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# **Guidance to Industry**

## **Prior Notice of Imported Food Questions and Answers**

Comments and suggestions regarding this guidance may be submitted at any time. For questions regarding this document, contact:

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Food and Drug Administration  
Office of Regulatory Affairs  
Center for Food Safety and Applied Nutrition  
Center for Veterinary Medicine**

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**U.S. Department of Health and Human Services  
Food and Drug Administration  
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### Prior Notice of Imported Food Questions and Answers

This guidance document represents 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, please contact: Domenic Veneziano, Office of Regulatory Affairs, Office of Regional Operations, FDA, 5600 Fishers Lane, Rockville, MD 20857, Phone: 866-521-2297

#### I. INTRODUCTION

On October 10, 2003, the Food and Drug Administration (FDA) published an interim final 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 (68 FR 58974). The prior notice interim final 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), which requires that FDA receive prior notice of food imported into the United States. This guidance document provides a list of questions that have frequently 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 interim final rule. We intend to issue additional guidance as new questions arise. FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe 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 guidances means that something is suggested or recommended, but not required.

FDA is issuing this "Prior Notice Questions and Answers" document as level 1 guidance. FDA has determined that prior public participation is not feasible or appropriate because the interim final rule is effective on December 12, 2003, and is immediately implementing this guidance document, consistent with FDA's good guidance practice (GGP) regulations (21 CFR 10.110(g)(3)). The agency will accept comment and revise the guidance if appropriate in accordance with 21 CFR 10.115(g)(3)(ii).

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**II. PRIOR NOTICE QUESTIONS AND ANSWERS**

**A. BACKGROUND**

**1. What is prior notice?**

Prior notice is notification to the FDA that an article of food, including animal feed or pet food, 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. (68 FR 58974; October 10, 2003).

Additional information on the prior notice regulation may be found on FDA's web site as <http://www.fda.gov>, select Bioterrorism Act. If your question is not answered by information on that web site, you can submit the question by email to the following address: <http://www.cfsan.fda.gov/~furl/helpf2.html>.

For additional information on the U.S. Bureau of Customs and Border Protection's (CBP's) procedures for prior notice, you may want to consult the CBP website at <http://www.customs.treas.gov>.

**2. Why is prior notice required to be submitted to FDA?**

Prior notice is required by new section 801(m) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 801(m)). Section 801(m) requires advance notification to FDA prior to the arrival of food imported or offered for import into the United States.

**3. When does prior notice go into effect?**

The prior notice regulation is effective on December 12, 2003. FDA intends to provide an initial transition period during which we will emphasize education regarding the requirements of prior notice to achieve compliance. Specific details regarding that transition period will be provided in an FDA Compliance Policy Guide. The Compliance Policy Guide will be available on FDA's website at [http://www.fda.gov/ora/compliance\\_ref/cpg/default.htm](http://www.fda.gov/ora/compliance_ref/cpg/default.htm).

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

Since publication of the Prior Notice and Registration interim final rule on October 10, 2003, FDA has conducted extensive domestic and international outreach and education about the new rule. FDA and CBP held a satellite downlink public meeting on October 28, 2003, and a series of public meetings across the U.S. to discuss the prior notice and registration interim final rules. Public meetings are announced on FDA's web site at <http://www.fda.gov>. In addition, we have prepared several tools, such as tutorials,

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90 instructions, and question-and-answer documents, to help importers and other affected  
91 persons to submit prior notice under either through ABI/ACS or PNSI. These are  
92 available on FDA's web site at <http://www.fda.gov>. CBP continues to issue instructions to  
93 ABI/ACS filers and brokers on complying with the prior notice regulation.

### **5. Where can I get more information about FDA's prior notice regulation?**

94  
95  
96 Information on the prior notice regulation may be found on FDA's web site at  
97 <http://www.fda.gov>. Many of your questions can be answered by reading the prior notice  
98 interim final rule or by reviewing the tutorials, fact sheet, and other materials that are  
99 posted on the web site. If your questions are not answered by information on that web  
100 site, you can send an email to the following address:  
101 <http://www.cfsan.fda.gov/~furl/help2.html>. FDA plans to periodically issue guidance  
102 documents to answer those questions that are not directly addressed in the prior notice  
103 interim final rule or its preamble. Thus, you will not receive an individual response to  
104 your email. You should check our web site at  
105 <http://www.fda.gov/oc/bioterrorism/bioact.html> periodically to obtain a copy of these  
106 guidance documents.  
107  
108

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

109  
110 For additional information on the U.S. Bureau of Customs and Border Protection's  
111 (CBP's) procedures for prior notice, you may want to consult the CBP website at  
112 <http://www.customs.treas.gov>.  
113  
114  
115

### **7. Is information about prior notice available in languages other than English?**

116  
117 Yes. Information about prior notice to FDA is available in other languages. Translations  
118 available are indicated at the top of the English version of documents located on the  
119 Internet at <http://www.cfsan.fda.gov/~dms/fsbtact.html>.  
120  
121

## **B. DEFINITIONS**

### **Food:**

### **8. For the purposes of the prior notice regulation, what is food?**

122  
123  
124  
125  
126  
127 Food is defined in the prior notice regulation by reference to section 201(f) of the FD&C  
128 Act, which defines food as articles used for food or drink for man or other animals,  
129 chewing gum, and articles used for components of any such articles (21 U.S.C. 321(f)).  
130 However, for purposes of prior notice, the definition of food does not include food  
131 contact substances or pesticides (21 CFR 1.276(b)(5)(i)). Examples of food subject to  
132 prior notice include: fruits, vegetables, fish, including seafood, dairy products, eggs, raw  
133 agricultural commodities for use as food or as components of food, animal feed  
134 (including pet food), food and feed ingredients, food and feed additives, dietary  
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136 supplements and dietary ingredients, infant formula, beverages (including alcoholic  
137 beverages and bottled water), live food animals, bakery goods, snack foods, candy, and  
138 canned foods.  
139

### 140 **9. Is a bulk commodity like raw cane sugar “food” that is subject to prior notice?**

141

142 Yes, if a bulk commodity like raw cane sugar is food under the definition if it is for use as  
143 food, including for use as a component of food. Raw agricultural commodities for use as  
144 food or as components of food are food for prior notice purposes (21 CFR  
145 1.276(b)(5)(ii)). FDA will consider an article as one that will be used for food if any of  
146 the persons involved in importing or offering the product for import (e.g., submitter,  
147 transmitter, manufacturer, grower, shipper, importer, owner, or ultimate consignee)  
148 reasonably believes that the substance is reasonably expected to be directed to a food use.  
149

### 150 **10. Are live animals "food" for prior notice purposes?**

151

152 Live animals are food for purposes of prior notice (21 CFR 1.276(b)(5)(ii)) if any of the  
153 persons involved in importing or offering the live animal for import (e.g., the submitter,  
154 transmitter, manufacturer, grower, shipper, importer, owner, or ultimate consignee)  
155 reasonably believes that the live animal is reasonably expected to be directed to a food  
156 use (21 CFR 1.276(b)(5)). Note that live food animals are not excluded from prior notice  
157 under section 801(m)(3)(B) of the FD&C Act and 21 CFR 1.277(b)(4) or (5) because live  
158 food animals do not fall within the exclusive jurisdiction of USDA under the Federal  
159 Meat Inspection Act or Poultry Products Inspection Act.  
160

### 161 **11. If USDA’s Animal Plant and Health Inspection Service (APHIS) inspects the live** 162 **animals when they are imported into the U.S., are the live animals “food” for** 163 **prior notice purposes?** 164

165 Yes. Live food animals that are subject to border inspections by APHIS are also subject  
166 to FDA's prior notice requirements: FDA and APHIS may both have jurisdiction over  
167 live animals. Note that the requirement for prior notice to FDA for live food animals  
168 does not alter the role of APHIS in, or any APHIS requirements relating to, inspection of  
169 live animals imported into the U.S.  
170

### 171 **12. Are game animals “food” for which prior notice must be given?**

172

173 Yes, if any person involved in importing the animal reasonably believes the animal is  
174 reasonably expected to be directed to a food use, the animal is food for which prior notice  
175 is required. (21 CFR 1.276(b)(5)) So, for example, elk imported to stock a ranch where  
176 the elk are hunted and used for food would be food under the prior notice definition. By  
177 contrast, elk imported for repopulating a national park where hunting the elk is not  
178 permitted would not be food for which prior notice is required. Note that live food game  
179 animals are not excluded from prior notice under section 801(m)(3)(B) of the FD&C Act  
180 and 21 CFR 1.277(b)(4) or (5) because neither these live food animals nor the products

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181 derived there from, fall within the exclusive jurisdiction of USDA under the Federal  
182 Meat Inspection Act or Poultry Products Inspection Act.

183

184 **13. Are chemicals used to manufacture food additives included in the definition of**  
185 **food for prior notice purposes?**

186

187 Yes, chemicals that are used for food or drink or are used for components of any such  
188 articles are food and are subject to the prior notice rule. However, if the chemicals are  
189 used for food contact substances or components of food contact substances or pesticides,  
190 prior notice is not required. (21 CFR 1.276(b)(5))

191

192 **14. What are some examples of food contact substances?**

193

194 Food packaging materials, empty food packages, ceramic dinnerware, brass drinking  
195 vessels, and corn husks to be used as tamale wrappers, are examples of food contact  
196 substances. Even though these foods are excluded from prior notice requirements in  
197 section 801(m) of the FD&C Act, they are still subject to other provisions of the FD&C  
198 Act, including section 801(a), and FDA will still make admissibility decisions about  
199 them.

200

201 **15. Are secondary direct additives, many of which are processing aids, exempt from**  
202 **prior notice as “food contact substances”?**

203

204 The term “secondary direct food additive” is not a defined term. Under 21 CFR  
205 1.276(b)(5), “food” excludes “food contact substances” and “pesticides.” Thus, if the  
206 “secondary direct food additive” is a food contact substance or a pesticide, it is not  
207 included in the definition of food, for purposes of prior notice, and prior notice is not  
208 required.

209

210 **FDA Country of Production:**

211

212 **16. What is the FDA Country of Production and how does it differ from CBP’s**  
213 **Country of Origin?**

214

215 For food that is in its natural state, the FDA Country of Production is generally the  
216 country where the food was grown or collected, including harvested and readied for  
217 shipment to the U.S. Articles of food grown, including harvested or collected and  
218 readied for shipment, in U.S. territories are considered to be grown in the U.S. (21 CFR  
219 1.276(b)(4)(i)). However, for wild fish, including seafood, that is caught or harvested  
220 outside U.S. waters by a vessel that is not registered in the U.S., the FDA Country of  
221 Production is the country in which the vessel is registered. (21 CFR 1.276(b)(4)(i))

222

223 For food that is no longer in its natural state, the FDA Country of Production is generally  
224 the country where the food was made or processed. However, if the article is made from  
225 wild fish aboard a vessel, the FDA Country of Production is the country in which the

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226 vessel is registered. If food that is no longer in its natural state was made in a Territory,  
227 the FDA Country of Production is the United States. (21 CFR 1.276(b)(4)(ii))  
228

229 The FDA Country of Production may be different from the CBP Country of Origin. For  
230 example, the CBP Country of Origin for beans that are grown and dried in the U.S., then  
231 rehydrated and canned in the Dominican Republic would be the U.S. The FDA Country  
232 of Production would be the Dominican Republic. However, for purposes of the prior  
233 notice provisions of the FD&C Act, the "article of food" is canned beans, not dried  
234 beans. From a food safety standpoint, FDA is most interested in knowing where the  
235 article of food was processed and canned. To avoid confusion between FDA's prior  
236 notice requirements and CBP requirements, the interim final rule uses the term "FDA  
237 Country of Production" instead of the term "originating country" or "country from which  
238 the article originates." "FDA Country of Production" is already familiar to customs  
239 brokers and self-filers using ABI/ACS interface with OASIS.  
240

### 241 **International Mail:**

242

#### 243 **17. Are express carriers, such as Federal Express, considered "international mail"?**

244

245 The term "international mail" only covers foreign national mail services. Express carriers,  
246 such as Federal Express, as well as express consignment operators, or other private  
247 delivery services are not considered international mail under the prior notice rule. (21  
248 CFR 1.276(b)(7))  
249

#### 250 **18. Port of Arrival/Port of Entry:**

251

#### 252 **What is the "port of arrival" and how does it differ from the "port of entry"?**

253

254 The port of arrival is the water, air, or land port at which the article of food is imported or  
255 offered for import into the U.S., i.e., the port where the article of food first arrives in the  
256 U.S. (21 CFR 1.276(b)(9)). Port of entry is given the same definition the CBP  
257 regulations use, which "refer[s] to any place designated by Executive order..., by order of  
258 the Secretary of the Treasury, or by Act of Congress, at which a Customs officer is  
259 authorized to accept entries of merchandise, to collect duties, and enforce the various  
260 provision of Customs and navigation laws..." (19 CFR 101.1)  
261

#### 262 **19. Can the port of arrival differ from the port where entry is made?**

263

264 Yes. The port of arrival is the port where the articles first arrive in the U.S. A  
265 consumption or warehouse entry or foreign trade zone admission documentation may be  
266 presented to CBP at a different port than the port of arrival. This port is often referred to  
267 as the "port of entry" or "port where entry is made." Note that timeframes for  
268 submission of prior notice are tied to the time of arrival in the port of arrival, not arrival  
269 in the so-called port of entry.  
270

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272 **United States:**

273

274 **20. Is prior notice required for foods that are imported into Puerto Rico?**

275

276 Yes. The prior notice interim final rule defines the United States to be the 50 states, the  
277 District of Columbia, and the Commonwealth of Puerto Rico, but not the U.S. Territories  
278 (21 CFR 1.276(b)(13)). Therefore, prior notice is required for food that comes from  
279 outside the U.S. into Puerto Rico, but not for food shipped from Puerto Rico into the 50  
280 states or the District of Columbia.

281

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

283

284 No. The prior notice interim final rule defines the United States to be the 50 states, the  
285 District of Columbia, and the Commonwealth of Puerto Rico, but not the U.S. Territories  
286 (21 CFR 1.276(b)(13)). Therefore, prior notice is not required for food shipped into a  
287 U.S. Territory. However, prior notice is required for food coming from a U.S. Territory  
288 (e.g., Guam, the U.S. Virgin Islands, and the Northern Mariana Islands) into the 50 states,  
289 the District of Columbia or the Commonwealth of Puerto Rico.

290

291 **22. Is prior notice required for shipments originating in another NAFTA country?**

292

293 Yes. Because the “United States” is defined for purposes of prior notice to be the  
294 Customs territory of the United States (21 CFR 1.276(b)(13)), food that is imported into  
295 the 50 states, the District of Columbia, or the Commonwealth of Puerto Rico from a  
296 country that is a signatory to the North American Free Trade Agreement (other than the  
297 United States) is subject to prior notice.

298

299 **C. SCOPE**

300

301 **General:**

302

303 **23. What is the scope of prior notice regulation? What shipments of food imported**  
304 **or offered for import into the United States require prior notice?**

305

306 If the article that is shipped to the United States is food within the meaning of 21 CFR  
307 1.276(b)(5), then prior notice is generally required, even if the item is intended for further  
308 processing, is not intended for consumption in the United States, or is not intended for  
309 commercial distribution. Thus, prior notice is required for all food for humans and other  
310 animals that is imported or offered for import into the United States for use, storage, or  
311 distribution in the United States, including food for gifts and trade and quality  
312 assurance/quality control samples, food for transshipment through the United States to  
313 another country, food for future export, and food for use in a U.S. Foreign Trade Zone.

314

315 **24. Are there any exceptions from the prior notice requirements?**

316

317 Yes. Prior notice is not required for:

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- 318 a. Food for an individual's personal use (i.e., for consumption by the individual,  
319 family, or friends, and not for sale or other distribution) when it is carried by or  
320 otherwise accompanies the individual when arriving in the United States;  
321 b. Food that was made by an individual in his/her personal residence and sent by that  
322 individual as a personal gift (i.e., for non-business reasons) to an individual in the  
323 United States;  
324 c. Food that is imported then exported without leaving the port of arrival until  
325 export; and  
326 d. Meat food products, poultry products, and egg products that are subject to the  
327 exclusive jurisdiction of the U.S. Department of Agriculture (USDA) at the time  
328 of importation. (21 CFR 1.277(b)).  
329

330 Prior notice also is not required under FDA requirements for food brought into the United  
331 States in a diplomatic pouch. (The Vienna Convention on Diplomatic Relations (1961)  
332 provides: "The diplomatic bag shall not be opened or detained." Art. 27(3) Any  
333 baggage or cargo marked "diplomatic bag" or "diplomatic pouch" is immune from  
334 search, including by electronic devices, and thus its contents are not subject to FDA's  
335 prior notice requirements.)  
336

337 **25. Are there exceptions from prior notice for any of the following:**

- 338 a. Food items of small value or quantity;  
339 b. Food samples for research and development or for testing purposes only and  
340 not for consumption; or  
341 c. Food samples for test marketing?  
342

343 There are no exemptions from prior notice requirements for:

- 344 a. Food based on the size or value of the shipment (68 FR 58993);  
345 b. Samples of food (including animal feed) for research and development.  
346 (However, if the samples are items that are in such early stages of research and  
347 development that they cannot yet be considered food under 21 CFR 1.276(b)(5),  
348 they would not be subject to prior notice requirements. An example of such an  
349 item is a substance being tested for possible preservative qualities before being  
350 tested in any food); or  
351 c. Samples of food, including animal feed, for test marketing.  
352

353 **Shipments from Farms:**

354  
355 **26. Is prior notice required for tomatoes from a foreign farm that packs and exports**  
356 **tomatoes to the U.S. since farms don't have to register?**  
357

358 Yes. The requirement for prior notice is not based on whether registration is required.  
359 FDA registration requirements (21 CFR 1.266(b)) apply to facilities that  
360 manufacture/process, pack, or hold food for consumption in the United States. The prior  
361 notice requirements apply to articles of food imported or offered for import into the  
362 United States. Although registration of farms is not required, the articles of food grown,  
363 harvested, or collected on farms are not exempt from prior notice requirements. Thus,

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364 generally, the food that a foreign farm exports to the U.S. is subject to the prior notice  
365 requirements. (21 CFR 1.277)

366

367 **Shipments for Charities:**

368

369 **27. Is there an exemption for food imported for charity?**

370

371 No. Food intended for charity is not exempt from prior notice. Although the registration  
372 interim final rule exempts nonprofit food establishments in which food is prepared for, or  
373 served directly to, the consumer from the requirements to register their facilities, (21 CFR  
374 1.266(e)), the prior notice interim final rule does not exempt food imported for use by  
375 those nonprofit food establishments. Thus, imported food that is imported for or by a  
376 U.S. charity is subject to prior notice. (21 CFR 1.277)

377

378 **U.S. Goods Returned:**

379

380 **28. Is prior notice required for “reimported” food product that was produced in the**  
381 **U.S., shipped to a foreign country, and then shipped back to the U.S. without**  
382 **further processing?**

383

384 Yes. FDA has determined that, for the purposes of section 801(m) of the FD&C Act, the  
385 phrase “imported or offered for import into the United States” applies to articles of food  
386 of U.S. origin that are “reimported” back into the U.S. (68 FR 58990; 21 CFR 1.277).  
387 These reimportations are most often referred to as American Goods Returned or U.S.  
388 Goods Returned.

389

390 **Food Not for Consumption in the U.S.:**

391

392 **29. If the food is not for consumption in the U.S., is prior notice required?**

393

394 Yes. Prior notice requirements apply even when the food is not for consumption in the  
395 United States. You must submit prior notice for food for that is for transshipment, further  
396 processing and export, or storage and export. In contrast, the requirement to register  
397 facilities applies only to food facilities that manufacture/process, pack, or hold food for  
398 consumption in the U.S.

399

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

402

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

405

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406 **Foreign Trade Zones:**

407

408 **31. Will food being admitted into a Foreign Trade Zone need to have prior notice?**

409

410 Yes. Food for admission into a Foreign Trade Zone is subject to the requirements of the  
411 prior notice regulation (21 CFR 1.277). However, prior notice is not required when the  
412 food is withdrawn from the FTZ, either as an export or for use within the United States.  
413 However, if the food is withdrawn from the FTZ for consumption entry into the United  
414 States, FDA will be notified and make the admissibility decision about the consumption  
415 entry at that time.

416

417 **Gifts:**

418

419 **32. Does prior notice apply to food sent as gifts from family living outside the U.S.?**

420

421 If the food was made by an individual in his/her personal residence and sent by that  
422 individual as a personal gift (i.e., for non-business reasons) to an individual in the United  
423 States, prior notice is not required (21 CFR 1.277(b)(2)). Other food products sent as  
424 gifts are subject to the prior notice requirement (21 CFR 1.277). FDA recognizes that, in  
425 these circumstances, the sender who purchased the food as a gift may not have the  
426 manufacturer/producer registration number. Thus, the sender can use the name and  
427 address of the firm that appears on the label. A registration number need not be provided  
428 (21 CFR 1.281(a)(6)).

429

430 **Airline Food:**

431

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

435

436 If the aircraft food is consumed on the flight or discarded and is not entered into the U.S.  
437 for use, storage, or distribution, it is outside the scope of the regulation and prior notice is  
438 not required (21 CFR 1.277(a)). By contrast, prior notice is required for in-flight food  
439 that is moved to U.S. caterers for use on export flights (21 CFR 1.277).

440

441 **Personal Baggage:**

442

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

445

446 No. Prior notice is not required for food that is carried by or otherwise accompanies an  
447 individual entering the United States (e.g., is in his or her carry-on or checked baggage)  
448 when the food is for that individual's personal use (21 CFR 1.277(b)(1)). Personal use  
449 means that the food is for consumption by the individual or by the individual's family  
450 and friends and is not for sale or other distribution.

451

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452 **Food Shipped by Express Carriers or Express Consignment Operators:**

453

454 **35. Is an article of food that is shipped by an express carrier or express consignment**  
455 **operators like Fed Ex exempt from prior notice?**

456

457 No, imported food transported into the U.S. via express carriers or express consignment  
458 operators is not exempt from the requirements of the prior notice regulation. Articles  
459 imported via these private delivery services are subject to prior notice, which must be  
460 submitted within the timeframe for the applicable mode of transportation (21 CFR 1.279).

461

462 **Food Shipped by International Mail:**

463

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

465

466 No, food sent to the U.S. via international mail is not exempt from the requirements of  
467 the prior notice regulation. Articles imported via international mail are subject to prior  
468 notice, which must be submitted before the article is sent to the U.S. (21 CFR 1.279(c))

469

470 **Personal Shipments:**

471

472 **37. Is prior notice required for food for personal use that is shipped by the**  
473 **individual while overseas and, therefore, does not accompany the individual**  
474 **when returning to the U.S.?**

475

476 Yes. Food purchased abroad and sent to the U.S. (i.e., does not accompany the individual  
477 when arriving in the U.S.) is subject to prior notice. (21 CFR 1.277)

478

479 **38. I have ordered food for my personal use that is being shipped to me through**  
480 **international mail. Do I need to provide prior notice to FDA?**

481

482 Yes, prior notice must be provided. The exception for food for “personal use” applies  
483 only when the food is carried by or otherwise accompanies an individual when arriving in  
484 the U.S. (21 CFR 1.277(b)(1)). This exception does not apply when the food is shipped  
485 to the U.S. Although you or any other person with knowledge of the required  
486 information may submit prior notice (21 CFR 1.278), it would make sense for the foreign  
487 shipper to provide prior notice because the PN Confirmation Number, which indicates  
488 that FDA has received and confirmed the prior notice for review, must accompany an  
489 article of food that is sent to the U.S. via international mail (21 CFR 1.279(e)).

490

491 **39. What if my order is shipped by an express carrier or express consignment**  
492 **operators like Fed Ex?**

493

494 Prior notice is still required. Food transported to the U.S. via express carriers or express  
495 consignment operators is not exempt from the requirements of the prior notice regulation.  
496 Articles imported via these private delivery services are subject to prior notice, which

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

499

### **Trade Samples:**

500

501  
502 **40. Is food that is a trade sample and that I carry with me into the United States**  
503 **exempt from prior notice?**

504

505 No. The exclusion for good carried by an individual applies when the food is for the  
506 individual's personal use when it is carried by or otherwise accompanies the individual  
507 when arriving in the United States. (21 CFR 1.277(b)(1)) However, trade samples are  
508 imported or offered for import to generate sales, which is a commercial, not personal,  
509 use.

510

### **Food Moved with Household Goods:**

511

512  
513 **41. Are foods included with my household goods subject to prior notice when I**  
514 **move to the U.S.?**

515

516 Yes.

517

### **Food Subject to USDA/FSIS Requirements:**

518

519  
520 **42. Is prior notice required for meat, poultry, or eggs that are under the jurisdiction**  
521 **of the U.S. Department of Agriculture (USDA)?**

522 If, at the time the food is imported or offered for import, the food is subject to the  
523 exclusive jurisdiction of the USDA's Federal Meat Inspection Act (21 U.S.C. 601 *et*  
524 *seq.*), the Poultry Products Inspection Act (21 U.S.C. 451 *et seq.*), or the Egg Products  
525 Inspection Act (21 U.S.C. 1031 *et seq.*), the food is not subject to the requirements of  
526 prior notice. (21 CFR 1.277(b)(4)-(b)(6))

527

## **D. REQUIREMENTS TO SUBMIT PRIOR NOTICE OF IMPORTED FOOD**

528

### **Submitters and Transmitters:**

529

530  
531  
532 **43. Who may submit prior notice to FDA?**

533

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

539

540 **44. May I submit a prior notice on behalf of another person?**

541

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

544

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

547

548 Yes. There are no geographic restrictions on the location of the submitter or the  
549 transmitter. (21 CFR 1.278)

550

551 **Deadlines for Prior Notice:**

552

553 **46. When must prior notice be submitted?**

554

555 Prior notice must be submitted and the submission must be confirmed by FDA no more  
556 than 5 days before arrival, except for food arriving by international mail, and no less  
557 than:

558 2 hours before arrival, if the food is arriving by land by road;

559 4 hours before arrival, if the food is arriving by land by rail

560 4 hours before arrival, if the food is arriving by air; and

561 8 hours before arrival, if the food is arriving by water. (21 CFR 1.279(a) and (b))

562

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

567

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

574

575 **Submitting Prior Notice:**

576

577 **47. How is prior notice submitted to FDA?**

578

579 You must submit prior notice to FDA electronically either through the U.S. Bureau of  
580 Customs and Border Protection's (CBP's) Automated Broker Interface of the Automated  
581 Commercial System (ABI/ACS) or FDA's Prior Notice System Interface.

582

583 • CBP's ABI/ACS allows prior notice to be submitted to FDA through the existing  
584 ABI/ACS interface (21 CFR 1.280(a)(1)); and

585 • FDA's Prior Notice System Interface (PNSI) is available through FDA's website at  
586 <http://www.access.fda.gov> (21 CFR 1.280(a)(2)).

587

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

590

591 **48. Do I have to submit prior notice information to both FDA and CBP?**

592

593 No. Prior notice must be submitted to FDA. If you are an authorized user of CBP's  
594 ABI/ACS you may submit prior notice to FDA through the ABI/ACS interface or  
595 through FDA's Prior Notice System Interface (PNSI) at [www.access.fda.gov](http://www.access.fda.gov). If you are  
596 not an authorized user of CBP's ABI/ACS, you may arrange for prior notice submission  
597 by an authorized user or submit prior notice through PNSI. Except, however, prior notice  
598 for the following, must be made through FDA's PNSI:

599

a. Articles of food shipped through international mail;

600

b. Transaction types that cannot be transmitted through ABI/ACS; and

601

c. Articles of food that have been refused admission under section 801(m)(1) of the  
602 FD&C Act. (21 CFR 1.280(a)(2))

603

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

606

607 Yes. You may submit prior notice through either system.

608

609 **50. I am shipping food by international mail. How do I provide Prior Notice?**

610

611 You provide prior notice to FDA through PNSI (21 CFR 1.280(a)(2)). Prior notice must  
612 be submitted and confirmed by FDA before the food is sent (21 CFR 1.279(c)). The  
613 Prior Notice (PN) Confirmation Number must appear on the Customs Declaration that  
614 accompanies the package (21 CFR 1.279(e)).

615

616 **51. What happens if the CBP or FDA system is not working?**

617

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

621

622 If we determine that our Prior Notice System Interface is not working, we will issue  
623 notification on our website (<http://www.fda.gov>) and on the Prior Notice System  
624 Interface, as well as through messages in ABI/ACS. If you do not use ABI/ACS, and the  
625 PNSI is down, you must submit prior notice by e-mail or fax to FDA.

626

627 If FDA determines that its automated import system (OASIS) is not working, FDA will  
628 issue notification on our website (<http://www.fda.gov>) and on the Prior Notice System  
629 Interface and all prior notices must be submitted to FDA by e-mail or by fax. The e-mail  
630 address and fax number, as well as more information on how to submit prior notice if  
631 FDA or CBP systems are not working, will be available at <http://www.fda.gov>.

632

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633 **52. What happens if my computer system is not functioning or I don't have**  
634 **electricity for a period of time?**  
635

636 If your computer is not functioning or there is no electricity to operate your computer but  
637 the Prior Notice System Interface and ABI/ACS are functioning, you must make  
638 arrangements to use a functioning computer to submit the required prior notice.  
639

640 **53. If I have problems submitting prior notice through the Prior Notice System**  
641 **Interface (PNSI), how can I get help?**  
642

643 Tutorials on use of PNSI are available on FDA's website at [www.fda.gov](http://www.fda.gov). If you are  
644 already familiar with how to use PNSI and you are having problems win an online  
645 submission through PNSI, in the U.S call toll-free 1-800-216-7331. From elsewhere, call  
646 301-575-0156. You may send a fax to 301-210-0247. These phone numbers will be  
647 staffed on business days from 7 AM until 11 PM U.S. Eastern Time. Requests for  
648 assistance also may be emailed to [furls@fda.gov](mailto:furls@fda.gov). For assistance with ABI/ACS  
649 transmission, contact your CBP client representative.  
650

651 **54. Can I submit the prior notice to the Prior Notice System Interface in a language**  
652 **other than English?**  
653

654 You must submit all prior notice information in the English language, except that an  
655 individual's name, the name of a company, and the name of a street may be submitted in a  
656 foreign language. All information, including these items, must be submitted using the  
657 Latin (Roman) alphabet (21 CFR 1.280(a)).  
658

659 If you are not comfortable with English, you may choose to use a transmitter to enter the  
660 information for you.  
661

662 **55. Can anyone submit prior notice through ACS/ABI?**  
663

664 No. CBP allows submissions through ACS/ABI only by brokers or filers that are  
665 recognized by CBP, e.g., licensed brokers and filers. Individuals can contract with a  
666 broker to transmit prior notice for them. In this case, the submitter is the person  
667 responsible for providing the information, but the broker is the transmitter.  
668

669 Brokers are licensed private individuals or companies that are regulated by CBP and who  
670 aid importers and exporters to move merchandise through CBP. Brokers provide the  
671 proper paperwork and payments to CBP for clients and charge a fee for this service.  
672 Before brokers apply for a license, they must pass the Customs broker examination. See:  
673 [http://www.customs.gov/xp/cgov/import/broker\\_management/brokers.xml](http://www.customs.gov/xp/cgov/import/broker_management/brokers.xml)  
674

675 Filers are licensed carriers and self-filers who submit entries on their own behalf. Filers  
676 are required to submit a written request to CBP port personnel for a filer code, which is  
677 subsequently assigned by CBP headquarters. See: Chapter 10 pp. 73-76.,

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678 [http://www.cbp.gov/ImageCache/cgov/content/import/brokers/broker\\_5fhandbook\\_2epdf](http://www.cbp.gov/ImageCache/cgov/content/import/brokers/broker_5fhandbook_2epdf)  
679 [/v1/broker\\_5fhandbook.pdf](http://www.cbp.gov/ImageCache/cgov/content/import/brokers/broker_5fhandbook.pdf)

680

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

684

685 **56. Do I have to submit prior notice if I do not have to file a consumption entry with**  
686 **CBP?**

687

688 Yes. The requirement to submit prior notice to FDA is different from the requirement to  
689 file a consumption entry with CBP. Some foods arriving in the United States do not  
690 require a CBP consumption entry at the time of arrival, such as entries that move under  
691 bond (in-bonds) from the port of arrival to an inland port and shipments into a Foreign  
692 Trade Zone. However, any article of food imported or offered for import into the United  
693 States requires prior notice, unless the food is specifically excluded from the requirement  
694 to submit prior notice (21 CFR 1.277).

695

696 **57. Can I submit any CBP entry or admission for food without prior notice?**

697

698 No, not if the entry or admission contains food subject to prior notice requirements. You  
699 can not submit a CBP import entry or admission if you have not submitted prior notice to  
700 FDA for an article of food that requires prior notice, because the Harmonized Tariff  
701 Schedule (HTS) codes have been flagged to indicate foods that require or may require  
702 prior notice. You must submit prior notice either through the ABI/ACS (along with the  
703 CBP entry information) or through the FDA Prior Notice System Interface at  
704 <http://www.access.fda.gov> (21 CFR 1.280(a)).

705

706 When you submit prior notice through the FDA Prior Notice System Interface, you will  
707 receive a Prior Notice (PN) Confirmation Number (21 CFR 1.279(d)). If you  
708 subsequently submit import entry or admission information through ABI/ACS, you must  
709 enter the PN Confirmation Number for that submission as an Affirmation of Compliance  
710 when the CBP entry or admission is filed. The PN Confirmation Number will allow CBP  
711 to confirm that prior notice was submitted to FDA.

712

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

715

716 If you cannot or do not want to use ABI/ACS, you must submit prior notice through the  
717 FDA Prior Notice System Interface at <http://www.access.fda.gov>. (21 CFR 1.280(a))  
718 You will receive a confirmation number when you complete the prior notice through the  
719 Prior Notice System Interface. (21 CFR 1.279(d)) The PN Confirmation Number must  
720 accompany the food when the article arrives in the U.S. (21 CFR 1.279(g))

721

722 **59. How do I submit prior notice for foods that are covered by Immediate**  
723 **Transportation or Transportation and Exportation entries?**

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724

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

729

730 **60. I regularly ship food to the United States in a truck, under bond, to St. Louis.**

731 **When and how do I need to file prior notice?**

732

733 The time frame for submitting prior notice is based on the mode of transportation and the  
734 port of arrival, i.e., the port where the food first arrives in the United States. This port  
735 may be different from the port where the entry documentation is presented to CBP. Prior  
736 notice for food arriving by truck (by land by road) must be confirmed by FDA for review  
737 at least 2 hours before the truck arrives at the port where it is crossing the border into the  
738 United States (21 CFR 1.279).

739

740 If you are entering under bond and want to file your CBP entry in St. Louis, you can file  
741 your prior notice either through FDA's Prior Notice System Interface or through CBP's  
742 ABI/ACS interface (21 CFR 1.280(a)). If you submit the prior notice through the FDA  
743 Prior Notice System Interface, you will receive a Prior Notice Confirmation Number (21  
744 CFR 1.279(d)). This Prior Notice (PN) Confirmation Number must be made available to  
745 CBP when entering the United States, and must be entered as an Affirmation of  
746 Compliance when you file your CBP entry information (21 CFR 1.279(g)).

747

748 **61. Is there a filing fee for prior notice?**

749

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

754

755 **Prior Notice Data Elements:**

756

757 **62. What information must be included in the prior notice?**

758

759 The information required for prior notice varies, based on the type of entry, mode of  
760 transportation for the entry, and whether the food is in its natural state. You should refer  
761 to the interim final rule (21 CFR 1.281) for details on the required information. The  
762 preamble to the interim final rule includes a chart that summarizes the information  
763 requirements (68 FR 58980). The interim final rule is available on FDA's web site  
764 [www.fda.gov](http://www.fda.gov). Tutorials on the FDA Prior Notice System Interface (PNSI) also are  
765 available on FDA's website to help guide you through the process for providing the  
766 required information when you submit prior notice through PNSI.

767

768 **63. How does the information required for prior notice of imported food shipments**  
769 **differ from information submitted to the CBP before December 12, 2003?**

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770

771 Most of the information required by 21 CFR 1.281 also is entry data required by CBP  
772 before December 12, 2003. The key differences are the information required about the  
773 identity of manufacturer, grower, owner, and submitter and the identification of the  
774 country from which the article is shipped.

775

### **776 64. What time do I enter for anticipated time of arrival?**

777

778 For prior notice, anticipated time of arrival is the local time when the food will arrive at  
779 the border. (21 CFR 1.281(a)(11)(iii)) For vessels, this would be when the vessel will  
780 dock in the port where the shipment is off-loaded. For planes, this would be when the  
781 plane is scheduled to land. For land vehicles, such as trucks, buses, and trains, this would  
782 be when they will cross at the border.

783

### **784 Changes to Prior Notice Submissions:**

785

### **786 65. Do I have to resubmit prior notice if the anticipated time of arrival changes?**

787

788 No. Prior notice does not need to be resubmitted if the anticipated arrival information  
789 changes (21 CFR 1.282(a)(2)(ii)). Although a new prior notice submission is not  
790 required, FDA staff may need time to respond to the changes in arrival information.

791

### **792 66. What should I do if information changes after I submit prior notice?**

793

794 The interim final rule requires that if required information (except estimated quantity,  
795 anticipated arrival information, and planned shipment information) changes after FDA  
796 has confirmed prior notice for review, the prior notice must be resubmitted (21 CFR  
797 1.282(a)(2)).

798

799 If the prior notice was submitted as part of a multi-line ABI/ACS entry, and information  
800 about one or more of the products changes, the entry must be deleted and resubmitted.  
801 Prior notice for the new product can be submitted as part of a new entry. If you  
802 submitted the prior notice via the FDA Prior Notice System Interface, you should cancel  
803 the prior notice via the FDA Prior Notice System Interface (21 CFR 1.282(b)).

804

### **805 67. Which changes require me to resubmit prior notice and which changes don't?**

806

807 Changes in the estimated quantity, anticipated arrival information, or planned shipment  
808 do not require resubmission of prior notice after FDA has confirmed your prior notice  
809 submission for review (21 CFR 1.282(a)(1)(i)-(iii)). For all other changes, e.g., if the  
810 identity of the manufacturer changes, you should cancel the prior notice and you must  
811 resubmit prior notice if you still intend to import or offer the food for import into the U.S.  
812 (21 CFR 1.282).

813

814

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814 **Changes to Shipments:**

815

816 **68. May I add another article of food to an existing prior notice after the prior**  
817 **notice has been submitted to FDA?**

818

819 No. Each article of food requires a separate prior notice (21 CFR 1.281(a)(5) and  
820 1.281(b)(4)) and receives a unique confirmation number (21 CFR 1.279(d)). However,  
821 FDA is allowing prior notices to be grouped in an ABI/ACS entry, or in an “envelope”  
822 for the FDA Prior Notice System Interface (PNSI) entries and In-Bonds submitted  
823 through ABI/ACS, in order to reduce data entry for transmitters and to simplify CBP  
824 review at the border. For submissions through PNSI, no articles of food can be added to  
825 an envelope after the Prior Notice Confirmation Number(s) has been received. For  
826 submissions through ABI/ACS, no additional lines may be added after the entry is  
827 accepted by ACS.

828

829 **69. What can I do if I want to add another article of food to a shipment after prior**  
830 **notice was submitted to the FDA?**

831

832 New articles of food cannot be added to an entry, or prior notice envelope, after it has  
833 been submitted to FDA (21 CFR 1.282). If a new article of food is being added to a  
834 shipment for which prior notice(s) has already been submitted and confirmed, a separate  
835 prior notice must be filed for that article under a new entry/envelope (21 CFR 1.281(a)  
836 and (b)). The submission time for the new prior notice will be different from that of the  
837 rest of the shipment, and this may have an effect on the ability of the shipment to enter  
838 the United States (21 CFR 1.279). For example, if you add another food to a truck at  
839 9:00am, that food is not covered by timely prior notice until 11:00am. The rest of the  
840 food on that same truck may be covered by prior notices submitted at 8:00 am and  
841 deemed timely at 10:00 am. It is recommended that the time for arrival be anticipated on  
842 the last article of food submitted and confirmed by FDA for review.

843

844 **70. What can I do if I want to remove an article of food from the information**  
845 **provided for a shipment?**

846

847 If the prior notice was submitted through ACS, you can delete the prior notice using the  
848 existing entry delete procedures. If you submitted the prior notice via the FDA Prior  
849 Notice System Interface, you should cancel the prior notice via the Prior Notice System  
850 Interface (21 CFR 1.282(b)).

851

852 **PNSI and ACS/ABI Features:**

853

854 **71. If I need to revise some information on a prior notice, will some of the fields be**  
855 **filled in by the computer automatically or will I need to start from the**  
856 **beginning?**

857

858 The answer depends on how the prior notice submission is being made. If submitting  
859 through the CPB Automated Broker Interface of the Automated Commercial System

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860 (ABI/ACS), the ability to pre-fill or otherwise support submission will depend on the  
861 functionality of the software used by the filer. The ABI/ACS interface is concerned with  
862 the validity of the information in the submission, not with how it was generated.

863

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

869

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

873

874 **Confirmation:**

875

876 **72. Will I receive confirmation that FDA has received the prior notice I submitted?**

877

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

885

886 **73. Is a copy of the prior notice required to accompany the food?**

887

888 To ensure that entry proceeds as smoothly as possible, the carrier or individual should  
889 consider having a copy of the reply message that contains a PN Confirmation Number in  
890 his/her possession upon arrival.

891

892 For food carried by or otherwise accompanying an individual that is not for personal use,  
893 the individual must provide a copy of the PN confirmation to FDA or CBP. Food  
894 covered by prior notice submitted through the FDA Prior Notice System Interface must  
895 be accompanied by a copy of the reply message that contains the PN Confirmation  
896 Number.

897

898 For international mail packages, the confirmation number must accompany the package.

899

900 **74. Does receipt of a PN Confirmation Number mean that the food will not be  
901 examined or sampled?**

902

903 No. Receipt of a PN Confirmation Number is evidence only that a prior notice has been  
904 received for FDA review. Based on review of the prior notice, FDA may determine that  
905 an article of food should not be allowed to proceed into the United States without further

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906 inspection and sampling at the border. The food may be refused under the prior notice  
907 regulation and section 801(m) of the FD&C Act and held if the prior notice is inaccurate  
908 or if it is untimely and FDA has not had sufficient time to receive, review, and respond to  
909 the prior notice information. In addition, FDA may examine or sample the food for food  
910 safety and security concerns and for determining whether the food is subject to refusal  
911 under section 801(a) of the FD&C Act.

912

913 **75. If receipt of the Prior Notice (PN) confirmation number does not mean the FDA**  
914 **has determined that timely prior notice was submitted or that the information**  
915 **submitted is accurate, what is the value of the PN Confirmation Number?**

916

917 The Prior Notice (PN) Confirmation Number is FDA's notice to you that that your prior  
918 notice was submitted to and received for review by FDA. It is the signal to you that the  
919 time frame for prior notice for the food covered by that prior notice submission has  
920 started. In addition, the PN Confirmation Number provides a mechanism for prior notice  
921 data, submitted to FDA, to be matched with an entry submitted to CBP. The timeliness of  
922 prior notice can not be assessed until the food actually arrives in the United States and,  
923 often, the accuracy of the prior notice can not be fully determined until the food is  
924 examined upon arrival.

925

### 926 **E. CONSEQUENCES**

927

#### 928 **Inadequate prior notice:**

929

930 **76. What does FDA consider to be inadequate prior notice?**

931

932 Inadequate prior notice is when:

- 933 a. There is no prior notice submitted for an article of food imported or offered for
- 934 import into the United States; and/or
- 935 b. The information submitted in the prior notice is inaccurate; and/or
- 936 c. The prior notice is not submitted in concurrence with the required timeframes.

937

938 FDA's enforcement policies on inadequate prior notice are being set out in a separate  
939 guidance document. This Compliance Policy Guide will be available on FDA's website  
940 at [http://www.fda.gov/ora/compliance\\_ref/cpg/default.htm](http://www.fda.gov/ora/compliance_ref/cpg/default.htm).

941

942 **77. What are some examples of inadequate prior notice?**

943

944 The following examples of inadequate prior notice are for 5 articles of food (foods A, B,  
945 C, D, & E) arriving at the border by truck:

- 946 a. Prior notice was submitted for only 4 of the 5 articles of food (foods A, B, C, &  
947 D). Inadequate prior notice, e.g., no prior notice, was provided for food E.
- 948 b. Prior notice for food A was submitted and confirmed for FDA review with PN  
949 Confirmation Number 999. Food B arrives associated with PN Confirmation  
950 Number 999. Inadequate prior notice, e.g., inaccurate prior notice, was provided  
951 for food B.

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952 c. Prior notice for food A was submitted and confirmed for FDA review at 9:00am  
953 on February 2, 2005. Food A arrives at the port of arrival at 9:30 am on February  
954 2, 2005, but CBP has not received an examination decision response from FDA.  
955 Inadequate prior notice, e.g., untimely prior notice, was provided for food A.  
956

957 FDA's enforcement policies on inadequate prior notice are being set out in a separate  
958 guidance document. This Compliance Policy Guide will be available on FDA's website  
959 at [http://www.fda.gov/ora/compliance\\_ref/cpg/default.htm](http://www.fda.gov/ora/compliance_ref/cpg/default.htm).  
960

961 **78. What happens to food that is imported or offered for import without adequate**  
962 **prior notice?**  
963

964 Articles of food arriving with no prior notice, inaccurate prior notice, or untimely prior  
965 notice may be refused admission and, other than food arriving by international mail or  
966 carried by or otherwise accompanying an individual, if refused, will be handled in one of  
967 the following ways:

- 968 a. Immediately exported, with CBP concurrence, from the port of arrival; or
- 969 b. Held within the port of entry, unless directed by CBP or FDA. (21 CFR  
970 1.283(a)(1)(i)-(iii) and (b))  
971

972 Refused food is considered general order merchandise under section 490(a) of the Tariff  
973 Act (19 U.S.C. 1490(a)) and may move only under appropriate custodial bond (21 CFR  
974 1.283(a)(2)). If the refused article is moved, the submitter must notify FDA of the hold  
975 location within 24 hours of refusal. The refused food may not be delivered to the  
976 importer, owner, or ultimate consignee. (21 CFR 1.283(a)(2)(ii))  
977

978 For food that is carried by or accompanies an individual arriving in the U.S. and the food  
979 is not for personal use, if adequate prior notice is not submitted or if the PN confirmation  
980 number cannot be provided to FDA or CBP, the food is subject to refusal. If before  
981 leaving the port, the individual does not arrange to have the food held at the port or  
982 exported, the article may be destroyed (21 CFR 1.283(b)).  
983

984 For food arriving by international mail, if prior notice is inadequate or if the PN  
985 Confirmation Number is not affixed, the article will be held for FDA inspection and  
986 disposition. If refused and there is a return address, the parcel may be returned to sender.  
987 If there is no return address or the food in the shipment appears to present a hazard, FDA  
988 may dispose of or destroy the parcel at its expense. If FDA does not respond within 72  
989 hours of the CBP hold, CBP may return the parcel back to the sender or, if there is no  
990 return address, destroy the parcel, at FDA expense.  
991

992 FDA's enforcement policies on inadequate prior notice are being set out in a separate  
993 guidance document. This Compliance Policy Guide will be available on FDA's website  
994 at [http://www.fda.gov/ora/compliance\\_ref/cpg/default.htm](http://www.fda.gov/ora/compliance_ref/cpg/default.htm).  
995  
996

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996 **79. Will my food be held if it arrives earlier than the anticipated time of arrival I**  
997 **submitted?**

998  
999 If arrival occurs before the anticipated arrival time, the food could be refused and held  
1000 until the prior notice timeframe has elapsed (21 CFR 1.279) or until processing is  
1001 complete, which ever comes first. However, if the prior notice has been fully processed  
1002 by FDA, the food will not be refused because the anticipated arrival time has not yet  
1003 come (21 CFR 1.283(a)(1)(ii)). However, if FDA plans to examine the food, it may be  
1004 held to allow time for FDA staff to arrive.

1005  
1006 **80. What does it mean if, after I receive a Prior Notice (PN) Confirmation Number,**  
1007 **FDA later refuses the same article of food?**

1008  
1009 The PN Confirmation Number only confirms that the submission is complete and facially  
1010 valid. If FDA's review process determines that the prior notice is inaccurate after receipt  
1011 of the prior notice is confirmed by issuance of the PN Confirmation Number, the article  
1012 of food is still subject to refusal under 21 CFR 1.283(a)(1)(ii).

1013  
1014 **81. Does meeting all the requirements of prior notice mean that the article of food**  
1015 **will not be held or examined further?**

1016  
1017 No, the food must meet the requirements of all other applicable regulations as well. If  
1018 FDA decides to take no prior notice action for an article of food under 21 CFR 1.283 or  
1019 1.285(a), this decision has no bearing on whether the article of food is admissible or will  
1020 be granted admission under other provisions of the FD&C Act or other U.S. laws. Thus,  
1021 for imported food or food offered for import, FDA will continue its normal investigative  
1022 and enforcement activities for food safety and security concerns and for determining  
1023 whether the food is subject to refusal under section 801(a) of the FD&C Act.

1024  
1025 **82. Who will be notified if FDA determines that a food needs to be held for**  
1026 **examination when it arrives at the border?**

1027  
1028 FDA will communicate the decision to examine articles of food to CBP.

1029  
1030 **Transition period:**

1031  
1032 **83. Does FDA plan to provide a transition period for implementing the prior notice**  
1033 **regulation?**

1034  
1035 FDA intends to provide an initial transition period during which we will emphasize  
1036 education regarding the requirements of prior notice to achieve compliance. Specific  
1037 details regarding that transition period will be provided in an FDA Compliance Policy  
1038 Guide. The Compliance Policy Guide will be available on FDA's website at  
1039 [http://www.fda.gov/ora/compliance\\_ref/cpg/default.htm](http://www.fda.gov/ora/compliance_ref/cpg/default.htm). (68 FR 58974)

1040

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1041 **84. Will import food shipments be held or refused admission for lack of prior notice**  
1042 **if they are in route to the U.S. before December 12, 2003 but do not arrive until**  
1043 **after the prior notice rule is in effect?**  
1044

1045 Rather than hold or refuse admission of shipments that are in route before December 12,  
1046 and arrive on or soon after December 12, FDA intends generally to provide information  
1047 on the requirements of prior notice.  
1048

1049 **III. ELECTRONIC ACCESS**  
1050

1051 Persons with access to the Internet may obtain this document "Prior Notice Questions and  
1052 Answers" at <http://www.cfsan.fda.gov/guidance.html>.  
1053

1054 Dated: December <insert date>, 2003  
1055  
1056  
1057