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#### List of Subjects in 21 CFR Part 1

Cosmetics, Drugs, Exports, Food labeling, Imports, Labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 1 be amended as follows:

#### PART 1—GENERAL ENFORCEMENT REGULATIONS

1. The authority citation for 21 CFR part 1 continues to read as follows:

**Authority:** 15 U.S.C. 1453, 1454, 1455; 21 U.S.C. 304, 321, 331, 334, 343, 350c, 350d, 352, 355, 360b, 362, 371, 374, 381, 382, 393; 42 U.S.C. 216, 241, 243, 262, 264.

2. Subpart I is added to part 1 to read as follows:

#### Subpart I—PRIOR NOTICE OF IMPORTED FOOD

##### General Provisions

Sec.

1.276 What imported food is subject to this subpart?

1.277 What definitions apply to this subpart?

1.278 What are the consequences of failing to submit adequate prior notice or otherwise failing to comply with this subpart?

#### Requirements to Submit Prior Notice of Imported Food

Sec.

1.285 Who is authorized to submit prior notice for an article of food that is imported or offered for import into the United States?

1.286 When must the prior notice be submitted to FDA?

1.287 How must you submit the prior notice?

1.288 What information must be submitted in the prior notice?

1.289 What changes are allowed to a prior notice after it has been submitted to FDA?

1.290 Under what circumstances must you submit a product identity amendment to your prior notice after you have submitted it to FDA?

1.291 What is the deadline for product identity amendments under § 1.290?

1.292 How do you submit a product identity amendment to a prior notice?

1.293 What are the consequences if you do not submit a product identity amendment to your prior notice?

1.294 What must you do if the anticipated arrival information (required under § 1.288(k)(1)) submitted in your prior notice changes?

#### General Provisions

##### § 1.276 What imported food is subject to this subpart?

(a) This subpart applies to food for humans and other animals that is imported or offered for import into the United States (U.S.), including U.S. foreign trade zones, for consumption, storage, immediate export from the port of entry, transshipment through the United States to another country, or import for export.

(b) This subpart does not apply to:

(1) Food that is carried by an individual entering the United States in that individual's personal baggage for that individual's personal use;

(2) Meat food products that at the time of importation are subject to the exclusive jurisdiction of the U.S. Department of Agriculture (USDA) under the Federal Meat Inspection Act (21 U.S.C. 601 *et seq.*);

(3) Poultry products that at the time of importation are subject to the exclusive jurisdiction of USDA under the Poultry Products Inspection Act (21 U.S.C. 451 *et seq.*); and

(4) Egg products that at the time of importation are subject to the exclusive jurisdiction of USDA under the Egg Products Inspection Act (21 U.S.C. 1031 *et seq.*).

##### § 1.277 What definitions apply to this subpart?

(a) The act means the Federal Food, Drug, and Cosmetic Act.

(b) The definitions of terms in section 201 of the act (21 U.S.C. 321) apply when the terms are used in this subpart.

(c) In addition, for the purposes of this subpart:

(1) *Calendar day* means every day shown on the calendar.

(2) *Country from which the article of food was shipped* means the country in which the article of food was loaded onto the conveyance that brings it to the United States.

(3) *Food* has the meaning given in section 201(f) of the act. Examples of food include, but are not limited to, fruits, vegetables, fish, dairy products, eggs, raw agricultural commodities for use as food or components of food, animal feed, including pet food, food and feed ingredients and additives, including substances that migrate into food from food packaging and other articles that contact food, dietary supplements and dietary ingredients, infant formula, beverages, including alcoholic beverages and bottled water, live food animals, bakery goods, snack foods, candy, and canned foods.

(4) *Originating country* means the country from which the article of food originates. If the article of food is fresh produce or fresh aquacultured fish or seafood, the originating country is the country in which it is grown and harvested. If the article of food is wild-caught fish or seafood and it is harvested in the waters of the United States or by a U.S. flagged vessel or processed aboard a U.S. flagged vessel, the originating country is the United States. Otherwise, the originating country is the country in which the article of food is produced.

(5) *Port of entry* means the water, air, or land port at which the article of food is imported or offered for import into the United States, i.e., the port where food first arrives in the United States. This port may be different than the port where the article of food is entered for U.S. Customs Service purposes.

(6) *You* means the purchaser or importer of an article of food who resides or maintains a place of business in the United States, or an agent who resides or maintains a place of business in the United States acting on the behalf of the U.S. purchaser or importer or, if the article of food is imported with the intention of in-bond movement through the United States for export, i.e., Transportation for Exportation or Immediate Export entries, the arriving carrier or, if known, the in-bond carrier.

##### § 1.278 What are the consequences of failing to submit adequate prior notice or otherwise failing to comply with this subpart?

(a) If an article of food is imported or offered for import with no prior notice or inadequate (e.g., untimely, inaccurate, or incomplete) prior notice, the food shall be refused admission