

Guidance for Industry

Prior Notice of Imported Food Questions and Answers (Edition 3)

Draft Guidance

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For questions regarding this draft document contact the Division of Food Defense Targeting (DFDT) at 866-521-2297.

**U.S. Department of Health and Human Services
Food and Drug Administration
Office of Regulatory Affairs
Center for Food Safety and Applied Nutrition
Center for Veterinary Medicine
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This is the third version of the FDA guidance “Prior Notice of Imported Food Questions and Answers,” which FDA issued in December 2003 and revised in May 2004. Revisions/additions are noted by date. The question numbering system and Table of Contents have been revised for clarity.

TABLE OF CONTENTS

I. INTRODUCTION

II. PRIOR NOTICE QUESTIONS AND ANSWERS

A. BACKGROUND

1. General
2. Outreach

B. DEFINITIONS

1. Food – General
2. Food – Chemicals and Food Additives
3. Food – Live Animals
4. Food – Seeds
5. Food – Placebos
6. Food -- Popcorn Used as Packing Material
7. FDA Country of Production
8. International Mail
9. Port of Arrival/Port of Entry
10. United States

C. SCOPE

1. General
2. Airline Food
3. Charities
4. Express Carriers or Express Consignment Operators
5. Farms
6. Food Not for Consumption in the U.S.
7. Foreign Trade Zones
8. Gifts
9. Household Goods
10. International Mail
11. In-transit Shipments
12. Meat
13. [Reserved]
14. Produce
15. Personal Baggage
16. Personal Shipments
17. Samples
18. U.S. Goods Returned

*Contains Nonbinding Recommendations
Draft-Not for Implementation*

- D. REQUIREMENTS TO SUBMIT PRIOR NOTICE OF IMPORTED FOOD
 - 1. Submitter and Transmitter
 - 2. Deadlines for Prior Notice
 - 3. Submitting Prior Notice
 - 4. General Information Requirements
 - 5. Registration Numbers
 - 6. Grower Identity
 - 7. Product Identity
 - 8. Ultimate Consignee
 - 9. Refusal Country
 - 10. Changes to Prior Notice Submissions
 - 11. Changes to Shipments
 - 12. PNSI and ACS/ABI Features
 - 13. Confirmation

- E. CONSEQUENCES
 - 1. Inadequate Prior Notice
 - 2. Transition Period and Exercise of Enforcement Discretion

III. ELECTRONIC ACCESS

IV. WHERE TO GET ADDITIONAL INFORMATION

- A. **Prior Notice Help Desk**
- B. **Useful Websites**

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This draft guidance, when finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You may use an alternate approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate telephone number listed on the title page of this guidance.

I. INTRODUCTION

On November 7, 2008, the Food and Drug Administration (FDA or we) published a final rule (Prior Notice rule) in the Federal Register requiring submission to FDA of prior notice of food, including food for animals, that is imported or offered for import into the United States (73 FR 66294). The Prior Notice rule implements section 801(m) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 381(m)), which was added by section 307 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) (Public Law 107-188), and requires that FDA receive prior notice of food imported into the United States. Section 304 of the FDA Food Safety Modernization Act (FSMA) (Public Law 111-353) amended section 801(m) of the FD&C Act.

On May 5, 2011, FDA published an interim final rule "Information Required in Prior Notice of Imported Food" (76 FR 25542). The interim final rule amended the Agency's regulations on prior notice of imported food. As required by section 304 of FSMA, FDA issued the interim final rule to require an additional element of information in a prior notice of imported food. This change requires a person submitting prior notice of imported food, including food for animals, to report the name of any country to which the article has been refused entry. Section 304 of FSMA also required the interim final rule be published no later than 120 days following the date of enactment of the legislation and that the amendment made by section 304 take effect 180 days after the date of enactment. The effective date of the interim final rule was July 3, 2011.

¹ This guidance has been prepared by the Division of Food Defense Targeting in cooperation with the Center for Food Safety and Applied Nutrition and the Center for Veterinary Medicine of the U.S. Food and Drug Administration.

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On May 30, 2013, FDA published a final rule (78 FR 32359) that adopted, without change, the interim final rule.

This guidance document provides a list of questions that frequently have been asked about the requirements of the prior notice regulation, and the answers to those questions. This document is being issued to help the food industry and others comply with the legal requirements established by the Prior Notice rule.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidance describes the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidance means that something is suggested or recommended, but not required.

II. PRIOR NOTICE QUESTIONS AND ANSWERS

A. BACKGROUND

1. General

1.1 What is prior notice?

[Response updated March 2014] Prior notice is notification to the FDA that an article of food, including food for animals, is being imported or offered for import into the United States in advance of the arrival of the article of food at the U.S. border.

Additional information on the prior notice regulation may be found in sections 1.276-1.285 of Title 21 of the Code of Federal Regulations (CFR), and on FDA's web site at <http://www.fda.gov/Food/GuidanceRegulation/ImportsExports/Importing/ucm114217.htm>. For additional information on the U.S. Customs and Border Protection's (CBP's) procedures for prior notice, you may want to consult the CBP website at <http://www.cbp.gov>.

1.2 Why is prior notice required to be submitted to FDA?

[Response updated March 2014] Prior notice is required by section 801(m) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 381(m)). Section 801(m) of the FD&C Act requires advance

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notification to FDA prior to the arrival of food imported or offered for import into the U.S.

1.3 When did prior notice go into effect?

[Question/response updated March 2014] The prior notice requirements took effect on December 12, 2003, with the publication of the Prior Notice Interim Final Rule (IFR) (68 FR 58974; October 10, 2003).

1.4 What if I have a question about or need clarification on 21 CFR part 1, subpart I?

[Response updated March 2014] In addition to this document, you may wish to review the preambles to the 2003 interim final rule, the 2008 final rule, the 2011 interim final rule, and the 2013 final rule which answer many of the questions that we have received regarding prior notice requirements. The rules may be found at

<http://www.fda.gov/Food/GuidanceRegulation/ImportsExports/Importing/ucm153853.htm>.

If you have further questions about prior notice, you can submit them to FDA by using the form at

<http://www.accessdata.fda.gov/scripts/email/cfsan/bioterrorismact/helpf2.cfm>.

Due to the large number of inquiries received and our limited resources, we issue guidance documents periodically to answer those questions that are not directly addressed in the Prior Notice rule or its preambles. Please check our website periodically to obtain a copy of these guidance documents at

<http://www.fda.gov/Food/GuidanceRegulation/ImportsExports/Importing/ucm2006836.htm>.

2. Outreach

2.1 How can industry learn how to comply with the Prior Notice rule and submit prior notice through the U.S. Customs and Border Protection (CBP) Automated Broker Interface of the Automated Commercial System (ABI/ACS) or FDA Prior Notice System Interface (PNSI)?

[Response updated March 2014] We have prepared several tools, such as tutorials, instructions, and question-and-answer documents, to help importers and other affected persons submit prior notice either through ABI/ACS or PNSI. These are available on FDA's website at

<http://www.fda.gov/Food/GuidanceRegulation/ImportsExports/Importing/ucm2006837.htm>.

2.2 Where can I get more information about FDA's prior notice regulation?

[Response updated March 2014] Information on the prior notice regulation may be found on FDA's web site at <http://www.fda.gov>. Many of your questions can be answered by reading the Prior Notice rule or by reviewing the tutorials, fact sheet, and other materials that are posted on the web site. If your questions are not answered by information on that website, you can send an email by using the form found at <http://www.accessdata.fda.gov/scripts/email/cfsan/bioterrorismact/helpf2.cfm>. We will likely answer the questions in guidance documents rather than through individual responses. Please check our website periodically to obtain a copy of these guidance documents at <http://www.fda.gov/Food/GuidanceRegulation/ImportsExports/Importing/ucm2006836.htm>.

2.3 Where can I get more information about CBP's procedures under the Bioterrorism Act and the prior notice regulation?

For additional information on the U.S. Customs and Border Protection's (CBP's) procedures for prior notice, consult the CBP website at <http://www.cbp.gov>.

B. DEFINITIONS

1. Food - General

1.1 For the purposes of the prior notice regulation, what is food?

[Response updated March 2014] Food is defined in § 1.276 by reference to section 201(f) of the FD&C Act, which defines food as articles used for food or drink for man or other animals, chewing gum, and articles used for components of any such articles (21 U.S.C. 321(f)). However, for purposes of prior notice, the definition of food does not include food contact substances or pesticides (21 CFR 1.276(b) (5)(i)). Examples of food subject to prior notice include: fish and seafood, live food animals, dairy products, shell eggs, fruits, vegetables, raw agricultural commodities for use as food or as components of food and animal feed (including pet food), food and feed ingredients, food and feed additives, infant formula, beverages (including alcoholic beverages and bottled water), bakery goods, snack foods, candy, canned foods, and dietary supplements and dietary ingredients.

1.2 Is a bulk commodity like raw cane sugar “food” subject to prior notice?

[Response updated March 2014] A bulk commodity is subject to prior notice if it is food as defined in 21 CFR 1.276(b)(5). This includes articles for use as food, including for use as a component of food. Raw agricultural commodities for use as food or as components of food such as raw cane sugar are food for prior notice purposes (21 CFR 1.276(b)(5)(ii)). For the purpose of prior notice, FDA considers an article as one that will be used for food if it is reasonably likely to be directed to a food use. For more discussion on this topic, please see the preamble to the 2008 final rule at 73 FR 66294 at 66300-01; November 7, 2008.

2. Food – Chemicals and Food Additives

2.1 Are chemicals used to manufacture food additives food for prior notice purposes?

[Response updated March 2014] Yes. Chemicals that are used for food or drink or are used for components of any such articles are food and are subject to FDA’s prior notice regulations. However, if the chemicals are used for food contact substances or pesticides or components of food contact substances or pesticides, prior notice is not required (See 21 CFR 1.276(b)(5)). For more discussion on this topic, please see the preamble to the 2008 final rule at 73 FR 66294 at 66301; November 7, 2008.

2.2 What are some examples of food contact substances?

[Response updated March 2014] Food packaging materials, empty food packages, ceramic dinnerware, brass drinking vessels, and corn husks to be used as tamale wrappers, are examples of food contact substances. Even though these foods are excluded from prior notice requirements in section 801(m) of the FD&C Act, they are still subject to other provisions of the FD&C Act, including section 801(a) of the FD&C Act (21 U.S.C. 381(a)) and FDA will continue to make admissibility decisions about them.

2.3 Are secondary direct food additives, many of which are processing aids, exempt from prior notice as “food contact substances”?

[Response updated March 2014] Some secondary direct food additives meet the definition of food contact substances as given in section 409(h)(6) of the FD&C Act (21 U.S.C. 348(h)(6)) and, therefore, would not be subject to the prior notice requirements (21 CFR 1.276(b)(5)(i)(A)). If a secondary direct food additive is not a food contact substance but is, for example, a food processing aid, then it would be subject to prior

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notice. For more discussion of this topic, please see the preamble to the 2008 final rule at 73 FR 66294 at 66301; November 7, 2008.

3. Food – Live Animals

3.1 Are live animals “food” for prior notice purposes?

[Response updated March 2014] Live animals are food for purposes of prior notice if the live animal is reasonably likely to be directed to a food use (73 FR 66294 at 66306; November 7, 2008) (see 21 CFR 1.276(b)(5)). Note that live food animals are not excluded from prior notice under section 801(m)(3)(B) of the FD&C Act and 21 CFR 1.277(b)(4) or (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.

Live animals are capable of multiple uses, such as food, pets, research, or letting them stay wild. In these situations, the question is whether it is reasonably likely to be directed to a food use. Cows are almost always directed to a food use eventually, even if that is not the immediate use.

Some small animals (e.g., guinea pigs) that are imported end up as food. When this food use is not intended or reasonably likely at the time of import, such as when they are imported as pets, then prior notice would not be required.

Horses are sometimes imported for a food use – slaughter and export as food. However, many are imported for non-food uses, such as shows, racing, and pets. When imported for a non-food use, a horse is not subject to prior notice requirements, unless it is reasonably likely to be directed to a food use.

3.2 If USDA’s Animal and Plant Health Inspection Service (APHIS) inspects the live animals when they are imported into the U.S., are the live animals “food” for prior notice purposes?

[Response updated March 2014] Yes. Live food animals that are subject to border inspections by APHIS are also subject to FDA’s prior notice requirements. FDA and APHIS may both have jurisdiction over live animals. Note that the requirement for prior notice to FDA for live food animals does not alter the role of APHIS in, or any APHIS requirements relating to, inspection of live animals imported into the U.S. With respect to food jointly regulated by USDA (including APHIS) and FDA, only food under the exclusive jurisdiction of USDA at the time of importation

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is excluded from prior notice. See 73 FR 66294 at 66306; November 7, 2008.

3.3 Are game animals “food” for which prior notice must be given?

[Response updated March 2014] Yes. If the animal is reasonably likely to be directed to a food use, the animal is food for which prior notice is required (See 21 CFR 1.276(b)(5)). For example, elk imported to stock a ranch where the elk are hunted and used for food would be food under the prior notice definition. By contrast, elk imported for repopulating a national park where hunting the elk is not permitted would not be food for which prior notice is required. Note that neither live game animals intended for food nor the food products derived from them are excluded from prior notice under section 801(m)(3)(B) of the FD&C Act and 21 CFR 1.277(b)(4) or (5); neither the live game animals intended for food nor the food products derived from them fall within the exclusive jurisdiction of USDA under the Federal Meat Inspection Act or Poultry Products Inspection Act.

4. Food - Seeds

4.1 Are seeds subject to prior notice requirements?

[Response updated March 2014] The answer depends on whether the seeds meet the definition of food. FDA considers a seed to be food if it is reasonably likely to be directed to a food use (73 FR 66294 at 66301; November 7, 2008). For example, if the seed is for use in animal feed, the seed is food and prior notice is required (21 CFR 1.276(b)(5); 21 CFR 1.277(a)). Similarly, if the seed is to be used for human food, such as sesame seeds to be used in baking or oilseeds for processing into edible oil, then prior notice must be submitted to FDA before the seed is imported or offered for import into the U.S.

If the seed will be used for the production of edible sprouts, such as alfalfa seeds for production of alfalfa sprouts, then you must provide prior notice to FDA before the seeds are imported or offered for import. By contrast, if the seed is only for cultivation (even if it is used to grow a plant that may subsequently be consumed as food), then prior notice is not required.

FDA has an enforcement discretion policy regarding seeds for planting. Under the policy, FDA and CBP would typically consider not taking any regulatory action regarding seeds that will be used for cultivation. The policy applies when no more than a small portion of that seed is diverted from cultivation to animal feed or other food use. It does not apply, however, where the seed is used for the production of edible sprouts, such as alfalfa seeds for the production of alfalfa sprouts. For further

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discussion, see FDA's Compliance Policy Guide on FDA's website at <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/FoodDefense/ucm153055.htm>.

5. Food - Placebos

5.1 [Question/response added March 2014] Is prior notice required for placebos that are imported for testing purposes?

If the product is for pharmaceutical testing purposes, e.g., for use in a clinical trial involving a prescription or non-prescription drug, then prior notice is not required. However, if the product is being imported for use in the testing of dietary supplements or dietary ingredients, prior notice is required.

6. Food - Popcorn Used as Packing Material

6.1 [Question/response added March 2014] Is prior notice required for popcorn that is used as a packing material for shipping?

When a substance is capable of having a food use and a nonfood use, FDA will consider the substance to be "food" for the purpose of prior notice if it is reasonably likely to be directed to a food use (73 FR 66294 at 66301; November, 7, 2008). Therefore, prior notice is required if the popcorn used as a packing material is reasonably likely to be directed to a food use.

7. FDA Country of Production

7.1 What is the FDA Country of Production and how does it differ from CBP's Country of Origin?

[Response updated March 2014] "FDA Country of Production" is defined in 21 CFR 1.276(b)(4). For food that is in its natural state (21 CFR 1.276(b)(4)(i)), the FDA Country of Production is generally the country where the food was grown or collected, including harvested and readied for shipment to the U.S. Articles of food grown, including harvested or collected and readied for shipment, in U.S. territories are considered to be grown in the U.S. (21 CFR 1.276(b)(4)(i)). However, for wild fish, including seafood, that is caught or harvested outside U.S. waters by a vessel that is not registered in the U.S., the FDA Country of Production is the country in which the vessel is registered (21 CFR 1.276(b)(4)(i)). For further discussion on this topic, please see 73 FR 66294 at 66355; November 7, 2008.

For food that is no longer in its natural state, the FDA Country of Production is generally the country where the food was made or

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processed. However, if the article is made from wild fish aboard a vessel, the FDA Country of Production is the country in which the vessel is registered (21 CFR 1.276(b)(4)(i)). If food that is no longer in its natural state was made in a U.S. Territory, the FDA Country of Production is the U.S. (21 CFR 1.276(b)(4)(ii)).

The FDA Country of Production may be different from the CBP Country of Origin. For example, the CBP Country of Origin for beans that are grown and dried in the U.S., then rehydrated and canned in the Dominican Republic would be the U.S. (see 19 CFR 177.22). The FDA Country of Production would be the Dominican Republic. Therefore, for purposes of the prior notice provisions of the FD&C Act, the “article of food” is canned beans, not dried beans. From a food safety standpoint, FDA is most interested in knowing where the article of food was processed and canned. To avoid confusion between FDA’s prior notice requirements and CBP requirements, the rule uses the term “FDA Country of Production” instead of the term “originating country” or “country from which the article originates.” “FDA Country of Production” is already familiar to customs brokers and self-filers using the ABI/ACS interface with FDA’s Operational and Administrative System for Import Support (OASIS). For more information see 73 FR 66294 at 66355; November 7, 2008.

8. International Mail

8.1 Are express carriers, such as Federal Express, considered “international mail”?

[Response updated March 2014] As stated in 21 CFR 1.276(b)(8), the term “international mail” only covers foreign national mail services. Express carriers, such as Federal Express, as well as express consignment operators, or other private delivery services are not considered international mail unless such service is operating under contract as an agent or extension of a foreign mail service (21 CFR 1.276(b)(8)).

9. Port of Arrival/Port of Entry

9.1 What is the “port of arrival” and how does it differ from the “port of entry”?

[Response updated March 2014] The port of arrival is the water, air, or land port at which the article of food is imported or offered for import into the U.S., i.e., the port where the article of food first arrives in the U.S. (21 CFR 1.276(b)(11)). 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 U.S. According to FDA regulations at 21 CFR 1.276(b)(12), the term “port of

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entry” means the port of entry as defined in 19 CFR 101.1. The term port of entry according to CBP regulations “refer[s] to any place designated by Executive Order..., 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 Customs and navigation laws.” (19 CFR 101.1).

9.2 Can the port of arrival differ from the port of entry (i.e., port where entry is made)?

[Question/response updated March 2014] Yes. The port of arrival is the port where the articles first arrive in the U.S. A consumption or warehouse entry or foreign trade zone admission documentation may be presented to CBP at a different port of entry than the port of arrival. Note that timeframes for submission of prior notice are tied to the time of arrival in the port of arrival, not arrival in the port of entry.

10. United States

10.1 Is prior notice required for foods that are imported into Puerto Rico?

[Response updated March 2014] Yes. FDA regulations at 21 CFR 1.276(b)(15) define the U.S. to be the 50 states, the District of Columbia, and the Commonwealth of Puerto Rico, but not the U.S. Territories. Therefore, prior notice is required for food that comes from outside the U.S. into Puerto Rico, but not for food shipped from Puerto Rico into the 50 states or the District of Columbia.

10.2 Is prior notice required for foods that are imported into the U.S. Territories?

[Response updated March 2014] No. FDA regulations at 21 CFR 1.276(b)(15) define the U.S. to be the 50 states, the District of Columbia, and the Commonwealth of Puerto Rico, but not the U.S. Territories. Therefore, prior notice is not required for food shipped into a U.S. Territory. However, prior notice is required for food coming from a U.S. Territory (e.g., Guam, the U.S. Virgin Islands, and the Northern Mariana Islands) into the 50 states, the District of Columbia or the Commonwealth of Puerto Rico.

10.3 Is prior notice required for shipments originating in another North American Free Trade Agreement (NAFTA) country?

[Question/response updated March 2014] Yes. Because the “U.S.” is defined for purposes of prior notice to be the Customs territory of the U.S. (21 CFR 1.276(b)(15)), food that is imported into the 50 states, the District

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of Columbia, or the Commonwealth of Puerto Rico from a country that is a signatory to the North American Free Trade Agreement (other than the U.S.) is subject to prior notice.

C. SCOPE

1. General

1.1 What is the scope of the prior notice regulation? What shipments of food imported or offered for import into the U.S. require prior notice?

[Response updated March 2014] If the article that is shipped to the U.S. is food within the meaning of 21 CFR 1.276(b)(5), then prior notice generally is required, even if the item is intended for further processing, is not intended for consumption in the U.S., or is not intended for commercial distribution. Thus, prior notice is required for all food for humans and other animals that is imported or offered for import into the U.S. for use, storage, or distribution in the U.S., including food for gifts and trade and quality assurance/quality control samples, food for transshipment through the U.S. to another country, food for future export, and food for use in a U.S. Foreign Trade Zone.

1.2 Are there any exemptions from the prior notice requirements?

[Response updated March 2014] Yes. As stated in 21 CFR 1.277(b), prior notice is not required for:

- a. Food for an individual's personal use (i.e., for consumption by the individual, family, or friends, and not for sale or other distribution) when it is carried by or otherwise accompanies the individual when arriving in the U.S.;
- b. Food that was made by an individual in his/her personal residence and sent by that individual as a personal gift (i.e., for non-business reasons) to an individual in the U.S.;
- c. Food that is imported then exported without leaving the port of arrival until export;
- d. Meat food products, poultry products, and egg products that are subject to the exclusive jurisdiction of the U.S. Department of Agriculture (USDA) at the time of importation; and
- e. 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).

1.3 Are there exemptions from prior notice for any of the following:

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- a. **Food items of small value or quantity;**
- b. **Food samples for research and development or for testing purposes only and not for consumption; or**
- c. **Food samples for test marketing?**

[Response updated March 2014] There are no exemptions from prior notice requirements for:

- a. Food based on the size or value of the shipment (73 FR 66294 at 66317; November 7, 2008);
- b. Samples of food, including food for animals, for research and development (73 FR 66294 at 66314-15; November 7, 2008). However, if the samples are items that are in such early stages of research and development that they cannot yet be considered food under 21 CFR 1.276(b)(5), they would not be subject to prior notice requirements. An example of such an item is a substance being tested for possible preservative qualities before being tested in any food. FDA has an enforcement discretion policy regarding food imported or offered for import without prior notice that will be used for quality assurance, research or analysis purposes, or “in vivo” testing in non-food producing laboratory animals. Under the policy, FDA and CBP should typically consider not taking any regulatory action when the samples of food are imported in quantities consistent with quality assurance, research, or analysis purposes, and the entire sample is used up by the analysis/testing or destroyed upon completion of the analysis/testing. For further discussion, see FDA’s Compliance Policy Guide on FDA’s website at <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/FoodDefense/ucm153055.htm>); or
- c. Samples of food, including food for animals, for test marketing (73 FR 66294 at 66314-15; November 7, 2008).

2. Airline Food

2.1 Is aircraft food exempt from prior notice, since any excess is incinerated at the U.S. airport? Is in-flight food, imported in bulk and moved in-bond to U.S. caterers, for use on export flights exempt?

If the aircraft food is consumed on the international flight or discarded and is not entered into the U.S. for use, storage, or distribution, it is outside the scope of the regulation, and prior notice is not required (21 CFR 1.277(a)).

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By contrast, prior notice is required for in-flight food that is moved to U.S. caterers for use on export flights or on domestic flights (21 CFR 1.277).

3. Charities

3.1 Is there an exemption for food imported for charity?

[Response updated March 2014] No. Food intended for charity is not exempt from prior notice. Although the Registration rule exempts nonprofit food establishments in which food is prepared for, or served directly to, the consumer from the requirements to register their facilities, (21 CFR 1.226(e)), the Prior Notice rule does not exempt food imported for use by those nonprofit food establishments. Thus, imported food that is imported for or by a U.S. charity is subject to prior notice (21 CFR 1.277).

4. Express Carriers or Express Consignment Operators

4.1 Is an article of food that is shipped by an express carrier or express consignment operators like FedEx exempt from prior notice?

[Response updated March 2014] No, imported food transported into the U.S. via express carriers or express consignment operators is not exempt from the requirements of the prior notice regulation. Articles imported via these private delivery services are subject to prior notice, which must be submitted within the timeframe for the applicable mode of transportation (21 CFR 1.279). See 73 FR 66294 at 66317; November 7, 2008.

5. Farms

5.1 Is prior notice required for tomatoes from a foreign farm that packs and exports tomatoes to the U.S. given that farms typically don't have to register?

[Response updated March 2014] Yes. The requirement for prior notice is not based on whether registration is required. FDA registration requirements apply to facilities that manufacture/process, pack, or hold food for consumption in the U.S. (21 CFR 1.225). The prior notice requirements apply to articles of food imported or offered for import into the U.S. Farms, as defined in 21 CFR 1.227(b)(3) and that fall within the exemption, are exempt from registration. However, the articles of food grown, harvested, or collected on farms are not exempt from prior notice requirements. Thus, generally, the food that a foreign farm exports to the U.S. is subject to the prior notice requirements (21 CFR 1.277).

6. Food Not for Consumption in the U.S.

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6.1 If the food will not be consumed in the U.S., is prior notice required?

[Response updated March 2014] Yes. Prior notice requirements apply even when the food will not be consumed in the U.S. You must submit prior notice for food that is for transshipment, further processing and export, or storage and export (See 21 CFR 1.277(a)). In contrast, the requirement to register facilities applies only to food facilities that manufacture/process, pack, or hold food for consumption in the U.S.

7. Foreign Trade Zones

7.1 Will imported food being admitted into a Foreign Trade Zone (FTZ) need to have prior notice?

[Response updated March 2014] Yes. Imported food for admission into a Foreign Trade Zone is subject to the prior notice regulation per 21 CFR 1.277. Prior notice is required before arrival in the U.S. and is, therefore, required prior to admission into a Foreign Trade Zone.

7.2 If I submit prior notice before a food is admitted into a FTZ, do I need to submit prior notice again before a food is withdrawn from the FTZ?

[Response updated March 2014] No. Because prior notice must be submitted before arrival and admission into a FTZ, prior notice is not required when the food is withdrawn from the FTZ, either as an export or for use within the U.S. However, if the food is withdrawn from the FTZ for consumption entry into the U.S., FDA must be notified and will make the admissibility decision about the consumption entry at that time.

8. Gifts

8.1 Does prior notice apply to homemade food sent as gifts from family living outside the U.S.?

[Response updated March 2014] No. 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 non-business reasons) to an individual in the U.S., prior notice is not required (21 CFR 1.277(b)(2)). Other food products sent as gifts are subject to the prior notice requirement (see 21 CFR 1.277). FDA's compliance policy pertaining to food products sent as gifts can be found at <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/FoodDefense/ucm153055.htm>.

8.2 Does prior notice apply to food in its natural state, grown by an individual, and sent to an individual in the U.S. as a gift?

[Response updated March 2014] No. Homegrown food sent by one individual to another as a gift (i.e., for non-business reasons) is not subject to prior notice (21 CFR 1.277(b)(2)). Other food products sent as gifts are subject to the prior notice requirement (see 21 CFR 1.277). FDA's compliance policy pertaining to food products sent as gifts can be found at <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/FoodDefense/ucm153055.htm>.

8.3 Is prior notice required if an individual purchases a food product, made by a third party, and sends it to an individual in the U.S. as a gift?

[Response updated March 2014] Yes. Food products, other than those that are homemade, sent as gifts are subject to the prior notice requirement (21 CFR 1.277(a)). FDA recognizes that, in these circumstances, the sender who purchased the food as a gift may not have the manufacturer registration number. In this situation, the sender can provide the name and full address of the manufacturer and the reason the registration number is not provided (21 CFR 1.281(a)(6), (b)(5)).

FDA has an enforcement discretion policy that applies to food sent as a gift that is purchased at a commercial establishment for non-commercial purposes (i.e., not for sale, resale, barter, or business use) and sent by a non-commercial shipper (e.g., the individual delivers the food to a post office or common carrier for delivery to an individual in the U.S.). Under the policy, FDA and CBP should typically consider not taking any regulatory action when an article of food purchased at a commercial establishment and shipped by the purchaser is imported or offered for import and there is no prior notice. See FDA's Compliance Policy Guide on FDA's website at

<http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/FoodDefense/ucm153055.htm> for further discussion.

9. Household Goods

9.1 Are foods included with my household goods subject to prior notice when I move to the U.S.?

[Response updated March 2014] Yes. FDA regulations at 21 CFR 1.277 do not exclude household goods of individuals moving to the U.S. However, FDA has an enforcement discretion policy that applies to most household goods. Under the policy, FDA and CBP should typically consider not taking any regulatory action when an article of food is

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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. See FDA's Compliance Policy Guide on FDA's website at <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/FoodDefense/ucm153055.htm> for further discussion.

9.2 Are foods included with my household goods subject to prior notice even if the move is covered by the military?

[Response updated March 2014] Yes. FDA regulations at 21 CFR 1.277 do not exclude household goods of military personnel moving back to the U.S. However, FDA has an enforcement discretion policy that applies to most household goods. Under the 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. See FDA's Compliance Policy Guide on FDA's website at <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/FoodDefense/ucm153055.htm> for further discussion.

10. International Mail

10.1 Is food imported into the U.S. by international mail exempt from prior notice?

[Response updated March 2014] No. Food imported via international mail is subject to prior notice, which must be submitted before the food is sent to the U.S. (21 CFR 1.279(c)).

11. In-Transit Shipments

11.1 Is prior notice required for food transiting the U.S. for exportation to another country, e.g., for a Transportation and Exportation (T&E) entry?

Yes. Prior notice is required for food for transshipment through the U.S. to another country and food for future export (21 CFR 1.277(a)).

12. Meat

12.1 Is prior notice required for meat, poultry, or egg products that are under the jurisdiction of the U.S. Department of Agriculture (USDA)?

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[Response updated March 2014] If, at the time the food is imported or offered for import, the food is subject to the exclusive jurisdiction of the USDA's 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.), the food is not subject to the requirements of prior notice (21 CFR 1.277(b)(4)-(b)(6)). The USDA's Food Safety and Inspection Service (FSIS) enforces these laws.

12.2 Is prior notice required for meat intended for food for animals, including pet food and treats?

[Question/response updated March 2014] Yes. Meat intended for food for animals, such as that fed to zoo animals or meat products intended to be incorporated into food for animals, is not under the jurisdiction of USDA/FSIS and is subject to the prior notice requirements. These meats include meat derived from cattle, swine, goats, sheep, horses, and mules that are destined for food for animals.

12.3 [Question/response added March 2014] Is prior notice required for casings?

According to the United States Department of Agriculture (USDA) Food Safety and Inspection Service (FSIS) Directive 9000.2:

- Products labeled as (species) intestines are derived from the intestinal tract of livestock (animals) and are meat byproducts. As meat byproducts, intestines are under FSIS jurisdiction.
- Products labeled as (species) casings are derived from the intestines of livestock (animals) and are used as containers to prepare sausage and other meat food products. Casings are under the jurisdiction of the FDA.

Therefore, prior notice is required for (species) casings, but not (species) intestines.

Artificial casings that are not edible, e.g., those made of plastic, do not require prior notice.

13. [Reserved]

14. Produce

14.1 Is produce that is inspected by the Animal and Plant Health Inspection Service's Plant Protection and Quarantine (PPQ) or graded by USDA's Agricultural Marketing Service subject to FDA's prior notice requirements?

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Yes. Such produce is not under the exclusive jurisdiction of the USDA. Only imported food that is regulated exclusively by USDA is exempt from the prior notice requirements.

15. Personal Baggage

15.1 I am bringing food from a foreign country in my luggage and for my personal use. Do I need to submit prior notice to FDA?

[Response updated March 2014] No. Prior notice is not required for food that is carried by or otherwise accompanies an individual when arriving in the U.S. (e.g., is in his or her carry-on or checked baggage) when the food is for that individual's personal use (21 CFR 1.277(b)(1)). Personal use means that the food is for consumption by the individual, the individual's pet(s), or by the individual's family and friends and is not for sale or other distribution. See 73 FR 66294 at 66305; November 7, 2008.

15.2 I plan to drive back to the U.S. from Canada with my trunk full of food I purchased there to serve at a family picnic. Is prior notice required?

[Response updated March 2014] No. Prior notice is not required for food that is carried by or otherwise accompanies an individual when arriving in the U.S. (e.g., is in his or her automobile) when the food is for that individual's personal use (21 CFR 1.277(b)(1)). Personal use means that the food is for consumption by the individual, individual's pet(s), or by the individual's family and friends and is not for sale or other distribution. See 73 FR 66294 at 66305; November 7, 2008.

15.3 I plan to drive back to the U.S. from Mexico with my trunk full of shellfish that I plan to sell at a flea market on the U.S. side of the border. Is prior notice required?

[Response updated March 2014] Yes. Prior notice is required for food that is imported or offered for import into the U.S. for use, storage, or distribution in the U.S. Prior notice is not required for food that is carried by or otherwise accompanies an individual entering the U.S. (e.g., is in his or her automobile) when the food is for that individual's personal use (21 CFR 1.277(b)(1)). Here, the shellfish are to be sold and are not for personal use.

15.4 I plan to drive back to the U.S. from Canada with my trunk full of samples of finished packaged foods for testing. Is prior notice required?

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[Response updated March 2014] Yes. Prior notice is required for food that is imported or offered for import into the U.S. for use, storage, or distribution in the U.S. Prior notice is not required for food that is carried by or otherwise accompanies an individual entering the U.S. (e.g., is in his or her automobile) when the food is for that individual's personal use (21 CFR 1.277(b)(1)). Here, the samples of finished packaged food are to be used for testing and not for personal use.

FDA has an enforcement discretion policy regarding food imported or offered for import without prior notice that will be used for quality assurance, research or analysis purposes, or "in vivo" testing in non-food producing laboratory animals. Under the policy, FDA and CBP should typically consider not taking any regulatory action when the samples of food are imported in quantities consistent with quality assurance, research, or analysis purposes, and the entire sample is used up by the analysis/testing or destroyed upon completion of the analysis/testing. For further discussion, see FDA's Compliance Policy Guide on FDA's website at

<http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/FoodDefense/ucm153055.htm>.

15.5 [Question/response added March 2014] While in Canada, I plan to buy animal food for my pets (such as, dog food, cat food, parakeet food, hay for my horses). Is prior notice required?

No. Prior notice is not required for food that is carried by or otherwise accompanies an individual entering the U.S. (e.g., food that is in his or her automobile or trailer) when the food is for that individual's personal use (21 CFR 1.277(b)(1)). FDA considers personal use to include food that is for consumption by the individual's personally owned pets or other companion animals and that is not for sale or other distribution (73 FR 66294 at 66305; November 7, 2008).

15.6 [Question/response added March 2014] I own a dairy farm in the U.S. and plan to go to Canada to buy a tractor trailer load of hay and bring the hay back to feed my cows. Is prior notice required for this hay?

Yes, prior notice is required because the personal use exemption would not apply in this situation. Prior notice is not required for food that is carried by or otherwise accompanies an individual entering when arriving in the U.S. (e.g., is in his or her automobile) when the food is for that individual's personal use (21 CFR 1.277(b)(1)). Personal use 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. See 73 FR 66294 at 66305; November 7, 2008. Here, the food is for livestock use – feeding

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the hay to your dairy cows whose milk is sold to others – rather than for personal use.

16. Personal Shipments

16.1 Is prior notice required for food for personal use that I ship to myself while overseas and, therefore, does not accompany me when I return to the U.S.?

[Response updated March 2014] Yes. Food purchased abroad and sent to the U.S. (i.e., does not accompany the individual when arriving in the U.S.) is subject to prior notice (21 CFR 1.277).

However, FDA has an enforcement discretion policy that applies to food for non-commercial purposes with a non-commercial shipper. Under the policy, FDA and CBP should typically consider not taking any regulatory action when an article of food purchased by a traveler and mailed to the traveler's U.S. address by the traveler is imported or offered for import without prior notice. See FDA's Compliance Policy Guide on FDA's website at

<http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/FoodDefense/ucm153055.htm> for further discussion.

16.2 I have ordered food for my personal use that is being shipped to me through international mail. Is prior notice required?

[Response updated March 2014] Yes. Prior notice must be provided. The exception for food for "personal use" applies only when the food is carried by or otherwise accompanies an individual when arriving in the U.S. (21 CFR 1.277(b)(1)). This exception does not apply when the food is shipped to the U.S.

Although you or any other person with knowledge of the required information may submit prior notice (21 CFR 1.278), it would make sense for the foreign shipper to provide prior notice because the prior notice (PN) Confirmation Number, which indicates that FDA has received and confirmed the prior notice for review, must accompany an article of food that is sent to the U.S. via international mail (21 CFR 1.279(e)).

16.3 What if my order is shipped by an express carrier or express consignment operators like FedEx?

[Response updated March 2014] Prior notice is required. Food transported to the U.S. via express carriers or express consignment operators is not exempt from the prior notice requirements. Prior notice

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must be submitted within the timeframe for the applicable mode of transportation (21 CFR 1.279).

17. Samples

17.1 Is food that is a trade sample and that I carry with me into the U.S. exempt from prior notice?

[Response updated March 2014] No. The exclusion for food carried by an individual applies when the food is for the individual's personal use and it is carried by or otherwise accompanies the individual when arriving in the U.S. (21 CFR 1.277(b)(1)). Trade samples are imported or offered for import to generate sales, which is a commercial, not personal, use.

17.2 Are samples of food that are intended for analytical testing for contaminants exempt from prior notice?

[Response updated March 2014] Yes. If the samples are articles of food, such as a head of lettuce or a can of juice, then prior notice is required. However, if the sample is in a form that is not an article of food, such as a slurry of lettuce for pesticide analysis or a sterile sample container filled with juice for heavy metal analysis, then prior notice would not apply.

FDA has an enforcement discretion policy regarding food imported or offered for import without prior notice that will be used for quality assurance, research or analysis purposes, or "in vivo" testing in non-food producing laboratory animals. Under the policy, FDA and CBP should typically consider not taking any regulatory action when the samples of food are imported in quantities consistent with quality assurance, research, or analysis purposes, and the entire sample is used up by the analysis/testing or destroyed upon completion of the analysis/testing. For further discussion, see FDA's Compliance Policy Guide on FDA's website at

<http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/FoodDefense/ucm153055.htm>.

18. U.S. Goods Returned

18.1 Is prior notice required for a "reimported" food product that was produced in the U.S., shipped to a foreign country, and then shipped back to the U.S. without further processing?

[Response updated March 2014] Yes. FDA has determined that, for the purposes of section 801(m) of the FD&C Act, the phrase "imported or offered for import into the U.S." applies to articles of food of U.S. origin

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that are “reimported” back into the U.S. See 78 FR 66294 at 66319 (November 7, 2008) and 21 CFR 1.277. These reimportations are most often referred to as American Goods Returned or U.S. Goods Returned.

D. REQUIREMENTS TO SUBMIT PRIOR NOTICE OF IMPORTED FOOD

1. Submitters and Transmitters

1.1 Who may submit prior notice to FDA?

Any person with knowledge of the required information may submit prior notice for an article of food. This person is the submitter. The submitter may also use another person to transmit the required information on his or her behalf. The person who transmits the information is the transmitter. The submitter and transmitter may be the same person (21 CFR 1.278).

1.2 May I submit a prior notice on behalf of another person?

Yes. Note that if you transmit the required information on behalf of a submitter, you are the transmitter.

1.3 Is it possible for the submitter to have his/her legal residence in the country of origin and for the transmitter to have his/her legal residence in the U.S.?

[Response updated March 2014] Yes. There are no geographic restrictions on the location of the submitter or the transmitter See 21 CFR 1.278.

2. Deadlines for Prior Notice

2.1 When must prior notice be submitted?

[Response updated March 2014] Except for food being sent by international mail, prior notice must be submitted and the submission must be confirmed by FDA no less than:

- 2 hours before arrival, if the food is arriving by land by road;
- 4 hours before arrival, if the food is arriving by land by rail;
- 4 hours before arrival, if the food is arriving by air; and
- 8 hours before arrival, if the food is arriving by water (21 CFR 1.279(a)).

For a prior notice submitted via Automated Broker Interface/Automated Commercial System (ABI/ACS), you may not submit prior notice more than 30 calendar days before the anticipated date of arrival (21 CFR

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1.279(b)(1)). For a prior notice submitted via the FDA Prior Notice System Interface (PNSI), you may not submit prior notice more than 15 calendar days before the anticipated date of arrival (21 CFR 1.279(b)(2)).

For an article of food sent by international mail, prior notice must be submitted and confirmed by FDA before the food is sent (21 CFR 1.279(c)). The Prior Notice (PN) Confirmation Number must appear on the Customs Declaration that accompanies the package (21 CFR 1.279(e)).

If you are carrying an article of food or if it otherwise accompanies you (i.e., the food is in your checked baggage or in the trunk of your car), and the food is not for personal use, you must submit prior notice according to the timeframe established for the mode of transportation you are using. You must receive confirmation from FDA and provide a copy of the confirmation, including the PN Confirmation Number, to CBP or FDA when arriving in the U.S. (21 CFR 1.279(f)).

2.2 What is the deadline if the food is transported by truck, but the truck arrives via ferry due to a water crossing?

In this case, the deadline is 2 hours prior to arrival.

2.3 What is the deadline if the food walks across the border, such as livestock that are driven across?

[Response updated March 2014] If cattle are driven across the border, then the food is arriving by land via road and the deadline is 2 hours prior to arrival (21 CFR 1.279(a)).

3. Submitting Prior Notice

3.1 How is prior notice submitted to FDA?

[Response updated March 2014] You must submit prior notice to FDA electronically either through the U.S. Customs and Border Protection's (CBP's) Automated Broker Interface of the Automated Commercial System (ABI/ACS) or FDA's Prior Notice System Interface (PNSI).

- CBP's ABI/ACS allows prior notice to be submitted to FDA through the existing ABI/ACS interface (21 CFR 1.280(a)(1)).
- FDA's PNSI is available through FDA's website at <http://www.access.fda.gov> (21 CFR 1.280(a)(2)).

Both the CBP ABI/ACS and the FDA PNSI are available 24 hours a day, 7 days a week for information submission.

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You must be authorized to use CBP's ABI/ACS interface (19 CFR 143.1), but anyone can use FDA's PNSI. If you are an authorized user of the ABI/ACS, you can provide prior notice as part of your CBP entry.

3.2 Do I have to submit prior notice information to both FDA and CBP?

[Response updated March 2014] No. Prior notice must be submitted to FDA. If you are an authorized user of CBP's ABI/ACS, you may submit prior notice to FDA through the ABI/ACS interface or through FDA's Prior Notice System Interface (PNSI) at www.access.fda.gov. If you are not an authorized user of CBP's ABI/ACS, you may arrange for the prior notice submission by an authorized user or you may submit prior notice through FDA's PNSI. However, prior notice must be submitted through FDA's PNSI for the following:

- Articles of food shipped through international mail;
- Transaction types that cannot be transmitted through ABI/ACS; and
- Articles of food that have been refused admission under section 801(m)(1) of the FD&C Act until such time as FDA and CBP issue a determination that ABI/ACS or its successor system can accommodate such transactions (21 CFR 1.280(a)(2)).

3.3 I am an authorized user of CBP's ABI/ACS. Can I use FDA's Prior Notice System Interface (PNSI) to submit prior notice?

Yes. You may submit prior notice through either system.

3.4 I am shipping food by international mail. How do I provide prior notice?

[Response updated March 2014] You must provide prior notice to FDA through the FDA Prior Notice System Interface (PNSI) (21 CFR 1.280(a)(2)). Prior notice must be submitted and confirmed by FDA before the food is sent (21 CFR 1.279). The Prior Notice (PN) Confirmation Number must appear on the Customs Declaration that accompanies the package (21 CFR 1.279(e)).

3.5 What happens if the CBP or FDA system for submitting prior notice is not working?

[Response updated March 2014] If CBP's ABI/ACS is not available or if your broker's or your self-filing system is not working, you must submit prior notice through the FDA Prior Notice System Interface (PNSI) at www.access.fda.gov (21 CFR 1.280(b)).

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If we determine that the PNSI or the FDA automated import system (Operational and Administrative System for Import Support (OASIS)) is not working, a notification will be posted on the Agency's website (<http://www.fda.gov>). FDA will accept prior notice submissions in the format it deems appropriate during the system(s) outage (21 CFR 1.280(c)).

3.6 What happens if my computer system is not functioning or I don't have electricity for a period of time?

If your computer is not functioning or there is no electricity to operate your computer, but the Prior Notice System Interface and ABI/ACS are functioning, you must make arrangements to use a functioning computer to submit the required prior notice.

3.7 If I have problems submitting prior notice through the FDA Prior Notice System Interface (PNSI), how can I get help?

[Response updated March 2014] Tutorials on use of PNSI are available on FDA's website at <http://www.fda.gov>. If you are already familiar with how to use the PNSI and you are having problems with an online submission through the PNSI, you can gain assistance through the following means:

- Phone:
 - For PNSI account questions and/or problems: in the U.S., call toll-free 1-800-216-7331; from elsewhere, call 301-575-0156.
 - For assistance using PNSI: in the U.S., call 866-521-2297; from elsewhere, call 571-468-1488.
- Facsimile: You may send a fax to 301-436-2804.
- Email: Requests for assistance also may be emailed to furls@fda.gov using the form found at <http://www.accessdata.fda.gov/scripts/email/cfsan/bioterrorismact/helpf2.cfm>.

This technical assistance is available on business days from 7:30 a.m. until 11:00 p.m. U.S. Eastern Time. For assistance with ABI/ACS transmission, contact your CBP client representative.

Both the CBP and FDA systems for prior notice are available 24 hours a day, 7 days a week for submitting prior notice.

3.8 Can I submit the prior notice through the FDA Prior Notice System Interface (PNSI) or through ABI/ACS in a language other than English?

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[Response updated March 2014] 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 these items, must be submitted using the Latin (Roman) alphabet (21 CFR 1.280(a)).

If you are not comfortable with English, you may choose to use a transmitter to enter the information for you.

3.9 Can anyone submit prior notice through CBP's ABI/ACS?

No. CBP allows submissions through ABI/ACS only by authorized participants (19 CFR 143.1). Individuals can contract with a broker to transmit prior notice for them. In this case, the submitter is the person responsible for providing the information, but the broker is the transmitter.

Brokers are licensed private individuals or companies that are regulated by CBP and who aid importers and exporters to move merchandise through CBP, including often filing entry of the merchandise with CBP. Brokers provide the proper paperwork and payments to CBP for clients and charge a fee for this service. Before brokers apply for a license, they must pass the Customs broker examination. See

http://www.cbp.gov/xp/cgov/trade/trade_programs/broker/broker_exam/

Filers are required to submit a written request to CBP port personnel for a filer code, which is subsequently assigned by CBP headquarters. See Chapter 10 pp. 73-76 at

http://www.cbp.gov/linkhandler/cgov/trade/legal/directives/broker_handbook.ctt/broker_handbook.pdf

Individuals who choose not to use a broker or who choose not to become recognized by CBP as a filer can submit their prior notice only through the FDA Prior Notice System Interface (PNSI).

3.10 Do I have to submit prior notice if I do not have to file a "consumption" entry with CBP?

[Response updated March 2014] Yes. The requirement to submit prior notice to FDA is different from the requirement to file a consumption entry with CBP. Some foods arriving in the U.S. do not require a CBP consumption entry at the time of arrival, such as entries that move under bond (in-bonds) from the port of arrival to an inland port and shipments into a Foreign Trade Zone. See <http://www.cbp.gov>. However, any article of food imported or offered for import into the U.S. requires prior notice, unless the food is specifically excluded from the requirement to submit prior notice (21 CFR 1.277).

3.11 Can I submit any CBP entry or admission for food without prior notice?

[Response updated March 2014] No, not if the entry or admission contains food subject to the prior notice requirements. You cannot submit a CBP import entry or admission if you have not submitted prior notice to FDA for an article of food that requires prior notice, because the Harmonized Tariff Schedule (HTS) codes have been flagged to indicate foods that require or may require prior notice. You must submit prior notice either through the Automated Broker Interface of the CBP's Automated Commercial System (ABI/ACS) or its successor system (along with the CBP entry information) or through the FDA Prior Notice System Interface (PNSI) at <http://www.access.fda.gov> (21 CFR 1.280(a)).

When you submit prior notice through the FDA PNSI, you will receive a Prior Notice (PN) Confirmation Number (21 CFR 1.279(d)). If you subsequently submit import entry or admission information through the CBP ABI/ACS or its successor system you must enter the PN Confirmation Number for that submission as an Affirmation of Compliance when the CBP entry or admission is filed. See 68 FR 58974 at 58999; October 10, 2003. The PN Confirmation Number will allow CBP to confirm that prior notice was submitted to FDA.

3.12 I cannot or do not want to use CBP's ABI/ACS. What other way can I submit prior notice?

[Response updated March 2014] If you cannot or do not want to use the CBP ABI/ACS or its successor system, you must submit prior notice through the FDA Prior Notice System Interface (PNSI) at <http://www.access.fda.gov> (21 CFR 1.280(a)). You will receive a confirmation number when you complete the prior notice through the PNSI (21 CFR 1.279(d)). The Prior Notice (PN) Confirmation Number must accompany the food when the article arrives in the U.S. (21 CFR 1.279(g)).

3.13 How do I submit prior notice for foods that are covered by Immediate Transportation (IT) or Transportation and Exportation (T&E) entries?

[Response updated March 2014] The U.S. Customs and Border Protection (CBP) has modified the Automated Broker Interface of the Automated Commercial System (ABI/ACS) interface to allow for submission of prior notice to FDA for IT and T&E entries. Prior notice for such entries may also be made through FDA's Prior Notice System Interface.

3.14 I ship the same food weekly to the U.S. in a truck under bond to St. Louis. When and how do I need to file prior notice? Can I file one prior notice to cover all of these repetitive shipments?

[Response updated March 2014] The time frame for submitting prior notice is based on the mode of transportation and the port of arrival, i.e., the port where the food first arrives in the U.S. (Note that this port may be different from the port where the entry documentation is presented to CBP.) Prior notice for food arriving by truck (by land by road) must be confirmed by FDA for review at least 2 hours before the truck arrives at the port of arrival where it is crossing the border into the U.S. (21 CFR 1.279(a)).

If you are entering under bond and want to file your CBP entry in St. Louis, you can file your prior notice either through FDA's Prior Notice System Interface (PNSI) or through CBP's ABI/ACS interface (21 CFR 1.280(a)). If you submit the prior notice through the FDA PNSI, you will receive a Prior Notice (PN) Confirmation Number (21 CFR 1.279(d)). This PN Confirmation Number must accompany the food when it arrives in the U.S. and must be made available to CBP upon arrival (21 CFR 1.279(g)).

You may not file one prior notice to cover all the repetitive shipments. Each article of food requires prior notice (21 CFR 1.281). The Prior Notice rule states that, except for food imported by international mail, you may not submit prior notice more than 15 calendar days before the anticipated date of arrival of the food at the anticipated port of arrival if submitted by the FDA PNSI system and not more than 30 calendar days before the anticipated date of arrival of the food at the anticipated port of arrival if submitted by the CBP ABI/ACS system (21 CFR 1.279(b)). Therefore, you would need to submit a prior notice for each article of food contained in each of the weekly shipments.

3.15 Is there a filing fee for prior notice?

No. FDA does not charge a fee for filing prior notice or for using FDA's Prior Notice System Interface. However, if you choose to use a broker to file the prior notice through the CBP ABI/ACS interface or its successor system, the broker may charge a fee for providing that service. The collection of duty by CBP is not affected by FDA's prior notice regulation.

4. General Information Requirements

4.1 What information must be included in the prior notice?

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[Response updated March 2014] The information required for prior notice varies, based on the type of entry, mode of transportation for the entry, and whether the food is in its natural state. You should refer to 21 CFR 1.281 for details on the required information. The preamble to the 2008 final rule includes a chart that summarizes the information requirements (73 FR 66294 at 66361; November 7, 2008). The rule is available on FDA's web site at <http://www.fda.gov/Food/GuidanceRegulation/ImportsExports/Importing/ucm153853.htm>.

Tutorials on the FDA Prior Notice System Interface (PNSI) also are available on FDA's website to help guide you through the process for providing the required information when you submit prior notice through PNSI. See <http://www.fda.gov/Food/GuidanceRegulation/ImportsExports/Importing/ucm2006837.htm>.

4.2 What time do I enter for anticipated time of arrival?

[Response updated March 2014] For prior notice, anticipated time of arrival relates to the local time of the anticipated port of arrival. See 21 CFR 1.281(a)(11). For vessels, this would be when the vessel is expected to dock in the port where it first arrives in the U.S. For planes, this would be when the plane is scheduled to land. For land vehicles, such as trucks, buses, and trains, this would be when the vehicle is expected to cross at the border. See 73 FR 66294 at 66356; November 7, 2008.

5. Registration Numbers

5.1 What food facility registration numbers must I provide as part of my prior notice submission?

[Response updated March 2014] If the food is no longer in its natural state, you must provide 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 (21 CFR 1.281(a)(6), (b)(5)).

6. Grower Identity

6.1 If a food from a known grower is commingled with food from unknown growers, may the submitter still identify only the consolidator instead of the grower?

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[Response updated March 2014] No. Section 801(m)(1) of the FD&C Act requires grower information to be submitted if it is known. The submitter may opt to provide the name and address of the firm that has consolidated the articles of food from different growers or different growing locations only when the submitter does not know the identity of any of the growers of the consolidated food. If the submitter knows the identity of any grower of a food that has been consolidated, a separate prior notice must be submitted for each article of food represented by a known grower. Therefore, in the situation in question, if the submitter knows the identity of a grower and the article of food associated with that grower, then one prior notice would be submitted for the article of food associated with the known grower and a second prior notice would be submitted for the remaining product. For the second prior notice, you could opt to identify the consolidator (21 U.S.C. 381; 21 CFR 1.281(a)(7), (b)(6)). See also 73 FR 66294 at 66355; November 7, 2008.

6.2 Does a grower need to be identified if an article of food can no longer be associated with a particular grower? May growing location be used instead?

[Response updated March 2014] If you do not know the identity of the grower associated with an article of food, you may opt to identify the consolidator or you may leave the data element empty. Section 801(m)(1) of the FD&C Act does not allow for growing location to be submitted in lieu of known grower information (21 U.S.C. 381(m)(1); 21 CFR 1.281(a)(7), (b)(6)).

7. Product Identity

7.1 If my shipment consists of just one type of food in the same size container but under different brand names, do I have to submit a separate prior notice for food labeled with each brand name?

[Response updated March 2014] FDA regulations do not require submission of the trade or brand name of the article; therefore, the fact that food is labeled under different brand names does not mean that each different label is a separate article of food for the purpose of submitting prior notice. However, a separate prior notice must be submitted for each article of food that has a different complete FDA product code, different package size, or different manufacturer or grower (21 CFR 1.281(a)). See also 73 FR 66294 at 66339 and 66345; November 7, 2008.

7.2 How many prior notice submissions are required and what is the estimated quantity of food shipped in each of the following four scenarios:

I sell fish to grocery stores in the US. The grocery stores will order the fish in bulk. The fish is packed shipped to the U.S. in one of the following manners:

- a. Bulk tote with 1,000 pounds of whole salmon**
 - b. 25 50 lb cardboard boxes containing 2-3 lb and 3-4 lb whole salmon (not individually wrapped); fish normally will be sold individually in a grocery market in a display case of ice**
 - c. 15 50lb cardboard boxes containing salmon fillets of various weights (not individually wrapped)**
 - d. Salmon fillets sold on styro-trays in a poly bag of various weights (typically 2-3 salmon fillets in a package); larger salmon may be cut and put in styro trays as well**
- a. You would be required to submit 1 prior notice. The estimated quantity would be 1,000 lbs of whole salmon.
 - b. You would be required to submit 1 prior notice. The estimated quantity would be 25 boxes of 50 lbs whole salmon.
 - c. You would be required to submit 1 prior notice. The estimated quantity would be 15 boxes of 50 lbs salmon fillets.
 - d. If the trays are unlabeled and sold by bulk weight, then 1 prior notice submission is required and the estimated quantity would be the bulk weight of the shipment. If the trays are labeled for retail sale, 1 prior notice submission is required and the estimated quantity would be the number of trays and the average tray weight.

8. Ultimate Consignee

8.1 [Question/response added March 2014] What name and address should be submitted as the ultimate consignee?

A significant number of people have asked this question, and there has been a lot of variation in what people have been submitting as the ultimate consignee. FDA considers the location where the imported food is to be delivered as the ultimate consignee for the purposes of prior notice.

The preamble to the 2008 final rule states that 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 Customs Directive No. 3550-079A, June 27, 2001, paragraph 6.3. This paragraph states:

The Ultimate Consignee at the time of entry or release is defined as the party in the United States, to whom the overseas shipper sold the imported merchandise. If at the time of entry or release the imported merchandise has not been sold, then the Ultimate Consignee at the time of entry or release is defined as the party in the U.S. to whom the

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overseas shipper consigned the imported merchandise. If the merchandise has not been sold or consigned to a United States 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.

The preamble only quoted the last sentence of paragraph 6.3, which is about the circumstances where the goods have not been sold or consigned to a U.S. party at the time of entry or release. Under these circumstances, the ultimate consignee is defined as the “Ship to / Deliver to” address. The only comment discussed in the preamble to the 2008 final rule that asked about a particular factual scenario asked about the aforementioned scenario. The preamble explained that:

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. (73 FR 66294 at 66357; November 7, 2008).

FDA believes that the facility where the goods are to be delivered should be considered the ultimate consignee in all circumstances. Under the Prior Notice rule, food that is imported or offered for import without adequate prior notice is subject to refusal of admission. If refused, among other things, the food may not be delivered to the importer, owner, or ultimate consignee (21 CFR 1.283(a)(2)(ii)). See also 68 FR 5428 at 5437-38; February 3, 2003. Having the “Ship to / Deliver to” address enables FDA to prevent delivery to these parties, such as when the food is delivered to a third party’s storage facility on behalf of, and accessible by, the importer or owner. For example, if the food is going to a warehouse for storage on behalf of Owner A, FDA needs the name and address of that warehouse to ensure that any food that has been refused admission under prior notice is not delivered there. Moreover, having the address where the food is actually delivered is important for product tracking, in case the food is or is suspected to be contaminated. See 68 FR 5428 at 5429; February 3, 2003. Knowing the name and address of the location where the food is to be delivered is also consistent with the purpose of prior notice – enabling FDA to target foods that may pose a significant risk to public health, based on the information submitted. The Agency targets food based on all parties in the supply chain, and there have been instances where FDA has had concerns with food based on where it was actually delivered.

The FDA regulations at 21 CFR 1.281 require the name and full address of the importer, owner, and ultimate consignee. If the food is delivered to the owner, then the name and full address of the owner is given for the ultimate consignee. The name and full address of the owner only needs

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to be given once, and does not need to be submitted separately when the owner is the same as the importer or ultimate consignee (21 CFR 1.281(a)(13), (c)(13)). If the food is owned by a foreign shipping firm and is being delivered to a public storage warehouse in the U.S. pending its sale, FDA considers the public storage warehouse to be the ultimate consignee and its name and address should be submitted in the prior notice. See 73 FR 66294 at 66304 and 66357; November 7, 2008. The name and address of the foreign shipping firm should be submitted as the owner, if it is different from the importer.

9. Refusal Country

9.1 [Question/response added March 2014] Title 21 CFR 1.281 (a)(18), (b)(12), and (c)(19) requires the name of any country that has refused entry of the article of food to be reported through prior notice. Specifically, what types of entry refusals should be reported through prior notice?

You should report refusals of entry/admission (also known as refusals) of food, including food for animals, based on food safety reasons given by the government of the country that refused entry/admission. See 78 FR 32359 at 32360; May 30, 2013.

- Food safety refusals include, but are not limited to, refusals for intentional or unintentional contamination, including the presence of biological, microbiological, chemical, or radiological contaminants.
- Refusals for commercial or other non-food safety reasons (e.g., product quotas, taxes, import permitting, and documentation issues) should not be reported.
- “Any country” refers to the country or countries, including the U.S., where an agency or representative of the government of the country has refused the article of food. See 78 FR 32359 at 32360; May 30, 2013.

9.2 [Question/response added March 2014] If an article of food is refused entry/admission upon arrival at a U.S. port, must the refusal be reported in subsequent prior notice(s) if the article is then offered for import at another U.S. port?

Yes. If the refusal was for a food safety reason, in a subsequent prior notice the refusal must be reported by indicating “U.S.” as the country of refusal. See 78 FR 32359 at 32360; May 30, 2013.

9.3 [Question/response added March 2014] Does ‘article’ refer to only the food in the specific shipment, or does it also refer to food from the same batch or lot numbers that was shipped to other countries?

For the purpose of reporting the information required under 21 CFR 1.281 (a)(18), (b)(12), and (c)(19), “article” refers to the specific food item for which prior notice is being submitted in a specific shipment.

Here, the term “article” does not refer to food from the same batch or lot numbers that is not being imported or offered for import into the U.S. and for which prior notice will not be submitted at the time of the specific shipment, or food of a similar type that was previously refused entry by a country. See 78 FR 32359 at 32360; May 30, 2013.

10. Changes to Prior Notice Submissions

10.1 Which changes require me to resubmit prior notice and which changes don’t?

[Response updated March 2014] Changes in the estimated quantity, anticipated arrival information, or planned shipment information do not require resubmission of prior notice after FDA has confirmed your prior notice submission for review (21 CFR 1.282(a)(1)(i) through (iii)). For all other changes (e.g., if the identity of the manufacturer changes), you should cancel the prior notice and you must resubmit prior notice if you still intend to import or offer the food for import into the U.S. (21 CFR 1.282).

10.2 Do I have to resubmit prior notice if the anticipated time of arrival changes?

[Response updated March 2014] No. Prior notice does not need to be resubmitted if the anticipated arrival information changes (21 CFR 1.282(a)(1)(ii)). However, although a new prior notice submission is not required, FDA staff may need additional time to respond to the changes in arrival information.

10.3 What should I do if other information changes after I submit prior notice?

[Response updated March 2014] As per FDA regulations, if required information (except estimated quantity, anticipated arrival , and planned shipment information or, for international mail, anticipated date of mailing) changes after FDA has confirmed prior notice for review, the prior notice must be resubmitted (21 CFR 1.282(a)(1),(2)).

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If the prior notice was submitted as part of a multi-line ABI/ACS entry, and information about one or more of the products changes, you should cancel the prior notice via the ABI/ACS by requesting that CBP cancel the entry. Prior notice for the new product can be submitted as part of a new entry. If you submitted the prior notice via the FDA Prior Notice System Interface (PNSI), you should cancel the prior notice via the FDA PNSI (21 CFR 1.282(b) and (c)). See also 73 FR 66294 at 66362-66363; November 7, 2008.

11. Changes to Shipments

11.1 May I add another article of food to an existing prior notice after the prior notice has been submitted to FDA?

[Response updated March 2014] No. Each article of food requires a separate prior notice (see 21 CFR 1.281(a)(5) and 1.281(b)(4)) and receives a unique confirmation number (21 CFR 1.279(d)). However, FDA is allowing prior notices to be grouped in an Automated Broker Interface of the Automated Commercial System (ABI/ACS) entry, or in an “prior notice envelope” for the FDA Prior Notice System Interface (PNSI) entries and In-Bonds submitted through ABI/ACS, in order to reduce data entry for transmitters and to simplify CBP review at the border. For submissions through PNSI, no articles of food can be added to a prior notice envelope after FDA has provided the Prior Notice Confirmation Number(s). For submissions through ABI/ACS, no additional lines may be added after the entry is accepted by ACS.

11.2 What can I do if I want to add another article of food to a shipment after prior notice was submitted to the FDA?

[Response updated March 2014] New articles of food cannot be added to an entry, or prior notice envelope, after it has been submitted to FDA. See 21 CFR 1.282. If a new article of food is being added to a shipment for which prior notice(s) has already been submitted and confirmed, a separate prior notice must be filed for that article under a new entry/envelope. See 21 CFR 1.281(a) and (b). The submission time for the new prior notice will be different from that of the rest of the shipment, and this may have an effect on the ability of the shipment to enter the U.S. See 21 CFR 1.279. For example, if you add another food to a truck at 9:00 am, that food is not covered by timely prior notice until 11:00 am.; the rest of the food on that same truck may be covered by prior notices submitted at 8:00 am and deemed timely at 10:00 am. It is recommended that the time for arrival be anticipated on the last article of food submitted and confirmed by FDA for review.

11.3 What can I do if I want to remove an article of food from the information provided for a shipment?

[Response updated March 2014] If the prior notice was submitted through the Automated Broker Interface of the Automated Commercial System (ABI/ACS), you should cancel the prior notice by requesting that CBP cancel the existing entry. If you submitted the prior notice via the FDA Prior Notice System Interface (PNSI), you should cancel the prior notice via the PNSI (21 CFR 1.282(b) and (c)).

12. FDA Prior Notice System Interface (PNSI) and Automated Broker Interface of the Automated Commercial System (ABI/ACS) Features

12.1 If I need to revise some information on a prior notice, will some of the fields be filled in by the computer automatically or will I need to start from the beginning?

[Response updated March 2014] The answer depends on how the prior notice submission is being made. If submitting through the CBP Automated Broker Interface of the Automated Commercial System (ABI/ACS), the ability to pre-fill or otherwise support submission will depend on the functionality of the software used by the filer. The ABI/ACS interface is concerned with the validity of the information in the submission, not with how it was generated.

If submitting through FDA's Prior Notice System Interface (PNSI), the answer varies based on the status of the submission. The PNSI will allow a transmitter to pre-enter information and save the draft until the time of actual submission. Before the draft is submitted, changes can be made easily to the draft because information previously entered will be pre-filled.

After the prior notice has been submitted to FDA, no changes can be made unless requested by FDA to correct an error found during the review process before a Prior Notice (PN) Confirmation Number issues to the transmitter (21 CFR 1.282).

12.2 My food is being shipped in several different containers. Does the FDA Prior Notice System Interface (PNSI) accept multiple container numbers?

[Response updated March 2014] Yes. In PNSI, you may enter one or more container numbers, separated by commas, each with a minimum of one character and a maximum of twenty five characters that are either a letter or a number, up to a total length of no more 1000 characters.

13. Confirmation

13.1 Will I receive confirmation that FDA has received the prior notice I submitted?

Yes. FDA will notify the transmitter that the prior notice has been confirmed for review with a reply message that contains a Prior Notice (PN) Confirmation Number. For prior notice submissions through the CBP ABI/ACS, the PN Confirmation Number together with the “PN received” message will be made available to the transmitter (broker or filer) through the ABI/ACS. For prior notice submissions through the FDA Prior Notice System Interface (PNSI), a PN Confirmation Number will be provided to the transmitter through PNSI as soon as FDA confirms your prior notice for review.

13.2 Is a copy of the prior notice required to accompany the food?

[Response updated March 2014] To ensure that entry proceeds as smoothly as possible, the carrier or individual should consider having a copy of the reply message that contains a Prior Notice (PN) Confirmation Number in his/her possession upon arrival.

For food carried by or otherwise accompanying an individual that is not for personal use, the individual must provide a copy of the PN confirmation to FDA or CBP upon arrival (21 CFR 1.279(f)). Food covered by prior notice submitted through the FDA Prior Notice System Interface must be accompanied by a copy of the reply message that contains the PN Confirmation Number (21 CFR 1.279(g)).

For international mail packages, the PN Confirmation Number must accompany the package (21 CFR 1.279(e)).

13.3 Does receipt of a Prior Notice (PN) Confirmation Number mean that the food will not be examined or sampled? Does meeting all the requirements of prior notice mean that the article of food will not be held or examined further?

[Response updated March 2014] No. Receipt of a PN Confirmation Number is evidence only that a prior notice has been received for FDA review. Based on review of the prior notice, FDA may determine that an article of food should not be allowed to proceed into the U.S. without further inspection and sampling at the border. The food may be refused under the prior notice regulation and section 801(m) of the FD&C Act and held if the prior notice is inaccurate or if it is untimely and FDA has not had sufficient time to receive, review, and respond to the prior notice information.

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Furthermore, the food must meet the requirements of all other applicable U.S. regulations. If FDA decides not to take action on an article of food under 21 CFR 1.283 or 1.285(a), this decision has no bearing on whether the article of food is admissible or will be granted admission under other provisions of the FD&C Act or other U.S. laws. Thus, for imported food or food offered for import, FDA will continue its normal investigative and enforcement activities for food safety and security concerns and for determining whether the food is subject to refusal under section 801(a) of the FD&C Act.

13.4 If receipt of the Prior Notice (PN) Confirmation Number does not mean the FDA has determined that timely prior notice was submitted or that the information submitted is accurate, what is the value of the PN Confirmation Number?

[Response updated March 2014] The PN Confirmation Number is FDA's notice to you that your prior notice was submitted and received for review by FDA. It is the signal to you that the time frame for prior notice for the food covered by that prior notice submission has started. In addition, the PN Confirmation Number provides a mechanism for prior notice data, submitted to FDA, to be matched with an entry submitted to CBP. The timeliness of prior notice cannot be assessed until the food actually arrives in the U.S. and, often, the accuracy of the prior notice cannot be fully determined until the food is examined upon arrival.

13.5 Do I need to submit samples to accompany my prior notice submission or to accompany the shipment?

[Response updated March 2014] No. There is no need or opportunity to send samples to FDA with the prior notice submission (21 CFR 1.280(a)). FDA will use the information provided with the prior notice to determine whether to inspect or sample the article of food when it arrives in the U.S.

E. CONSEQUENCES

1. Inadequate Prior Notice

1.1 What does FDA consider to be inadequate prior notice?

[Response updated March 2014] Inadequate prior notice is when:

- a. There is no prior notice submitted for an article of food imported or offered for import into the U.S.;
- b. The information submitted in the prior notice is inaccurate; and/or

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- c. The prior notice is not submitted in accordance with the required timeframes.

FDA's enforcement policies on inadequate prior notice are stated in a separate guidance document. This Compliance Policy Guide was updated in May 2009 and is available on FDA's website at <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/FoodDefense/ucm153055.htm>.

1.2 What are some examples of inadequate prior notice?

[Response updated March 2014] The following examples of inadequate prior notice are for five articles of food (foods A, B, C, D, & E) arriving at the border by truck:

- a. Prior notice was submitted for only 4 of the 5 articles of food (foods A, B, C, & D). Inadequate prior notice, e.g., no prior notice, was provided for food E.
- b. Prior notice for food A was submitted and confirmed for FDA review with PN Confirmation Number 999. Food B arrives associated with PN Confirmation Number 999. Inadequate prior notice, e.g., inaccurate prior notice, was provided for food B.
- c. Prior notice for food A was submitted and confirmed for FDA review at 9:00 am on November 2, 2013. Food A arrives at the port of arrival at 9:30 am on November 2, 2013, but CBP has not received an examination decision response from FDA. Inadequate prior notice, e.g., untimely prior notice, was provided for food A.
- d. The prior notice for food C includes a registration number for the manufacturer, but this registration number does not match the actual registration number of the manufacturer of the food. Inadequate prior notice, e.g., inaccurate prior notice, was provided for food C.
- e. The same manufacturer is given in the prior notice for foods A-E; however, each food was manufactured by a different firm and the registration number does not match the actual registration numbers of the manufacturers of foods B-E. Inadequate prior notice, e.g., inaccurate prior notice, was provided for foods B-E.

FDA's enforcement policies on inadequate prior notice are stated in a separate guidance document. This Compliance Policy Guide was updated in May 2009 and is available on FDA's website at <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/FoodDefense/ucm153055.htm>

1.3 What happens to food that is imported or offered for import without adequate prior notice?

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[Response updated March 2014] Except for food arriving by international mail or carried by, or otherwise accompanying, an individual, articles of food arriving with no prior notice, inaccurate prior notice, or untimely prior notice may be refused admission and, if refused, will be handled in one of the following ways:

- a. Immediately exported, with CBP concurrence, from the port of arrival; or
- b. Held within the port of entry, unless directed by CBP or FDA. See 21 CFR 1.283(a)(1)(i)-(iii) and (b).

Refused food is considered general order merchandise under section 490(a) of the Tariff Act (19 U.S.C. 1490(a)) and may move only under appropriate custodial bond (21 CFR 1.283(a)(2)). If the refused article is moved, the submitter must notify FDA of the hold location before the food is moved there. The refused food may not be delivered to the importer, owner, or ultimate consignee (21 CFR 1.283(a)(2)(ii)).

For food that is carried by or accompanies an individual arriving in the U.S. and the food is not for personal use, if adequate prior notice is not submitted or if the Prior Notice (PN) confirmation number cannot be provided to FDA or CBP, the food is subject to refusal. If before leaving the port, the individual does not arrange to have the food held at the port or exported, the article may be destroyed (21 CFR 1.283(b)).

For food arriving by international mail, if prior notice is inadequate or if the PN Confirmation Number is not affixed, the article will be held for FDA inspection and disposition. If refused and there is a return address, the parcel may be returned to 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 (21 CFR 1.283(e)).

FDA's enforcement policies on inadequate prior notice are stated in a separate guidance document. This Compliance Policy Guide was updated in May 2009 and is available on FDA's website at <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/FoodDefense/ucm153055.htm>

1.4 Will my food be held if it arrives earlier than the anticipated time of arrival I submitted?

[Response updated March 2014] If arrival occurs before the anticipated arrival time, the food could be refused and held until the prior notice

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timeframe has elapsed (see 21 CFR 1.279) or until processing is complete, whichever comes first. However, if the prior notice has been fully processed by FDA, the food will not be refused because the anticipated arrival time has not yet come (21 CFR 1.283(a) (1) (iii)). However, if FDA plans to examine the food, it may be held to allow time for FDA staff to arrive.

1.5 What does it mean if, after I receive a Prior Notice (PN) Confirmation Number, FDA later refuses the same article of food?

[Response updated March 2014] The PN Confirmation Number only confirms that the submission is complete and facially valid. If FDA's review process determines that the prior notice is inaccurate after receipt of the prior notice is confirmed by issuance of the PN Confirmation Number, the article of food is still subject to refusal under 801(m) of the FD&C Act and 21 CFR 1.283(a)(1).

1.6 Who will be notified if FDA determines that a food needs to be held for examination when it arrives at the border?

FDA will communicate the decision to examine articles of food to CBP.

2. Exercise of Enforcement Discretion

2.1 What enforcement policy is described in FDA's Compliance Policy Guide "Guidance for FDA and CBP Staff/Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002?"

[Response updated March 2014] The Compliance Policy Guide describes and provides guidance on FDA's and CBP's strategy for enforcing and otherwise achieving compliance with the Prior Notice rule. The guidance does not establish legally enforceable responsibilities nor does it create or confer any rights for or on any person and does not operate to bind FDA, CBP, or the public.

III. ELECTRONIC ACCESS

Persons with access to the Internet may obtain this document "Prior Notice Questions and Answers" at <http://www.fda.gov/Food/GuidanceRegulation/ImportsExports/Importing/ucm2006836.htm>.

IV. WHERE TO GET ADDITIONAL INFORMATION

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A. PRIOR NOTICE HELP DESK

Phone:

- For PNSI account questions and/or problems: in the U.S., call toll-free 1-800-216-7331; from elsewhere, call 301-575-0156.
- For assistance using PNSI: in the U.S., call 1-866-521-2297; from elsewhere, call 571-468-1488.

Fax: 301-436-2804

E-mail: furls@fda.gov

B. USEFUL WEBSITES

FDA Home Page	http://www.fda.gov
FDA Website on the Bioterrorism Act	http://www.fda.gov/RegulatoryInformation/Legislation/ucm148797.htm
FDA's Prior Notice System Interface (PNSI)	http://www.access.fda.gov
FDA's Prior Notice Compliance Policy Guide	http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/FoodDefense/ucm153055.htm
Prior Notice Rule	http://www.fda.gov/Food/GuidanceRegulation/ImportsExports/Importing/ucm153853.htm
Website on the Bioterrorism Act, including Prior Notice	http://www.fda.gov/Food/GuidanceRegulation/ImportsExports/Importing/ucm114217.htm
Main Prior Notice Website	http://www.fda.gov/Food/GuidanceRegulation/ImportsExports/Importing/ucm2006836.htm
Website that Contains this Guidance Document	http://www.fda.gov/Food/GuidanceRegulation/ImportsExports/Importing/ucm2006836.htm
Form for Submitting Questions on Prior Notice	http://www.accessdata.fda.gov/scripts/email/cfsan/bioterrorismact/helpf2.cfm
CBP Home Page	http://www.cbp.gov

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CBP Broker Management Handbook	http://www.cbp.gov/linkhandler/cgov/trade/legal/directives/broker_handbook.ctt/broker_handbook.pdf
CBP Website on Becoming a Broker	http://www.cbp.gov/xp/cgov/trade/trade_programs/broker/brokers.xml