles of food arriving by rail may be held at the minimum prior notice submission timeframe.

Data from the PNC for 2007 show that only about 4 percent of the articles of food imported from Canada and only about 2 percent of the articles of food imported from Mexico are imported by land by rail. Thus, articles of food arriving by land by rail represent only a slight fraction of all prior notices received and are therefore not necessarily the constraining factor when the PNC is staffed at its current level. Although we cannot rule out the possibility that some additional effects may be associated with articles of food imported from by land by rail under Option 2A, we assume those effects would be negligible. We therefore do not estimate additional costs for articles of food arriving by land by rail for Option 2A.

Reducing the prior notice submission timeframe to "wheels-up" for food imported by air on flights originating in North and Central America, South America (north of the equator only), the Caribbean, and Bermuda will eliminate the need for any resubmission of prior notice information for those shipments. Because prior notice does not need to be submitted until "wheels-up," the probability of *not* having the correct prior notice information on the shipment is eliminated.

However, according to 2007 data from the PNC, if the minimum prior notice submission time is reduced from 4 hours to "wheels up" for some articles of food arriving by air, approximately 5 percent of the prior notice reviews would not be completed in time if flight time was less than 3 hours given the current PNC staffing level. Perishable produce and seafood imported into the United States from the Bahamas, Belize, the Dominican Republic, El Salvador, Haiti, Honduras, Jamaica, and Nicaragua can all be flown to Miami, Florida in less than 3 hours.

Perishable produce and seafood imported by air from Canada and Mexico also can be flown into the United States in less than 3 hours.

Table 14 of this document shows that while there is no value loss from perishable produce and seafood having to resubmit prior notice (because the minimum prior notice submission timeframe is "wheels-up"), there may be a loss of value for about 5 percent of perishable produce and seafood coming from the locations listed previously if the PNC does not have more than its current level of personnel to review and respond to prior notices when the minimum prior notice time frame is "wheels-up." Even if the PNC cannot respond to all prior notices for articles of food arriving in the United States by air when the flight time is less than 3 hours, we would still not expect the costs (value loss on perishable produce and seafood) to importers of these articles of food to be less than the costs in Option 1 where the minimum prior notice time frame is 4 hours for articles of food arriving by air. Again we note that this analysis is based on the typical review time for prior notice for articles of food arriving by air. No matter what the minimum prior notice submission timeframe, there will always be some articles of food for which the PNC will not be able to respond and complete its risk assessment within the timeframe allotted.

To estimate the potential loss in value for perishable products due to a delay in PNC review, we use the following information in table 14 of this document: (1) The total retail value of the perishable products from Central America, adjusted to encompass perishable products coming from countries whose flight times to the United States are less than 3 hours; (2) the total retail value of perishable products from Canada and Mexico, adjusted to reflect the proportion of these articles of food that arrive into the United States by air (8 percent for Canada and 3 percent

for Mexico); and (3) the estimated loss for the delay in review, which we equate to 1 hour¹⁷ of the perishable product's lifespan.

TABLE 14.--LOSS IN VALUE CAUSED BY DELAYED PRIOR NOTICE REVIEW UNDER OPTION 2A FOR SHIPMENTS ARRIVING BY AIR ("WHEELS-UP MINIMUM NOTICE REQUIREMENT")

| Perishable Produce | Dollars |
|-----------------------------------------------------------------------------------------------------------------------------|-----------------|
| 2001 Impolled Mexican produce total retail value | \$3,458,525,000 |
| 3% of total retail value for Mexican produce | \$103,756,000 |
| 5% Experience a 0.6% loss in value due wait time past minimum submission timeframe | |
| Total lost value for Mexican produce | \$31,000 |
| 2001 Impolled Canadian produce total retail value | \$401,826,000 |
| 8% of total retail value for Canadian produce | \$32,146,000 |
| 5% Experience a 0.6% in value due wait time past minimum submission time frame | |
| Total/ost for Canadian produce | \$10,000 |
| 2001 Impolled Central American produce total retail value (coming from countries that are less than 3 hours by air to U.S.) | \$62,510,000 |
| 5% Experience a 0.6% loss in value due wait time past minimum submission timeframe | |
| Total lost value for Central American produce | \$19,000 |
| Total lost value for produce | \$60,000 |
| Perishable Seafood | Dollars |
| 2001 Impolled Mexican seafood total retail value | \$112,277,000 |
| 3% of total retail value for Mexican seafood | \$3,368,000 |
| 5% Experience a 2.1% loss in value due wait time past minimum submission time frame | |
| Total lost value for Mexican seafood | \$4,000 |
| 2001 Imported Canadian seafood total retail value | \$1,863,218,000 |
| 8% of total retail value for Canadian seafood | \$149,057,000 |
| 5% Experience a 2.1% loss in value due wait time past minimum submission timeframe | |
| Total lost value for Canadian seafood | \$157,000 |
| 2001 Imported Central American seafood total retail value (coming from countries that are less than 3 hours by air to U.S.) | \$73,021,000 |
| 5% Experience a 2.1% loss in value due wait time past minimum submission timeframe | |
| Total lost value for Central American seafood | \$77,000 |
| Total lost value for seafood | \$238,000 |

Table] 5 of this document presents a summary of the costs associated with Option 2A, including the costs of the option at the OMB-recommended discount rates of 3 and 7 percent.

¹⁷ We chose 1 hour as the loss in value because the PNC, staffed at its current level, will not complete its review for articles of food arriving by air when flights are less than 3 hours and prior notice is required at "wheels-up," but generally will complete its review when the minimum prior notice time for articles of food arriving by air is 4 hours.

TABLE 15 --SUMMARY OF COSTS FOR OPTION 2A

| | (In Thousands of Dollars) |
|----------------------------------------------------------------------------------------|---------------------------|
| Learning costs | \$71,037 |
| Coordination costs | \$43,574 |
| Computer acquisition costs | \$10,594 |
| FDA prior notice system cost | \$13,000 |
| Annual costs to fill out prior notice screens | \$202,500 |
| Additional costs for BRASS users | \$0 |
| Lost value for produce | \$857 |
| Lost value for seafood | \$1,549 |
| Cost for truck time | \$0 |
| Costs of manufacturer registration number and <i>full</i> facility address requirement | \$52,800 |
| Total first year costs for Option 2 | \$395,911 |
| Annual costs after first year | \$218,727 |
| PV of costs at 7% for 20 years | \$2,482,785 |
| PV of costs at 3% for 20 years | \$3,426,122 |

b. Implications for the benefits of Option 2A. If FDA cannot appropriately review and respond to submitted prior notices within the reduced submission times frames under Option 2A given current FDA PNC staffing, there are two possible outcomes:

(1) Prior notice screening and risk assessment requirements will have to be relaxed so that fewer prior notices are forwarded to the PNC for intensive review. Taking this action will reduce the social benefits of the rule by increasing the probability that an article of food posing a significant health threat to humans or animals will enter the United States unchecked; or

(2) The PNC will be unable to complete its intensive review process for some or all of the prior notices forwarded to it within the shortened timeframes, and will frequently cause an unpredictable delay in the movement of these articles of food at the port of arrival until the PNC completes its review. This additional time for review will result in higher private costs to individuals importing articles of food into the United States than implied by the prior notice times.

Had the shortened review time frames in Option 2A been in effect in FY 2007, the PNC would have held at least 6,000 to 16,000 articles of food arriving by land by road. For air

,shipments, if the minimum prior notice submission time frame had been shortened to "wheels-up" approximately 728 prior notice reviews in FY 2007 would not have been completed for flights less than 3 hours. As a result, it would have been necessary for the PNC to delay the movement of these shipments at the port of arrival in order to complete their review and risk assessment.

To be able to review prior notices within a 1 hour prior notice submission time for articles of food arriving by land by road (given the current number and dispersion of prior notices by land by road and by other modes of transportation), the PNC estimates that it would need more than twice its current level of resources. The additional resources needed would include increasing the number of permanent employees who review prior notices from 27 to at least 50 FTEs, an increase in the number of first line supervisors, a tripling of computer access to both FDA and CBP systems, and a tripling of the current number of telephone lines.

If the minimum timeframe to submit prior notices for articles of food arriving by land by road was reduced to 30 minutes, the PNC may need 3 times the number of staff to handle the prior notice review volume within this timeframe.

c. Cost benefit summary table. Table 16 presents the costs of Options 2A annualized over 20 years.

TABLE J6.--UPDATED COST BENEFIT SUMMARY TABLE FOR OPTION 2A

| | Annualized Costs Over 20 Years at 7% Discount Rate (Millions) | Annualized Costs Over 20 Years at 3% Discount Rate (Millions) |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------|------------------------------------------------------------------------|
| Option 2A--J hour or 30 minute prior notice for food arriving by land by road, 2 hours for rail, "wheels-up" or 4 hours for air, 8 hour for vessels; The PNC is <u>staffed at its current level</u> | \$230 | \$227 |
| Benefits--FDA will know what articles of food are being imported or offered for import, before they arrive at the port. In the event of a potential threat of significant health risk to humans or animals, FDA will be able to mobilize and assist in the detention and removal of those products from U.S. commerce. | | |

Option 28: PNC has Increased Staff to Review and Respond to Prior Notices within the Minimum Time Frame Required

a. Costs of Option 2B. For Option 2B we assume the PNC staff has been at least doubled, if not tripled. As stated earlier in this analysis, the PNC estimates that it would need more than twice, and possibly three times its current number of permanent employees to review prior notices if the minimum submission timeframe was 1 hour or 30 minutes before arrival for articles of food arriving by land by road, "wheels-up" for food arriving by air, and 2 hours for food arriving by land by rail. In addition to increasing prior notice permanent review staff from 27 to 50 or even 100 or more FTEs, an increase in the number of first line supervisors would be necessary, as would a corresponding increase in both computer access and telephone lines to FDA and CBP systems.

Assuming that the costs to hire additional FTEs including overhead is \$150,000 per FTE, then doubling the number of prior notice reviewers by adding an additional 27 permanent employees to the existing 27 employees would cost at least \$4,050,000; tripling the number of prior notice reviewers would cost at least \$8,100,000. These costs could be higher if additional overhead is required. We include \$6,075,000 in our summary cost table for Option 2B as this represents the midpoint in costs between doubling and tripling the number of permanent employees at the PNC. These costs could be higher if additional overhead is required.

i. 1-hour or 30-minute minimum prior notice time for food arriving by land by road. Under this option, prior notices for perishable articles of food from Canada and Mexico that arrive in the United States by land by road must be submitted 1 hour or 30 minutes before the food arrives in the United States. Using the same probability of resubmission structure established in the analysis of the IFR (68 FR 58974 at 59025), this minimum submission time

should eliminate the probability of having to resubmit prior notice for all but 2.5 percent of those perishable products imported from Canada and Mexico by land by road.

Using the same formula we used in the analysis of Option I, we calculate the proportion of the total retail value of highly perishable produce and seafood from Canada and Mexico that arrives in the United States by land by road. We then adjust the new retail value, to calculate the lost product value (1 hour out of 168 hours for produce, 1 hour out of 48 hours for seafood) for the 2.5 percent of highly perishable produce and seafood from Canada and Mexico for which prior notices would have to be resubmitted due to changes in the shipment when the minimum submission time is 1 hour or 30 minutes.¹⁸

Table 17 of this document shows the loss in value caused by the cancelled and resubmitted prior notice information for the 2.5 percent of imported Mexican and Canadian perishable seafood and produce affected. We do not include the cost of truck time for this option, because the minimum prior notice time for articles of food arriving by vehicle is only 1 hour or 30 minutes.

¹⁸ In the IFR, we assumed a 2.5 percent prior notice resubmission rate when the minimum notice submission time for food imported by land by road was 1 hour. In this option, that minimum submission timeframe is 1 hour or 30 minutes for participants of eBP's accelerated entry programs.

TABLE 17.--Loss IN VALUE CAUSED BY RESUBMITTED PRIOR NOTICE UNDER OPTION 28 FOR SHIPMENTS ARRIVING BY LAND BY ROAD (1-HOUR OR 30-MINUTE MINIMUM NOTICE REQUIREMENT)

| Perishable Produce | Dollars |
|-------------------------------------------------------|-----------------|
| 200 J Imported Mexican produce total retail value | \$3,458,525,000 |
| 94% of total retail value for Mexican produce | \$3,251,014,000 |
| 0.6% Reduction in value for 2.5% of Mexican produce | \$488,000 |
| 200 I Imported Canadian produce total retail value | \$401,826,000 |
| 85% of total retail value for Canadian produce | \$341,552,000 |
| 0.6% Reduction in value for 2.5% of Canadian produce | \$51,000 |
| Total lost value for produce | \$539,000 |
| Perishable Seafood | Dollars |
| 200 I Imported Mexican seafood total retail value | \$112,277,000 |
| 94% of total retail value for Mexican seafood | \$105,540,000 |
| 2.1 % Reduction in value for 2.5% of Mexican seafood | \$55,000 |
| 200 I Imported Canadian seafood total retail value | \$1,863,218,000 |
| 85% of total retail value for Canadian seafood | \$1,583,638,000 |
| 2.1 % Reduction in value for 2.5% of Canadian seafood | \$831,000 |
| Total lost value for seafood | \$886,000 |

ii. 2-hour minimum prior notice time for food arriving by land by rail and "wheels-up" or 4-hour minimum prior notice time by air. The 2-hour minimum submission time for food imported by land by rail should reduce the probability of having to resubmit prior notice for virtually all articles of food imported from Canada and Mexico by that mode of transport. Data from the PNC for 2007 show that only about 4 percent of the articles of food imported from Canada and only about 2 percent of the articles of food imported from Mexico are imported by land by rail. We do not calculate any lost value due to prior notice resubmission for products shipped by rail.

Reducing the prior notice submission time frame to "wheels-up" for food imported by air on flights originating in North and Central America, South America (north of the equator only), the Caribbean, and Bermuda will eliminate the need for any resubmission of prior notice information for those shipments. Because prior notice does not need to be submitted until "wheels-up", the probability of not having the correct prior notice information on the shipment is eliminated.

A 4-hour minimum prior notice time for flights not originating in North and Central America, South America (north of the equator only), the Caribbean, and Bennuda will not constrain these imports because flights from locations other than those listed will all take longer than 4 hours. Therefore, the probability of having incorrect shipment information is all but eliminated as the shipment information can be verified before the prior notice is sent.

Table 18 of this document presents a summary of the costs associated with Option 2B, including the costs of the option at the OMB-recommended discount rates of 3 and 7 percent.

TABLE 18.--SUMMARY OF COSTS FOR OPTION 2B

| | (In Thousands of Dollars) |
|---------------------------------------------------------------------------------|---------------------------|
| Learning costs | \$71,037 |
| Coordination costs | \$43,574 |
| Computer acquisition costs | \$10,594 |
| FDA prior notice system cost and cost of additional FTEs | \$19,075 |
| Annual costs to fill out prior notice screens | \$202,500 |
| Additional costs for BRASS users | \$0 |
| Lost value for produce | \$539 |
| Lost value for seafood | \$886 |
| Cost for truck time | \$0 |
| Costs of manufacturer registration number and full facility address requirement | \$52,800 |
| Total first year costs for Option 2 | \$401,005 |
| Annual costs after 1st year | \$218,353 |
| PY of costs at 7% for 20 years | \$2,483,938 |
| PY of costs at 3% for 20 years | \$3,425,873 |

b. Benefits of Option 2B. Importers will benefit from the shorter times for submitting prior notice under Option 2B because it is less likely that articles of food will need to "wait" longer than the minimum prior notice time frame before entering the United States. Submitting FDA's Prior Notice information at the same time as CBP's entry information may reduce costs for submitters.¹⁹ If FDA's Prior Notice and CBP submissions can be done simultaneously,

¹⁹ Comments on the IFR stated several reasons for recommending that prior notice timeframes be the same as CBP's advance electronic information timeframes for food arriving by air and by land (both by road and by rail): (I) It would minimize the complexity of the process by presenting a more streamlined flow of information and avoid

submitters may be able to coordinate the two entry submissions so as to reduce total submission costs.

c. Cost benefit summary table. Table 19 presents the costs of Options 2B annualized over 20 years.

TABLE 19 --UPDATED *COST* BENEFIT SUMMARY TABLE FOR OPTION 2B

| | Annualized Costs Over 20 Years at 7% Discount Rate (Millions) | Annualized Costs Over 20 Years at 3% Discount Rate (Millions) |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------|---------------------------------------------------------------|
| Option 2B--1 hour or 30 minute prior notice for food arriving by land by road, 2 hours for rail, "wheels-up" or 4 hours for air, 8 hour for vessels; the PNC has increased staff | \$229 | \$226 |
| Benefits--FDA will know what articles of food are being imported or offered for import, before they arrive at the port. In the event of a potential threat of significant health risk to humans or animals, FDA will be able to mobilize and assist in the detention and removal of those products. | | |

Option 3: Minimum prior notice time is 2 hours for articles of food arriving by land by road, 4 hours for articles of food arriving by land by rail and by air, and 8 hours for articles of food arriving by water; information is submitted electronically, most changes in information require resubmission; the manufacturer registration number is not required when the submitter is unable to determine it.

Option 3 represents Option 1 with a change to the requirement for providing the identity of the manufacturer.

As stated in Option 1, smaller importers or individuals that buy food for import into the United States from brokers, wholesalers, or foreign retailers because they are too small to buy directly from food manufacturers may find it difficult to continue importing certain products when manufacturer name, registration number, and partial address is required on prior notice.

unnecessary duplication, (2) it would result in fewer errors, (3) it would provide better compliance rates, (4) it would allow for fewer disruptions at the border, (5) it would significantly reduce the burden on the trade community without creating additional security risks, and (6) it would allow operators at close border points to load and verify truck loads and travel routes prior to submitting notice.

However, the final rule provides an alternative for submitters in providing the identity of the manufacturer when they are unable to determine the manufacturer's registration number. Under the final rule, submitters may provide the name and full address of the site-specific manufacturing facility along with the reason why the registration number was not provided.

Most of the comments concerned with the identity of the manufacturer were concerned about submitters not being able to provide registration number; a smaller percentage of the comments also raised concerns about being able to provide the name and address of the manufacturer. Unlike the manufacturer's registration number, which many may view as confidential business information that is to be disclosed only on a "need to know" basis, the name and full address of a facility is public information that not only is typically in phone books and on the Internet, but it also often is provided on documents typically exchanged between buyers and sellers (e.g., receipts, purchase orders, and bills of lading).

Even with the flexibility of not requiring the manufacturer registration number on prior notice when the submitter is unable to determine it, there will likely be some adjustment costs for small importers and individuals. These adjustments to business practices should be less costly and occur less often than those in Option 1 because importers no longer have to provide the manufacturer registration number but may instead provide only the site-specific facility name and full address and the reason the registration number is not provided.

We adjust the costs of the final rule to now reflect the requirement that if the manufacturer's registration number is not available, then the name and full address of the site-specific manufacturing facility must be provided. For Option I, using information from table 9 of this document, we estimated that about 2.91 percent of prior notices submitted for FY 2007 did not contain the appropriate manufacturer name, address, and/or registration number as

required by the codified of the IFR. With the extra flexibility in manufacturer identity allowed by Option 3, we expect the percentage of prior notices still affected by this requirement to be 1.21 percent (2.91 percent - 1.70 percent). We expect those who submitted prior notice under the IFR using reason code K--Unable to determine the registration number of the manufacturer (1.70 percent), should likely be able to submit the manufacturer site-specific name and full address as required by the prior notice final rule codified. We expect that those who submitted prior notice under the IFR using reason codes I, L, M, and 0 (0.56 percent, 0.16 percent, 0.16 percent, and 0.33 percent, respectively), could still have problems submitting the identity of the manufacturer as required by the final rule.

We must further adjust the 1.21 percent of prior notices expected to still be affected by the manufacturer identity requirement of prior notice to address the fact that the final rule is more restrictive than the IFR in regards to providing the identity of the manufacturer on prior notice for food sent by an individual as a personal gift.

In cases of food sent by an individual as a personal gift, the IFR allows the name and address on the product label to substitute for the manufacturer's name, address, and registration number on prior notice. The final rule requires that if the manufacturer's registration number is not available, the full name and address of the site-specific facility that manufactured the gift must be included on prior notice.²⁰ Therefore, we add 0.38 percent (for reason code G--Individual gift label name/address in lieu of registration number from the November 2004 revision of the IFR CPG) to the 1.21 percent we expect may have problems with the manufacturer identity requirement of the final rule. Thus, we expect a total of 1.59 percent of all

²⁰ FDA plans to continue its enforcement policy that it should typically consider not taking any regulatory action for prior notice violations relating to individual gifts; however, the final rule does require at least the name and full address of the site-specific facility where the gift was manufactured.

prior notices annually to be affected by the revised manufacturer identity requirement of the final rule as opposed to the 2.91 percent affected by the manufacturer identity requirement of the IFR.

We can again use the data from table 10 of this document, adjusted now by 1.59 percent instead of 2.91 percent, to determine the potential imported food value affected by the final rule requirement that either the registration number or the name and address of the site-specific facility be included in prior notice. We repeat the data from table 10 here in table 20 of this document. As with Option 1, we present the best and worst case scenarios to represent the possible range of imported foods value that may be affected by the final rule requirement and then adjust that value to reflect changes in business practices and businesses ceasing importing food into the United States. Taking the midpoint of the lost value due to cessation of importation (\$21 million) plus the costs to the 1,725 firms to change business practices, we estimate that the cost of the manufacturer identity requirement in the final rule to be about \$28.8 million.

TABLE 20 --IMPORTS OF GOODS BY END USE CATEGORY AND COMMODITY (2006 SEASONALLY ADJUSTED DATA)

| | Best Case Scenario (Millions) | Worst Case Scenario (Millions) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|-----------------------------------|
| Foods, feeds, and beverages (FFB) total | \$64,782 | \$64,782 |
| Categories of imported food products subtracted | | |
| Meat products | \$5,611 | \$5,611 |
| Fish and shellfish | \$9,867 | |
| Vegetables | \$4,943 | |
| Cane and beet sugar | \$1,121 | |
| Cocoa beans | \$520 | |
| Tea, spices, etc. | \$715 | |
| Food oils, oilseeds | \$1,999 | |
| Feedstuff and food grains | \$1,577 | |
| Fruits, frozen juices | \$5,503 | |
| Nuts | \$856 | |
| Green coffee | \$2,035 | |
| Dairy products and eggs | \$1,070 | |
| Remaining value of imports that may be affected by identity of the manufacturer requirement | \$28,965 | \$59,171 |
| Imported value reduced further to represent that only 1.59% of prior notice submissions could not provide manufacturing facility site-specific information on prior notice for CY 2007 | \$461 | \$941 |
| 3 percent of imported food value lost through cessation of importation into U.S. | \$13.8 to \$28.2 million | |
| Costs that reflect change in business practices for 1,725 submitters (80 hours x \$56.74 per hour) | \$7.8 million | |
| Total Value Affected | \$28.8 million | |

Source of original data. U.S. Census Bureau, U.S. Bureau of Economic Analysis, US DOC News, November 9, 2007, pages 12 and 15, available online at <http://www.bea.gov/newsreleases/international/trade/2007/pdf/trad0907.pdf> (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.)

a. Changes in to the final rule that are not quantified. The final rule is more restrictive than the IFR in regards to providing the identity of the manufacturer on prior notice for the importation of transshipments. For transshipments, the IFR allows the name and full address of the manufacturer to substitute for the manufacturer's name and partial address, and registration number on prior notice. The final rule requires that if the manufacturer's registration number is not available, the site-specific full name and address of the facility that manufactured the article of food must be included on prior notice. We do not expect this requirement of the final rule to

affect transshipments significantly as the final rule does allow the importer to provide the site-specific name and full address of the manufacturing facility instead of the registration number.

Also, for the final rule, FDA removed a few of the prior notice data elements that are required in the IFR. Specifically, submitters no longer need to include the fax number of the submitter and transmitter, the anticipated border crossing, the country of the carrier, or the 6-digit HTS code on their prior notices. Other changes include making the shipper's registration number optional but always requiring its full addresses; and the option of submitting the tracking number for articles of food arriving by express consignment instead of anticipated arrival information when the prior notice is submitted through PNSI. However, these and other changes in filing requirements, on net, are not large enough to affect the time needed to file prior notice or the costs charged by brokers to file prior notice; therefore, we do not update the estimated time needed or the estimated costs charged to file prior notice.

Table 21 of this document presents a summary of the revised estimated costs associated with Option 3, the final rule, including the marginal costs to importers who may be affected by the identity of the manufacturer requirement. Also included in table 21 of this document are the discounted present value of the costs at the OMB-recommended discount rates of 3 and 7 percent.

TABLE 2J --SUMMARY OF COSTS FOR OPTION 3--THE FINAL RULE

| | (In Thousands of Dollars) |
|------------------------------------------------------|---------------------------|
| Learning costs | \$71,037 |
| Coordination costs | \$43,574 |
| Computer acquisition costs | \$10,594 |
| FDA prior notice system cost | \$13,000 |
| Annual costs to fill out prior notice screens | \$202,500 |
| Additional costs for BRASS users | \$61,003 |
| Lost value for produce | \$4,261 |
| Lost value for seafood | \$1,533 |
| Cost for truck time | \$0 |
| Costs of change in manufacturer identity requirement | \$28,800 |
| Total first year costs for Option 3 | \$446,302 |
| Annual costs after first year | \$293,118 |
| Present value (PV) of costs at 7% for 20 years | \$3,248,454 |
| PV of costs at 3% for 20 years | \$4,509,571 |

¹ Annual costs Include the startup costs of prior notice to the estimated 10 percent of new businesses that enter the market each year.

b. Benefits of Option 3 (final rule). Option 3 allows for the submission of alternative manufacturer information that could be used to verify the registration status of the manufacturer. This is more flexible to importers than the requirements of Option 1, the IFR. Once the facility has been identified in the database and a valid registration has been verified, the manufacturer information required on prior notice for Option 3 provides the same level of security and assurance as the registration number required by Option 1.

c. Cost benefit summary table. Table 22 presents the costs of Option 3 annualized over 20 years.

TABLE 22 --UPDATED COST BENEFIT SUMMARY TABLE FOR OPTION 3

| | Annualized Costs Over 20 Years at 7% Discount Rate (Millions) | Annualized Costs Over 20 Years at 3% Discount Rate (Millions) |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------|---------------------------------------------------------------|
| Option 3--2-hour prior notice for vehicle, 4-hour for rail and air, 8-hour for vessels; change in the identity of the manufacturer requirement (Final rule) | \$655 | \$652 |
| Benefits--FDA will know what articles of food are being imported or offered for import, before they arrive at the port. In the event of a threat of significant public health risk to humans or animals, FDA will be able to mobilize and assist in the detention and removal of those products. The benefits of the final rule are enhanced by the change in the identity of the manufacturer requirement. | | |

Summary Table of All Options Analyzed

| TABLE 23.--COSTS AND BENEFITS OF ALL OPTIONS ANALYZED | | | | |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|-------------------------|-------------------------|-------------------------|
| Costs | Option 1 | Option 2A | Option 2B | Option 3 |
| | In Thousands of Dollars |
| Learning costs | \$71,037 | \$71,037 | \$71,037 | \$71,037 |
| Coordination costs | \$43,574 | \$43,574 | \$43,574 | \$43,574 |
| Computer acquisition costs | \$10,594 | \$10,594 | \$10,594 | \$10,594 |
| FDA prior notice system cost | \$13,000 | \$13,000 | \$19,075 | \$13,000 |
| costs to fill out prior notice screens | \$202,500 | \$202,500 | \$202,500 | \$202,500 |
| Additional costs for BRASS users | \$61,003 | \$0 | \$0 | \$61,003 |
| Lost value for produce | \$4,261 | \$857 | \$539 | \$4,261 |
| Lost value for seafood | \$11,533 | \$1,549 | \$886 | \$11,533 |
| Cost for truck time | \$0 | \$0 | \$0 | \$0 |
| Costs of change in manufacturer identity requirement | \$52,800 | \$52,800 | \$52,800 | \$28,800 |
| Total first year costs | \$470,302 | \$395,911 | \$401,005 | \$446,302 |
| Annual costs | \$293,118 | \$218,727 | \$218,353 | \$293,118 |
| PV of costs at 7% for 20 years | \$3,270,884 | \$2,482,785 | \$2,483,938 | \$3,248,454 |
| PV of costs at 3% for 20 years | \$4,532,872 | \$3,426,122 | \$3,425,873 | \$4,509,571 |
| Benefits for all options (benefits not quantified) | | | | |
| FDA will know what articles of food are being imported or offered for import, before they arrive at the port. In the event of a threat of significant public health risk to humans or animals, FDA will be able to mobilize and assist in the detention and removal of those products. | | | | |

Sensitivity Analysis

The prior notice rule is unique in that the rule is published with an accompanying Compliance Policy Guide (CPG). The CPG provides guidance regarding enforcement of the prior notice requirements, including describing the circumstances where FDA and CBP should typically consider not taking any regulatory action even though certain requirements are not met. In some of these circumstances, the compliance policy applies when alternative information is submitted. If we estimate the costs of the IFR taking into account information from the IFR CPG and compare those costs to the final rule taking into account information from the final rule draft CPG, the main cost difference, as when comparing Option 1 and Option 3, is the cost of the change regarding providing the manufacturer identity.

For Option I (the IFR) we estimated that this cost was about \$52.8 million and for Option 3 (the final rule) we estimated this cost was about \$28.8 million. If information based on the ePG is included *in* the estimate of the cost of the IFR and final rule, then the rule costs regarding providing the identity of the manufacturer are \$0 and \$5.9 million respectively. The costs regarding providing the identity of the manufacturer is \$0 under the IFR taking into account information from the IFR ePG based on the assumption that the submitter would use one of the reason codes in table 9 (A through O) when the submitter is not able to satisfy some or all of the requirements regarding providing the identity of the manufacturer of the product. The same cost under the final rule taking into account information from the final rule draft ePG is about \$5.9 million²¹ based on the assumption that if the submitter would otherwise use reason code L or M in table 9, because it was unable to determine the identity of the site-specific manufacturer, it would now change supply chains, find some other means to continue importing the food, or cease importing the food because it finds it unprofitable to attempt to continue to do so under the circumstances (0.32 percent or 31,513 of the 9.8 million entry lines for which prior notice was submitted in 2007).

As discussed in more detail elsewhere in this document, the benefit of not including reason codes L and M in the final rule draft ePG is that knowing the identity of the facility involved in the food's production, as opposed to the identity of the facility's headquarters or the invoicing firm, is critical to ensuring that FDA can effectively determine whether food should be held because it is from an unregistered manufacturing facility.

²¹ We calculated this cost using the same method we used in Option I (table 10) and Option 3 (table 20) except we use 0.32 percent for the reduction of imported value and to reduce the number of submitters from 108,500 to reflect changing business practices.

B. Small Entity Analysis (or Final Regulatory Flexibility Analysis)

FDA has examined the economic implications of this final rule as required by the Regulatory Flexibility Act (5 U.S.c. 601-612). If a rule has a significant economic impact on a substantial number of small entities, the *Regulatory Flexibility Act* requires agencies to analyze regulatory options that *would* lessen the economic effect of the rule on small entities consistent with statutory objectives. FDA finds that this final rule may have a significant economic impact on a substantial number of small entities. While this final rule provides more flexibility to small entities than the IFR because the final rule allows the full address of the site-specific manufacturer to be given instead of the partial address and registration number on prior notice, this information may still be difficult for some businesses to obtain.

Comments on the IFR Related to Small Businesses

(Comment) One comment states that smaller U.S. importers cannot afford the additional costs charged by a broker to submit the FDA information via the ABI system. As a result, they are having their foreign suppliers submit prior notice. Some small companies estimate that, including Web site disruptions, 80 packages would take 40 to 80 hours for prior notice. The comment believes that this is totally unmanageable.

(Response) We account for increase in broker costs due to prior notice in our analysis; the comment estimate of the time it takes to complete prior notice is accurately reflected in the IFR and final rule analysis. FDA expects importers to modify their business practices to find the most cost effective way to deal with prior notice requirements. In this case, the small importer can avoid higher broker fees by having the foreign supplier submit the prior notice. Another alternative would be for the small importer to submit prior notice themselves through PNSI. We would expect small firms would comply in whichever manner is most cost effective. It is also

possible some of the costs of prior notice could be passed on to consumers in the form of higher retail prices for some foods; in this case the small importer would not feel the complete impact of the higher broker submission costs.

(Comment) The cost to complete a prior notice to send food by mail, for companies that ship low volumes of inexpensive food products, is higher than the value of the product being shipped and therefore shipping to the United States may be discontinued.

(Response) FDA stated in the analysis of the IFR that the costs of completing prior notice submissions may be partially passed along to the consumer in the form of higher retail prices for some foods (68 FR 58974 at 59024). FDA's IFR analysis also acknowledged the possibility that companies in the business of sending small shipments of food to private individuals in the United States may stop shipping to U.S. addresses (68 FR 58974 at 59067).

(Comment) A number of postal services take issue with the requiring of filing prior notice for personal food items. The comments state that the labor-intensive process of mailing personal food items will cause a decrease in the items being shipped, thus decreasing the business of the mail system.

(Response) When the cost of shipping increases, the number of items shipped is indeed likely to decrease. Although some reduction in postal revenues would represent a dead-weight loss, it is primarily a transfer, not a social cost and therefore is not included in the cost estimates for this analysis.

(Comment) Several comments express concern about their continued ability to import fine wine because although they can obtain the name and address of the site-specific manufacturer of the wine, obtaining the manufacturers' (i.e., the wineries') registration numbers for these products often is difficult to those not in the winery's direct distribution chain. The

comments state that smaller importers, wholesalers, retailers, restaurants, clubs, or hotels will be negatively affected by not having the registration number for the manufacturer of the fine wine. The comments further state that the prior notice rule will negatively impact small producers by reducing the number of potential representatives and sales venues as secondary fine wine market importers disappear.

(Response) FDA does not believe that the fine wine industry will be negatively affected by the prior notice final rule. The final rule at § 1.281(a)(6) requires the identity of the manufacturer as follows: 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 (hereafter "the identity of the manufacturer"). Even if a wine importer, retailer, or wholesaler cannot obtain the registration number (e.g., the winery refuses to disclose its registration number because the importer, retailer, or wholesaler is outside the winery's distribution chain), the prior notice can include the name and full address of the winery, which comments stated is obtainable. We do not include additional costs to fine wine manufacturers or importers in this final rule analysis; however, we do refine the estimate of the difference between the **IFR** requirements and this final rule modification.

(Comment) Smaller importers that buy from brokers and wholesalers because they are too small to buy directly from larger food manufacturers will be put out of business. These smaller importers allege that they will not be able to provide the manufacturers' registration numbers on their prior notices as required by the final rule. The comments argue that the registration number requirement interferes with small businesses' rights to free trade because now only larger businesses that deal with the manufacturers directly, rather than buying through

brokers and wholesalers, will be able to obtain the manufacturer's information that is required for prior notice.

(Response) The final rule provides an alternative for submitters to provide the identity of the manufacturer when the manufacturer's registration number is not obtainable. Under the final rule, submitters may provide the name and full address of the site-specific manufacturing facility along with a reason as to why the registration number was not used in the prior notice.

(Comment) While most comments state that the name and address of the manufacturer could be submitted in prior notice, one comment states that re-sellers will not normally supply the name of their supplier or the name of the manufacturer of a particular product to their customers. The comment asserts that supplying the name of the manufacturer would allow that customer to circumvent the re-seller and attempt to make direct contact with the supplier or manufacturer, thus taking business away from the re-seller. Another comment states, however, that smaller importers buy from brokers and wholesalers specifically because they are too small to buy directly from larger manufacturers and other corporations, as large entities typically would not find it cost-effective to deal with smaller importers.

(Response) Depending on the business atmosphere, FDA believes that it is likely that many resellers will be willing to supply the name and the address of the manufacturers of the products they sell. Unlike the manufacturer's registration number, which many may view as confidential business information that is to be disclosed only on a "need to know" basis, the name and full address of a facility is public information that not only is typically in phone books and on the Internet, but it also often is provided on documents typically exchanged between buyers and sellers (e.g., receipts, purchase orders, and bills of lading). The issues discussed in these comments are addressed further in Options 1 and 3.

Costs per Small Entity

FDA does not have detailed information on the approximately 108,500 persons (e.g. exporters, U.S. importers or U.S. purchasers or their agents) that will be primarily responsible for submitting the prior notice information; table 3 gives a description of some of these entities. Many of these submitters may have fewer than 100 employees²², thus making them small businesses as defined by the Small Business Administration. Because many of the prior notice submitters are likely to be small businesses, all options considered in the Final Regulatory Impact Analysis in section IV.A of this document are regulatory relief options.

FDA does not have enough information about the 108,500 prior notice submitters to perform a detailed analysis of the costs per small business by industry sector. We do, however, update some of the costs per submitter that were presented in the IFR Regulatory Flexibility Analysis (68 FR 59066). Table 24 of this document shows the average costs per submitter to learn the rule, coordinate information, and submit prior notice. Table 24 also shows the average costs to the submitter to absorb the costs of not being able to use BRASS, to absorb costs of lost value of perishable products, and the cost regarding providing the identity of the manufacturer.

Table 24 --Costs per Submitter for PN Final Rule Chosen Option

| Activity | Total Costs | Cost per importer (n = 108,500) |
|------------------------------------------------------|---------------|------------------------------------|
| Learning costs | \$71,037,000 | \$655 |
| Coordination costs | \$43,574,000 | \$402 |
| Annual costs to fill out prior notice screens | \$202,500,000 | \$1,866 |
| Costs for BRASS users | \$61,003,000 | \$562 |
| Lost value for perishables | \$15,794,000 | \$146 |
| Costs of change in manufacturer identity requirement | \$28,800,000 | \$265 |
| Total estimated average costs per submitter | | \$3,896 |

²² For NAICS industry sector 42-Wholesale Trade, a business is defined as small by SBA if it has fewer than 100 employees.

C. Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA) Major Rule

SBREFA (Public Law 104-121) defines a major rule for the purpose of Congressional review as having caused or being likely to cause one or more of the following: An annual effect on the economy of \$100 million or more; a major increase in costs or prices; significant adverse effects on competition, employment, productivity, or innovation; or significant adverse effects on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets. In accordance with the Small Business Regulatory Enforcement Fairness Act, OMB has determined that this final rule is not a major rule for the purpose of Congressional review.

V. Paperwork Reduction Act of 1995

The collection of information provisions of this final rule are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.c. 3501-3520). The collections of information in §§ 1.280, 1.281, 1.282, 1.283, and 1.285 have been approved under OMB Control No. 0910-0520.

From the IFR to the final rule, FDA removed a few of the required prior notice data elements. Specifically, submitters no longer need to include the fax number of the submitter and transmitter, the anticipated border crossing, the country of the carrier, or the 6-digit HTS code in their prior notices. Other changes include the addition of the registration number of the transshipper for articles of food for transshipment, storage and export, or manipulation and export; flexibility in submitting the registration number and the city and country of the manufacturer and shipper instead of full addresses of these entities; and the option of submitting the tracking number for articles of food arriving by express consignment instead of anticipated

arrival information when the prior notice is submitted through PNSI. However, these and other changes in filing requirements, on net, are not large enough to affect the time needed to file prior notice or the costs charged by brokers to file prior notice. Therefore we do not re-estimate a Paperwork Reduction Act burden for this final rule.

VI. Analysis of Environmental Impact

The agency has carefully considered the potential environmental effects of this action. FDA has concluded under 21 CFR 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VII. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency has concluded that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is *not* required.

VIII. References

The following references have been placed on display in the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. (FDA has verified the Web site addresses, but FDA is not responsible

for any subsequent changes to the Web sites after this document publishes in the FEDERAL REGISTER.)

1. Taube, Anthony C., Memorandum to file, November 13, 2006.

2. U.S. Customs and Border Protection,
http://www.cbp.gov/linkhandler/cgov/trade/cargo_security/ctpat/fast_ref_guide.ctt/fast_ref_guide.pdf.

3. The NAICS Association, September 29,2008, available online at <http://www.naics.com>.

4. U.S. International Trade in Goods and Services
September 2007, U.S. Census Bureau, U.S. Bureau of Economic Analysis, US DOC News, November 9,2007, pages 12 and 15, available online at
<http://www.bea.gov/newsreleases/international/trade/2007/pdf/trad0907.pdf>.

5. The Small Business Administration, Office of Advocacy, Frequently Asked Questions Updated September 2008, available online at <http://www.sba.gov/advo/stats/sbfag.pdf>.

List of Subjects in 21 CFR Part 1

Cosmetics, Drugs, Exports, Food labeling, Imports, Labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 1 is amended as follows:

PART I--GENERAL ENFORCEMENT REGULATIONS

I. The authority citation for 21 CFR part 1 continues to read as follows:

Authority: 15 U.S.c. 1453, 1454, 1455; 19U.S.C. 1490, 1491; 21 U.S.c. 321, 331, 332, 333, 334, 335a, 343, 350c, 350d, 352,355, 360b,362,371,374, 38 1,382,393;42U.S.C.216, 241,243,262,264.

2. Accordingly, ~~the interim final rule amending~~ subpart I, consisting of §§ 1.276 through] _____ ~~was published in the FEDERAL REGISTER of October 10, 2003 (68 FR 58974) and~~ ~~corrected by a technical amendment (February 2, 2004; 69 FR 4851)~~ is revised to read as follows:

per
J. Wickliffe,
OFR
10-31-02
AR

Subpart I--PRIOR NOTICE OF IMPORTED FOOD

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General Provisions

§ 1.276 What definitions apply to this subpart?

(a) The act means the Federal Food, Drug, and Cosmetic Act.

(b) The definitions of terms in section 201 of the act (21 U.S.C. 321) apply when the terms are used in this subpart, unless defined in this section.

(1) Calendar day means every day shown on the calendar.

(2) Country from which the article originates means FDA Country of Production.

(3) Country from which the article is shipped means 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.

(4) FDA Country of Production means: (i) 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.

(ii) 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.

(5) Food has the meaning given in section 201(f) of the act, except as provided in paragraph (b)(5)(i) of this section.

(i) For purposes of this subpart, food does not include:

(A) Food contact substances as defined in section 409(h)(6) of the act (21 U.S.c. 348(h)(6)); or

(B) Pesticides as defined in 7 U.S.c. 136(u).

(ii) 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.

(6) FuJI 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.

(7) Grower means a person who engages in growing and harvesting or collecting crops (including botanicals), raising animals (including fish, which includes seafood), or both.

(8) International mail means 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.

(9) 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.

(10) No longer in its natural state means 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 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.

(11) Port of arrival means 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).

(12) Port of entry, in section 801(m) and (l) of the act (21 U.S.C. 381(m) and (1)), means the port of entry as defined in 19 CFR 101.1.

(13) Registration number means 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.

(14) Shipper means 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.

(15) United States means 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.

(16) You means the person submitting the prior notice, i.e., the submitter or the transmitter, if any.

§ 1.277 What is the scope of this subpart?

(a) This subpart applies to all food for humans and other animals that is imported or offered for import into the United States for use, storage, or distribution in the United States, including food for gifts and 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.

(b) Notwithstanding paragraph (a) of this section, this subpart does not apply to:

(1) Food for an individual's personal use when it is carried by or otherwise accompanies the individual when arriving in the United States;

(2) 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;

(3) Food that is imported then exported without leaving the port of arrival until export;

(4) Meat food products that at the time of importation are subject to the exclusive jurisdiction of the U.S. Department of Agriculture (USDA) under the Federal Meat Inspection Act (21 U.S.C. 601 et seq.);

(5) 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.);

(6) 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.); and

(7) Articles of food subject to Article 27(3) of The Vienna Convention on Diplomatic Relations (1961), i.e., shipped as baggage or cargo constituting the diplomatic bag.

Requirements To Submit Prior Notice of Imported Food

§ 1.278 Who is authorized to submit prior notice?

A prior notice for an article of food may be submitted by any person with knowledge of the required information. This person is the submitter. The submitter also may use another person to transmit the required information on his/her behalf. The person who transmits the information is the transmitter. The submitter and transmitter may be the same person.

§ 1.279 When must prior notice be submitted to FDA?

(a) Except as provided in paragraph (c) of this section, you must submit the prior notice to FDA and the prior notice submission must be confirmed by FDA for review as follows:

(1) If the article of food is arriving by land by road, no less than 2 hours before arriving at the port of arrival;

(2) If the article of food is arriving by land by rail, no less than 4 hours before arriving at the port of arrival;

(3) If the article of food is arriving by air, no less than 4 hours before arriving at the port of arrival; or

(4) If the article of food is arriving by water, no less than 8 hours before arriving at the port of arrival.

(b) Except in the case of an article of food imported or offered for import by international mail:

(1) If prior notice is submitted via Automated Broker Interface/Automated Commercial System (*ABUACS*), you may not submit prior notice more than 30-calendar days before the anticipated date of arrival.

(2) If prior notice is submitted via the FDA Prior Notice System Interface (*FDA PNSI*), you may not submit prior notice more than 15-calendar days before the anticipated date of arrival.

(c) Notwithstanding paragraphs (a) and (b) of this section, if the article of food is arriving by international mail, you must submit the prior notice before the article of food is sent to the United States.

(d) FDA will notify you that your prior notice has been confirmed for review with a reply message that contains a Prior Notice (PN) Confirmation Number. Your prior notice will be considered submitted and the prior notice time will start when FDA has confirmed your prior notice for review.

(e) The PN Confirmation Number must accompany any article of food arriving by international mail. The PN Confirmation Number must appear on the Customs Declaration (e.g., CN22 or CN23 or U.S. equivalent) that accompanies the package.

(f) A copy of the confirmation, including the PN 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 U.S. Customs and Border Protection (CBP) or FDA upon arrival.

(g) The PN 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.

§ 1.280 How must you submit prior notice?

(a) You must submit the prior notice electronically to FDA. You must submit all prior notice information 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 the items listed in the previous sentence, must be submitted using the Latin (Roman) alphabet. Unless paragraph (c) of this section applies, you must submit prior notice through:

(1) The U.S. Customs and Border Protection (CBP) Automated Broker Interface of the Automated Commercial System (ABI/ACS); or

(2) The FDA PNSI at <http://www.access.fda.gov>. You must submit prior notice through the FDA Prior Notice System Interface (FDA 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 that have been refused under section 80I(m)(1) of the act and under this

subpart must be submitted through the FDA PNSI until such time as FDA and CBP issue a determination that ACS or its successor system can accommodate such transactions.

(b) If a customhouse 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 the FDA PNSI.

(c) If FDA determines that FDA PNSI or the Operational and Administration System for Import Support (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.

§ 1.281 What information must be in a prior notice?

(a) General. For each article of food that is imported or offered for import into the United States, except by international mail, you must submit the information for the article that is required in paragraphs (a)(1) through (a)(17) of this section:

(1) The name of the individual submitting the prior notice and his/her business address, phone number, and e-mail address, and the name and address of the submitting firm, if applicable. 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;

(2) If different from the submitter, the name of the individual and firm, if applicable, transmitting the prior notice on behalf of the submitter and his/her business address, phone number, and e-mail address. 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;

(3) The entry type;

(4) The U.S. Customs and Border Protection (CBP) entry identifier (e.g., CBP entry number or in-bond number), if available;

(5) The identity of the article of food being imported or offered for import, as follows:

(i) The complete FDA product code;

(ii) The common or usual name or market name;

(iii) The estimated quantity of food that will be shipped, described from largest container to smallest package size; and

(iv) The lot or code numbers or other identifier of the food if required by the act or FDA regulations, e.g., low-acid canned foods, by § 113.60(c) of this chapter; acidified foods, by § II4.80(b) of this chapter; and infant formula, by § 106.90 of this chapter;

(6) For an article of food that is no longer in its natural state, the identity of the manufacturer, as follows:

(i) The name of the manufacturer; and

(ii) Either the registration number, city, and country of the manufacturer or both the full address of the manufacturer and the reason the registration number is not provided;

(7) For an article of food that is in its natural state, the name and growing location address of the grower, if known. If the submitter does not know the identity of the grower or, if the article has been consolidated and the submitter does not know the identity of any of the growers, you may provide the name and address of the firm that has consolidated the articles of food from different growers or different growing locations;

(8) The FDA Country of Production;

(9) If the shipper is different from the manufacturer, the identity of the shipper, as follows:

(i) The name of the shipper; and

(ii) The full address of the shipper. If the address of the shipper is a registered facility,

You also may submit the registration number of the shipper's registered facility;

(j) The country from which the article is shipped;

(11) Anticipated arrival information about the article of food being imported or offered for import, as follows:

(i) The anticipated port of arrival;

(ii) The anticipated date on which the article of food will arrive at the anticipated port of arrival;

(iii) The anticipated time of that arrival; and

(iv) Notwithstanding paragraphs (a)(11)(i) through (a)(11)(iii) of this section, 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 prior notice is submitted via the FDA PNSI, the express consignment operator or carrier tracking number may be submitted in lieu of the information required in paragraphs (a)(11)(i) through (a)(11)(iii) of this section. Until such time as FDA and CBP issue a determination that ACS or its successor system can accommodate such transactions, the tracking number may not be submitted in lieu of information required in paragraphs (a)(11)(i) through (a)(11)(iii) of this section, if the prior notice is submitted via ABI/ACS.

(12) The name and full address of the importer. If the business address of the importer is a registered facility, you also may submit the registration number of the importer's registered facility. The identity of the importer is not required for an article of food that is imported or

offered for import for transshipment through the United States under a Transportation and Exportation entry;

(13) The name and full address of the owner if different from the importer or ultimate consignee. If the business address of the owner is a registered facility, you also may submit the registration number of the owner's registered facility. The identity of the owner is not required for an article of food that is imported or offered for import for transshipment through the United States under a Transportation and Exportation entry;

(14) The name and full address of the ultimate consignee. If the business address of the ultimate consignee is a registered facility, you also may submit the registration number of the ultimate consignee's registered facility. The identity of the ultimate consignee is not required for an article of food that is imported or offered for import for transshipment through the United States under a Transportation and Exportation entry;

(15) The mode of transportation;

(16) The Standard Carrier Abbreviation Code (SCAC) or International Air Transportation Association (IATA) code of the carrier which is, or will be, carrying the article of food from the country from which the article is shipped to the United States to the port of arrival, or if this code is not applicable, then the name of the carrier. If the carrier is a privately owned vehicle, the license plate number of the vehicle and the State or Province that issued the license plate number;

(17) Planned shipment information, as applicable to the mode of transportation and when it exists:

(i) The Airway Bill number(s) or Bill of Lading number(s), as applicable. This information is not required for an article of food when carried by or otherwise accompanying an

individual when entering the United States. 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 the FDA PNSI, the express consignment operator or carrier tracking number may be submitted in lieu of the Airway Bill number(s) or Bill of Lading number(s), as applicable. Until such time as FDA and CBP issue a determination that ACS or its successor system can accommodate such transactions, the tracking number may not be submitted in lieu of the Airway Bill number(s) or Bill of Lading number(s), if the prior notice is submitted via ABI/ACS;

(ii) For food arriving by ocean vessel, the vessel name and voyage number;

(iii) For food arriving by air carrier, the flight number. 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 the FDA PNSI, the express consignment operator or carrier tracking number may be submitted in lieu of the flight number. Until such time as FDA and CBP issue a determination that ACS or its successor system can accommodate such transactions, the tracking number may not be submitted in lieu of the flight number, if the prior notice is submitted via ABI/ACS;

(iv) For food arriving by truck, bus, or rail, the trip number;

(v) For food arriving as containerized cargo by water, air, or land, the container number(s). This information is not required for an article of food when carried by or otherwise accompanying an individual when entering the United States; and

(vi) For food arriving by rail, the car number. This information is not required for an article of food when carried by or otherwise accompanying an individual.

(b) Articles arriving by international mail. For each article of food that is imported or offered for import into the United States by international mail, you must submit the information for the article that is required in paragraphs (b)(1) through (b)(11) of this section:

(1) The name of the individual submitting the prior notice and his/her business address, phone number, and e-mail address, and the name and address of the submitting firm, if applicable. 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;

(2) If different from the submitter, the name of the individual and firm, if applicable, transmitting the prior notice on behalf of the submitter and his/her business address, phone number, and e-mail address. 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;

(3) The entry type (which will be a mail entry);

(4) The identity of the article of food being imported or offered for import, as follows:

(i) The complete *FDA* product code;

(ii) The common or usual name or market name;

(iii) The estimated quantity of food that will be shipped, described from largest container to smallest package size; and

(iv) The lot or code numbers or other identifier of the food if required by the act or FDA regulations, e.g., low-acid canned foods, by § 113.60(c) of this chapter; acidified foods, by § 114.80(b) of this chapter; and infant formula, § 106.90 of this chapter;

(5) For an article of food that is no longer in its natural state, the identity of the manufacturer, as follows:

(i) The name of the manufacturer; and

(ii) Either the registration number, city, and country of the manufacturer or both the full address of the manufacturer and the reason the registration number is not provided;

(6) For an article of food that is in its natural state, the name and growing location address of the grower, if known. If the submitter does not know the identity of the grower or, if the article has been consolidated and the submitter does not know the identity of any of the growers, you may provide the name and address of the firm that has consolidated the articles of food from different growers or different growing locations;

(7) The FDA Country of Production;

(8) If the shipper is different from the manufacturer, the identity of the shipper, as follows:

(i) The name of the shipper; and

(ii) The full address of the shipper. If the address of the shipper is a registered facility, you also may submit the registration number of the shipper's registered facility;

(9) The country from which the article is shipped (i.e., mailed);

(10) The anticipated date of mailing; and

(11) The name and address of the U.S. recipient.

(c) Refused articles. If the article of food has been refused under section 801 (m)(1) of the act and under this subpart, you must submit the information for the article that is required in paragraphs (c)(1) through (c)(18) of this section. However, if the refusal is based on

~~§ 1.283(a)(1)(iii) (Untimely Prior Notice), you do not have to resubmit any information~~

previously submitted unless it has changed or the article has been exported and the original prior notice was submitted through ABI/ACS. If the refusal is based on § 1.283(a)(1)(ii), you should cancel the previous submission per § 1.282(b) and (c).

(1) The name of the individual submitting the prior notice and his/her business address, phone number, and e-mail address, and the name and address of the submitting firm, if applicable. 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;

(2) If different from the submitter, the name of the individual and firm, if applicable, transmitting the prior notice on behalf of the submitter and his/her business address, phone number, and e-mail address. 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;

(3) The entry type;

(4) The CBP entry identifier (e.g., CBP entry number or in-bond number), if available;

(5) The identity of the article of food being imported or offered for import, as follows:

(i) The complete FDA product code;

(ii) The common or usual name or market name;

(iii) The quantity of food that was shipped, described from largest container to smallest package size; and

(iv) The lot or code numbers or other identifier of the food if required by the act or FDA regulations, e.g., low-acid canned foods, by § 113.60(c) of this chapter; acidified foods, by § 114.80(b) of this chapter; and infant formula, by § 106.90 of this chapter;

(6) For an article of food that is no longer in its natural state, the identity of the manufacturer, as follows:

(i) The name of the manufacturer; and

(ii) Either the registration number, city, and country of the manufacturer or both the full address of the manufacturer and the reason the registration number is not provided;

(7) For an article of food that is in its natural state, the name and growing location address of the grower, if known. If the submitter does not know the identity of the grower or, if the article has been consolidated and the submitter does not know any of the growers, you may provide the name and address of the firm that has consolidated the articles of food from different growers or different growing locations;

(8) The FDA Country of Production;

(9) If the shipper is different from the manufacturer, the identity of the shipper, as follows:

(i) The name of the shipper; and

(ii) The full address of the shipper. If the address of the shipper is a registered facility, you also may submit the registration number of the shipper's registered facility;

(10) The country from which the article is shipped;

(II) Arrival information about the article of food being imported or offered for import, as follows:

(i) The port of arrival; and

(ii) The date on which the article of food arrived at the port of arrival.

(iii) Notwithstanding paragraph (c)(II) of this section, if the article of food arrived 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 the FDA PNSI, the express consignment operator or carrier tracking number may be submitted in lieu of the information required in paragraph (c)(II) of this section. Until such time as FDA and CBP issue a determination that ACS or its successor system can accommodate such transactions, the tracking number may not be submitted in lieu of information required in paragraph (c)(II) of this section, if the prior notice is submitted via ABI/ACS;

(12) The name and full address of the importer. If the business address of the importer is a registered facility, you also may submit the registration number of the importer's registered facility. The identity of the importer is not required for an article of food that is imported or offered for import for transshipment through the United States under a Transportation and Exportation entry;

(13) The name and full address of the owner, if different from the importer or ultimate consignee. If the business address of the owner is a registered facility, you also may submit the registration number of the importer's registered facility. The identity of the is not required for an article of food that is imported or offered for import for transshipment through the United States under a Transportation and Exportation entry;

(14) The name and full address of the ultimate consignee. If the business address of the ultimate consignee is a registered facility, you also may submit the registration number of the ultimate consignee's registered facility. The identity of the ultimate consignee is not required for an article of food that is imported or offered for import for transshipment through the United States under a Transportation and Exportation entry;

(15) The mode of transportation;

(16) The SCAC or IATA code of the carrier which carried the article of food from the country from which the article is shipped to the United States to the port of arrival, or if this code is not applicable, then the name of the carrier. If the carrier is a privately owned vehicle, the license plate number of the vehicle and the State or Province that issued the license plate number;

(17) Shipment information, as applicable to the mode of transportation and when it exists:

(i) The Airway Bill number(s) or Bill of Lading number(s), as applicable; however, this information is not required for an article of food when carried by or otherwise accompanying an individual when entering the United States. If the article of food arrived 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 the FDA PNSI, the express consignment operator or carrier tracking number may be submitted in lieu of the Airway Bill number(s) or Bill of Lading number(s), as applicable. Until such time as FDA and CBP issue a determination that ACS or its successor system can accommodate such transactions, the tracking number may not be submitted in lieu of the Airway Bill number(s) or Bill of Lading number(s), if the prior notice is submitted via ABI/ACS;

(ii) For food that arrived by ocean vessel, the vessel name and voyage number;

(iii) For food that arrived by air carrier, the flight number. If the article of food arrived 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 the FDA PNSI, the express consignment operator or carrier tracking number may be submitted in lieu of the flight number. ~~Until such time as FDA and CBP issue a determination that ACS or its successor~~

system can accommodate such transactions, the tracking number may not be submitted in lieu of the flight number, if the prior notice is submitted via ABIACS;

(iv) For food that arrived by truck, bus, or rail, the trip number;

(v) For food that arrived as containerized cargo by water, air, or land, the container number(s); however, this information is not required for an article of food when carried by or otherwise accompanying an individual when entering the United States; and

(vi) For food that arrived by rail, the car number; however, this information is not required for an article of food when carried by or otherwise accompanying an individual;

(18) The location and address where the article of refused food will be or is being held, the date the article has arrived or will arrive at that location, and identification of a contact at that location.

§ 1.282 What must you do if information changes after you have received confirmation of a prior notice from FDA?

(a)(I) If any of the information required in § 1.281 (a), except the information required in:

(i) Section 1.281 (a)(5)(iii) (quantity),

(ii) Section 1.281 (a)(11) (anticipated arrival information), or

(iii) Section 1.281 (a)(17) (planned shipment information), changes after you receive notice that FDA has confirmed your prior notice submission for review, you must resubmit prior notice in accordance with this subpart unless the article of food will not be offered for import or imported into the United States.

(2) If any of the information required in § 1.281 (b), except the information required in § 1.281 (b)(10) (the anticipated date of mailing), changes after you receive notice that FDA has confirmed your prior notice submission for review, you must resubmit prior notice in accordance

with this subpart, unless the article of food will not be offered for import or imported into the United States.

(b) If you submitted the prior notice via the FDA PNSI, you should cancel the prior notice via the FDA PNSI.

(c) If you submitted the prior notice via *ABI/ACS*, you should cancel the prior notice via ACS by requesting that CBP cancel the entry.

Consequences

§ 1.283 What happens to food that is imported or offered for import without adequate prior notice?

(a) For each article of food that is imported or offered for import into the United States, except for food arriving by international mail or food carried by or otherwise accompanying an individual, the consequences are:

(1) Inadequate prior notice--(i) No prior notice. If an article of food arrives at the port of arrival and no prior notice has been submitted and confirmed by FDA for review, the food is subject to refusal of admission under section 801(m)(1) of the act (21 U.S.C. 381(m)(1)). If an article of food is refused for lack of prior notice, unless U.S. Customs and Border Protection (CBP) concurrence is obtained for export and the article is immediately exported from the port of arrival under CBP supervision, it must be held within the port of entry for the article unless directed by CBP or FDA.

(ii) Inaccurate prior notice. If prior notice has been submitted and confirmed by FDA for review, but upon review of the notice or examination of the article of food, the notice is determined to be inaccurate, the food is subject to refusal of admission under section 801(m)(1) of the act. If the article of food is refused due to inaccurate prior notice, unless CBP concurrence

is obtained for export and the article is immediately exported from the port of arrival under CBP supervision, it must be held within the port of entry for the article unless directed by CBP or FDA.

(iii) Untimely prior notice. If prior notice has been submitted and confirmed by FDA for review, but the full time that applies under § 1.279 for prior notice has not elapsed when the article of food arrives, the food is subject to refusal of admission under section 801(m)(1) of the act, unless FDA has already reviewed the prior notice, determined its response to the prior notice, and advised CBP of that response. If the article of food is refused due to untimely prior notice, unless CBP concurrence is obtained for export and the article is immediately exported from the port of arrival under CBP supervision, it must be held within the port of entry for the article unless directed by CBP or FDA.

(2) Status and movement of refused food. (i) An article of food that has been refused under section 801(m)(1) of the act and paragraph (a) of this section shall be considered general order merchandise as described in section 490 of the Tariff Act of 1930, as amended (19 U.S.c. 1490).

(ii) Refused food must be moved under appropriate custodial bond unless immediately exported under CBP supervision. If the food is to be held at the port, FDA must be notified of the location where the food is held at that port before the food is moved there. If the food is to be held at a secure facility outside the port, FDA must be notified of the location of the secure facility before the food is moved there. The refused food shall not be entered and shall not be delivered to any importer, owner, or ultimate consignee. If the food is to be held at a secure facility outside a port, the food must be taken directly to that secure facility.

(3) Segregation of refused foods. If an article of food that is refused is part of a shipment that contains articles of food that have not been placed under hold or other merchandise not subject to this subpart, the refused article of food may be segregated from the rest of the shipment. This segregation must take place where the article is held. FDA or CBP may supervise segregation. If FDA or CBP determines that supervision is necessary, segregation must not take place without supervision.

(4) Costs. Neither FDA nor CBP are liable for transportation, storage, or other expenses resulting from refusal.

(5) Export after refusal. An article of food that has been refused under paragraph (a) of this section may be exported with CBP concurrence and under CBP supervision unless it is seized or administratively detained by FDA or CBP under other authority. If an article of food that has been refused admission under paragraph (a) of this section is exported, the prior notice should be cancelled within 5-business days of exportation.

(6) No post-refusal submission or request for review. If an article of food is refused under section 801(m)(1) of the act and no prior notice is submitted or reSubmitted, no request for FDA review is submitted in accordance with paragraph (d) of this section, or export has not occurred in accordance with paragraph (a)(5) of this section, the article of food shall be dealt with as set forth in CBP regulations relating to general order merchandise (19 CFR part 127), except that, unless otherwise agreed to by CBP and FDA, the article may only be sold for export or destroyed.

(b) Food carried by or otherwise accompanying an individual. If food carried by or otherwise accompanying an individual arriving in the United States is not for personal use and does not have adequate prior notice or the individual cannot provide FDA or CBP with a copy of

the prior notice (PN) confirmation. the food is subject to refusal of admission under section 801 (m)(1) of the act. If before leaving the port, the individual does not arrange to have the food held at the port or exported, FDA or CBP may destroy the article of food.

(c) Post-Refusal prior notice submissions. (1) If an article of food is refused under paragraph (a)(1)(i) of this section (no prior notice) and the food is not exported, prior notice must be submitted in accordance with §§ 1.280 and 1.281(c).

(2) If an article of food is refused under paragraph (a)(1)(ii) of this section (inaccurate prior notice) and the food is not exported, the prior notice should be canceled in accordance with § 1.282 and you must resubmit prior notice in accordance with §§ 1.280 and 1.281(c).

(3) Once the prior notice has been submitted or resubmitted and confirmed by FDA for review, FDA will endeavor to review and respond to the prior notice submission within the timeframes set out in § 1.279.

(d) FDA review after refusal. (1) **If** an article of food has been refused admission under section 801 (m)(1) of the act, a request may be submitted asking FDA to review whether the article is subject to the requirements of this subpart under § 1.277, or whether the information submitted in a prior notice is complete and accurate. A request for review may not be used to submit prior notice or to resubmit an inaccurate prior notice.

(2) A request may be submitted only by the carrier, submitter, importer, owner, or ultimate consignee. A request must identify which one the requester is.

(3) A request must be submitted in writing to FDA and delivered by fax or e-mail. The location for receipt of a request is listed at <http://www.fda.gov>--see Prior Notice. A request must include all factual and legal information necessary for FDA to conduct its review. Only one request for review may be submitted for each refused article.

(4) The request must be submitted within 5-calendar days of the refusal. FDA will review and respond within 5-calendar days of receiving the request.

(5) If FDA determines that the article is not subject to the requirements of this subpart under § 1.277 or that the prior notice submission is complete and accurate, it will notify the requester, the transmitter, and CBP that the food is no longer subject to refusal under section 801(m)(1) of the act.

(e) International mail. If an article of food arrives by international mail with inadequate prior notice or the PN confirmation number is not affixed as required, the parcel will be held by CBP for 72 hours for FDA inspection and disposition. If FDA refuses the article under section 801 (m)(1) of the act and there is a return address, the parcel may be returned to sender marked "No Prior Notice--FDA Refused." If the article is refused and there is no return address or FDA determines that the article of food in the parcel appears to present a hazard, FDA may dispose of or destroy the parcel at its expense. If FDA does not respond within 72 hours of the CBP hold, CBP may return the parcel to the sender or, if there is no return address, destroy the parcel, at FDA expense.

(f) Prohibitions on delivery and transfer. (1) Notwithstanding section 801 (b) of the act, an article of food refused under section 801(m)(1) of the act may not be delivered to the importer, owner, or ultimate consignee until prior notice is submitted to FDA in accordance with this subpart, FDA has examined the prior notice, FDA has determined that the prior notice is adequate, and FDA has notified CBP and the transmitter that the article of food is no longer refused admission under section 801 (m)(1) of the act.

(2) During the time an article of food that has been refused under section 801 (m)(1) of the act is held, the article may not be transferred by any person from the port or other designated

secure facility until prior notice is submitted to FDA in accordance with this subpart, FDA has examined the prior notice, FDA has determined that the prior notice is adequate, and FDA has notified CBP and the transmitter that the article of food no longer is refused admission under section 80I(m)(I) of the act. After this notification by FDA to CBP and transmitter, entry may be made in accordance with law and regulation.

(g) Relationship to other admissibility decisions. A determination that an article of food is no longer refused under section 80I(m)(1) of the act is different than, and may come before, determinations of admissibility under other provisions of the act or other U.S. laws. A determination that an article of food is no longer refused under section 80I(m)(I) of the act does not mean that it will be granted admission under other provisions of the act or other U.S. laws.

§ 1.284 What are the other consequences of failing to submit adequate prior notice or otherwise failing to comply with this subpart?

(a) The importing or offering for import into the United States of an article of food in violation of the requirements of section 801 (m) of the act, including the requirements of this subpart, is a prohibited act under section 301(ee) of the act (21 U.S.c. 33I(ee)).

(b) Section 301 of the act prohibits the doing of certain acts or causing such acts to be done.

(I) Under section 302 of the act (21 U.S.c. 332), the United States can bring a civil action in Federal court to enjoin persons who commit a prohibited act.

(2) Under sections 301 and 303 of the act (21 U.S.c. 331 and 333), the United States can bring a criminal action in Federal court to prosecute persons who are responsible for the commission of a prohibited act.

(c) Under section 306 of the act (21 U.S.c. 335a), FDA can seek debarment of any person who has been convicted of a felony relating to importation of food into the United States or any person who has engaged in a pattern of importing or offering for import adulterated food that presents a threat of serious adverse health consequences or death to humans or animals.

§ 1.285 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?

(a) Consequences. If an article of food from a foreign facility that is not registered as required under section 415 of the act (21 U.S.c. 350d) and subpart H of this part is imported or offered for import into the United States, the food is subject to being held under section 801(1) of the act (21 U.S.c. 381 (l)).

(b) Hold. Unless CBP concurrence is obtained for export and the article is immediately exported from the port of arrival, if an article of food has been placed under hold under section 801(1) of the act, it must be held within the port of entry for the article unless directed by CBP or FDA.

(c) Status and movement of held food. (I) An article of food that has been placed under hold under section 801(1) of the act shall be considered general order merchandise as described in section 490 of the Tariff Act of 1930, as amended (19 U.S.c. 1490).

(2) Food under hold under section 801(1) of the act must be moved under appropriate custodial bond unless immediately exported under CBP supervision. If the food is to be held at the port, FDA must be notified of the location where the food is held at the port before the food is moved there. If the food is to be held at a secure facility outside the port, FDA must be notified of the location of the secure facility before the food is moved there. The food subject to hold shall not be entered and shall not be delivered to any importer, owner, or ultimate

consignee. If the food is to be held at a secure facility outside a port, the food must be taken directly to that secure facility.

(d) Segregation of held foods. If an article of food that has been placed under hold under section 801(1) of the act is part of a shipment that contains articles that have not been placed under hold, the food under hold may be segregated from the rest of the shipment. This segregation must take place where the article is held. FDA or CBP may supervise segregation. If FDA or CBP determine that supervision is necessary, segregation must not take place without supervision.

(e) Costs. Neither FDA nor CBP will be liable for transportation, storage, or other expenses resulting from any hold.

(f) Export after hold. An article of food that has been placed under hold under section 801 (l) of the act may be exported with CBP concurrence and under CBP supervision unless it is seized or administratively detained by FDA or CBP under other authority.

(g) No registration or request for review. If an article of food is placed under hold under section 801(1) of the act and no registration number or request for FDA review is submitted in accordance with paragraph (j) of this section or export has not occurred in accordance with paragraph (f) of this section, the food shall be dealt with as set forth in CBP regulations relating to general order merchandise, except that, unless otherwise agreed to by CBP and FDA, the article may only be sold for export or destroyed.

(h) Food carried by or otherwise accompanying an individual. If an article of food carried by or otherwise accompanying an individual arriving in the United States is not for personal use and is placed under hold under section 801(1) of the act because it is from a foreign facility that is not registered as required under section 415 of the act and subpart H of this part, the individual

may arrange to have the food held at the port or exported. If such arrangements cannot be made, the article of food may be destroyed.

(i) Post-hold submissions. (1) To resolve a hold, if an article of food is held under paragraph (b) of this section because it is from a foreign facility that is not registered, the facility must be registered and a registration number must be obtained.

(2) The FDA Prior Notice Center must be notified of the applicable registration number in writing. The notification must provide the name and contact information for the person submitting the information. The notification may be delivered to FDA by fax or e-mail. The contact information for these delivery methods is listed at <http://www.fda.gov>--see Prior Notice. The notification should include the applicable CBP entry identifier.

(3) If FDA determines that the article is no longer subject to hold, it will notify the person who provided the registration information and CBP that the food is no longer subject to hold under section 801(1) of the act.

(j) FDA review after hold. (1) If an article of food has been placed under hold under section 801 (l) of the act, a request may be submitted asking FDA to review whether the facility associated with the article is subject to the requirements of section 415 of the act. A request for review may not be submitted to obtain a registration number.

(2) A request may be submitted only by the carrier, submitter, importer, owner, or ultimate consignee of the article. A request must identify which one the requestor is.

(3) A request must be submitted in writing to FDA and delivered by fax or e-mail. The location for receipt of a request is listed at <http://www.fda.gov>--see Prior Notice. A request must include all factual and legal information necessary for FDA to conduct its review. Only one request for review may be submitted for each article under hold.

(4) The request must be submitted within 5-calendar days of the hold. FDA will review and respond within 5-calendar days of receiving the request.

(5) If FDA determines that the article is not from a facility subject to the requirements of section 415 of the act, it will notify the requestor and CBP that the food is no longer subject to hold under section 801 (l) of the act.

(k) International mail. If an article of food that arrives by international mail is from a foreign facility that is not registered as required under section 415 of the act and subpart H of this part, the parcel will be held by CBP for 72 hours for FDA inspection and disposition. If the article is placed under hold under section 801(l) of the act and there is a return address, the parcel may be returned to sender marked "No Registration--No Admission Permitted." If the article is under hold and there is no return address or FDA determines that the article of food in the parcel appears to present a hazard, FDA may dispose of or destroy the parcel at its expense. If FDA does not respond within 72 hours of the CBP hold, CBP may return the parcel to the sender marked "No Registration--No Admission Permitted" or, if there is no return address, destroy the parcel, at FDA expense.

(l) Prohibitions on delivery and transfer. Notwithstanding section 801(b) of the act, while an article of food is under hold under section 801(l) of the act, it may not be delivered to the importer, owner, or ultimate consignee. If an article of food is no longer subject to hold under section 801(l) of the act, entry may be made in accordance with law and regulation.

(m) Relationship to other admissibility provisions. A determination that an article of food is no longer subject to hold under section 801(l) of the act is different than, and may come before, determinations of admissibility under other provisions of the act or other U.S. laws. A

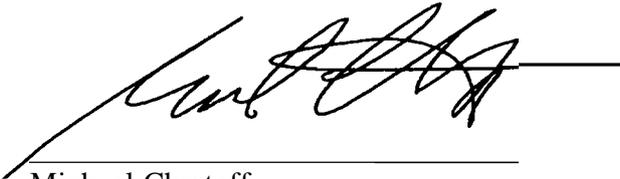
determination that an article of food is no longer under hold under section 801(1) of the act does not mean that it will be granted admission under other provisions of the act or other U.S. laws.

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10/30/08

Dated: 10/29/08 —

A handwritten signature in black ink, appearing to read "Michael Chertoff", is written over a horizontal line. The signature is stylized and cursive.

Michael Chertoff,
Secretary of Homeland Security.

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10/30/08

Dated: JUL 1 2008



Michael O. Leavitt,
~~Secretary of Health and Human Services.~~

CERTIFIED TO BE A TRUE
COPY OF THE ORIGINAL

