

## SUBCHAPTER A—GENERAL

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AUTHORITY: 15 U.S.C. 1453, 1454, 1455; 19 U.S.C. 1490, 1491; 21 U.S.C. 321, 331, 332, 333, 334, 335a, 343, 350c, 350d, 352, 355, 360b, 362, 371, 374, 381, 382, 393; 42 U.S.C. 216, 241, 243, 262, 264.

SOURCE: 42 FR 15553, Mar. 22, 1977, unless otherwise noted.

#### Subpart A—General Provisions

##### § 1.1 General.

(a) The provisions of regulations promulgated under the Federal Food, Drug, and Cosmetic Act with respect to the doing of any act shall be applicable

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also to the causing of such act to be done.

(b) The definitions and interpretations of terms contained in section 201 of the Federal Food, Drug, and Cosmetic Act shall be applicable also to such terms when used in regulations promulgated under that act.

(c) The definition of *package* in § 1.20 and of *principal display panel* in §§ 101.1, 201.60, 501.1, 701.10 and 801.60 of this chapter; and the requirements pertaining to uniform location, lack of qualification, and separation of the net quantity declaration in §§ 101.105(f), 201.62(e), 501.105(f), 701.13(f) and 801.62(e) of this chapter to type size requirements for net quantity declaration in §§ 101.105(i), 201.62(h), 501.105(i), 701.13(i) and 801.62(h) of this chapter, to initial statement of ounces in the dual declaration of net quantity in §§ 101.105(j) and (m), 201.62(i) and (k), 501.105(j) and (m), 701.13(j) and (m) and 801.62(i) and (k) of this chapter, to initial statement of inches in declaration of net quantity in §§ 201.62(m), 701.13(o) and 801.62(m) of this chapter, to initial statement of square inches in declaration of net quantity in §§ 201.62(n), 701.13(p) and 801.62(n) of this chapter, to prohibition of certain supplemental net quantity statements in §§ 101.105(o), 201.62(o), 501.105(o), 701.13(q) and 801.62(o) of this chapter, and to servings representations in § 501.8 of this chapter are provided for solely by the Fair Packaging and Labeling Act. The other requirements of this part are issued under both the Fair Packaging and Labeling Act and the Federal Food, Drug, and Cosmetic Act, or by the latter act solely, and are not limited in their application by section 10 of the Fair Packaging and Labeling Act.

[42 FR 15553, Mar. 22, 1977, as amended at 58 FR 17085, Apr. 1, 1993]

#### § 1.3 Definitions.

(a) *Labeling* includes all written, printed, or graphic matter accompanying an article at any time while such article is in interstate commerce or held for sale after shipment or delivery in interstate commerce.

(b) *Label* means any display of written, printed, or graphic matter on the immediate container of any article, or any such matter affixed to any con-

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sumer commodity or affixed to or appearing upon a package containing any consumer commodity.

#### § 1.4 Authority citations.

(a) For each part of its regulations, the Food and Drug Administration includes a centralized citation of all of the statutory provisions that provide authority for any regulation that is included in that part.

(b) The agency may rely on any one or more of the authorities that are listed for a particular part in implementing or enforcing any section in that part.

(c) All citations of authority in this chapter will list the applicable sections in the organic statute if the statute is the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, or the Fair Packaging and Labeling Act. References to an act or a section thereof include references to amendments to that act or section. These citations will also list the corresponding United States Code (U.S.C.) sections. For example, a citation to section 701 of the Federal Food, Drug, and Cosmetic Act would be listed: Sec. 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371).

(d) If the organic statute is one other than those specified in paragraph (c) of this section, the citations of authority in this chapter generally will list only the applicable U.S.C. sections. For example, a citation to section 552 of the Administrative Procedure Act would be listed: 5 U.S.C. 552. The agency may, where it determines that such measures are in the interest of clarity and public understanding, list the applicable sections in the organic statute and the corresponding U.S.C. section in the same manner set out in paragraph (c) of this section. References to an act or a section thereof include references to amendments to that act or section.

(e) Where there is no U.S.C. provision, the agency will include a citation to the U.S. Statutes at Large. Citations to the U.S. Statutes at Large will refer to volume and page.

(f) The authority citations will include a citation to executive delegations (i.e., Executive Orders), if any,

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necessary to link the statutory authority to the agency.

[54 FR 39630, Sept. 27, 1989]

### Subpart B—General Labeling Requirements

#### § 1.20 Presence of mandatory label information.

The term *package* means any container or wrapping in which any food, drug, device, or cosmetic is enclosed for use in the delivery or display of such commodities to retail purchasers, but does not include:

(a) Shipping containers or wrappings used solely for the transportation of any such commodity in bulk or in quantity to manufacturers, packers, processors, or wholesale or retail distributors;

(b) Shipping containers or outer wrappings used by retailers to ship or deliver any such commodity to retail customers if such containers and wrappings bear no printed matter pertaining to any particular commodity; or

(c) Containers subject to the provisions of the Act of August 3, 1912 (37 Stat. 250, as amended; 15 U.S.C. 231-233), the Act of March 4, 1915 (38 Stat. 1186, as amended; 15 U.S.C. 234-236), the Act of August 31, 1916 (39 Stat. 673, as amended; 15 U.S.C. 251-256), or the Act of May 21, 1928 (45 Stat. 635, as amended; 15 U.S.C. 257-257i).

(d) Containers used for tray pack displays in retail establishments.

(e) Transparent wrappers or containers which do not bear written, printed, or graphic matter obscuring the label information required by this part.

A requirement contained in this part that any word, statement, or other information appear on the label shall not be considered to be complied with unless such word, statement, or information also appears on the outer container or wrapper of the retail package of the article, or, as stated in paragraph (e) of this section, such information is easily legible by virtue of the transparency of the outer wrapper or container. Where a consumer commodity is marketed in a multiunit retail package bearing the mandatory

label information as required by this part and the unit containers are not intended to be sold separately, the net weight placement requirement of § 101.105(f) applicable to such unit containers is waived if the units are in compliance with all the other requirements of this part.

#### § 1.21 Failure to reveal material facts.

(a) Labeling of a food, drug, device, or cosmetic shall be deemed to be misleading if it fails to reveal facts that are:

(1) Material in light of other representations made or suggested by statement, word, design, device or any combination thereof; or

(2) Material with respect to consequences which may result from use of the article under: (i) The conditions prescribed in such labeling or (ii) such conditions of use as are customary or usual.

(b) Affirmative disclosure of material facts pursuant to paragraph (a) of this section may be required, among other appropriate regulatory procedures, by

(1) Regulations in this chapter promulgated pursuant to section 701(a) of the act; or

(2) Direct court enforcement action.

(c) Paragraph (a) of this section does not:

(1) Permit a statement of differences of opinion with respect to warnings (including contraindications, precautions, adverse reactions, and other information relating to possible product hazards) required in labeling for food, drugs, devices, or cosmetics under the act.

(2) Permit a statement of differences of opinion with respect to the effectiveness of a drug unless each of the opinions expressed is supported by substantial evidence of effectiveness as defined in sections 505(d) and 512(d) of the act.

#### § 1.23 Procedures for requesting variations and exemptions from required label statements.

Section 403(e) of the act (in this part 1, the term *act* means the Federal Food, Drug, and Cosmetic Act) provides for the establishment by regulation of reasonable variations and exemptions for small packages from the required declaration of net quantity of

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contents. Section 403(i) of the act provides for the establishment by regulation of exemptions from the required declaration of ingredients where such declaration is impracticable, or results in deception or unfair competition. Section 502(b) of the act provides for the establishment by regulation of reasonable variations and exemptions for small packages from the required declaration of net quantity of contents. Section 602(b) of the act provides for the establishment by regulation of reasonable variations and exemptions for small packages from the required declaration of net quantity of contents. Section 5(b) of the Fair Packaging and Labeling Act provides for the establishment by regulation of exemptions from certain required declarations of net quantity of contents, identity of commodity, identity and location of manufacturer, packer, or distributor, and from declaration of net quantity of servings represented, based on a finding that full compliance with such required declarations is impracticable or not necessary for the adequate protection of consumers, and a further finding that the nature, form, or quantity of the packaged consumer commodity or other good and sufficient reasons justify such exemptions. The Commissioner, on his own initiative or on petition of an interested person, may propose a variation or exemption based upon any of the foregoing statutory provisions, including proposed findings if section 5(b) of the Fair Packaging and Labeling Act applies, pursuant to parts 10, 12, 13, 14, 15, 16, and 19 of this chapter.

### § 1.24 Exemptions from required label statements.

The following exemptions are granted from label statements required by this part:

(a) *Foods.* (1) While held for sale, a food shall be exempt from the required declaration of net quantity of contents specified in this part if said food is received in bulk containers at a retail establishment and is accurately weighed, measured, or counted either within the view of the purchaser or in compliance with the purchaser's order.

(2) Random food packages, as defined in § 101.105(j) of this chapter, bearing la-

bel statements declaring net weight, price per pound or per specified number of pounds, and total price shall be exempt from the type size, dual declaration, and placement requirements of § 101.105 of this chapter if the accurate statement of net weight is presented conspicuously on the principal display panel of the package. In the case of food packed in random packages at one place for subsequent shipment and sale at another, the price sections of the label may be left blank provided they are filled in by the seller prior to retail sale. This exemption shall also apply to uniform weight packages of cheese and cheese products labeled in the same manner and by the same type of equipment as random food packages exempted by this paragraph (a)(2) except that the labels shall bear a declaration of price per pound and not price per specified number of pounds.

(3) Individual serving-size packages of foods containing less than ½ ounce or less than ½ fluid ounce for use in restaurants, institutions, and passenger carriers, and not intended for sale at retail, shall be exempt from the required declaration of net quantity of contents specified in this part.

(4) Individually wrapped pieces of *penny candy* and other confectionery of less than one-half ounce net weight per individual piece shall be exempt from the labeling requirements of this part when the container in which such confectionery is shipped is in conformance with the labeling requirements of this part. Similarly, when such confectionery items are sold in bags or boxes, such items shall be exempt from the labeling requirements of this part, including the required declaration of net quantity of contents specified in this part when the declaration on the bag or box meets the requirements of this part.

(5)(i) Soft drinks packaged in bottles shall be exempt from the placement requirements for the statement of identity prescribed by § 101.3 (a) and (d) of this chapter if such statement appears conspicuously on the bottle closure. When such soft drinks are marketed in a multiunit retail package, the multiunit retail package shall be exempt from the statement of identity declaration requirements prescribed by § 101.3

of this chapter if the statement of identity on the unit container is not obscured by the multiunit retail package.

(ii) A multiunit retail package for soft drinks shall be exempt from the declaration regarding name and place of business required by §101.5 of this chapter if the package does not obscure the declaration on unit containers or if it bears a statement that the declaration can be found on the unit containers and the declaration on the unit containers complies with §101.5 of this chapter. The declaration required by §101.5 of this chapter may appear on the top or side of the closure of bottled soft drinks if the statement is conspicuous and easily legible.

(iii) Soft drinks packaged in bottles which display other required label information only on the closure shall be exempt from the placement requirements for the declaration of contents prescribed by §101.105(f) of this chapter if the required content declaration is blown, formed, or molded into the surface of the bottle in close proximity to the closure.

(iv) Where a trademark on a soft drink package also serves as, or is, a statement of identity, the use of such trademark on the package in lines not parallel to the base on which the package rests shall be exempted from the requirement of §101.3(d) of this chapter that the statement be in lines parallel to the base so long as there is also at least one statement of identity in lines generally parallel to the base.

(v) A multiunit retail package for soft drinks in cans shall be exempt from the declaration regarding name and place of business required by §101.5 of this chapter if the package does not obscure the declaration on unit containers or if it bears a statement that the declaration can be found on the unit containers and the declaration on the unit containers complies with §101.5 of this chapter. The declaration required by §101.5 of this chapter may appear on the top of soft drinks in cans if the statement is conspicuous and easily legible, provided that when the declaration is embossed, it shall appear in type size at least one-eighth inch in height, or if it is printed, the type size shall not be less than one-sixteenth inch in height. The declaration may

follow the curvature of the lid of the can and shall not be removed or obscured by the tab which opens the can.

(6)(i) Ice cream, french ice cream, ice milk, fruit sherbets, water ices, quiescently frozen confections (with or without dairy ingredients), special dietary frozen desserts, and products made in semblance of the foregoing, when measured by and packaged in ½-liquid pint and ½-gallon measure-containers, as defined in the "Measure Container Code of National Bureau of Standards Handbook 44," Specifications, Tolerances, and Other Technical Requirements for Weighing and Measuring Devices, Sec. 4.45 "Measure-Containers," which is incorporated by reference, are exempt from the requirements of §101.105(b)(2) of this chapter to the extent that net contents of 8-fluid ounces and 64-fluid ounces (or 2 quarts) may be expressed as ½ pint and ½ gallon, respectively. Copies are available from the Center for Food Safety and Applied Nutrition (HFS-150), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, or available for inspection at the Office of the Federal Register, 800 North Capitol Street NW., suite 700, Washington, DC.

(ii) The foods named in paragraph (a)(6)(i) of this section, when measured by and packaged in 1-liquid pint, 1-liquid quart, and ½-gallon measure-containers, as defined in the "Measure Container Code of National Bureau of Standards Handbook 44," Specifications, Tolerances, and Other Technical Requirements for Weighing and Measuring Devices, Sec. 4.45 "Measure-Containers," which is incorporated by reference, are exempt from the dual net-contents declaration requirement of §101.105(j) of this chapter. Copies are available from the Center for Food Safety and Applied Nutrition (HFS-150), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, or available for inspection at the Office of the Federal Register, 800 North Capitol Street NW., suite 700, Washington, DC.

(iii) The foods named in paragraph (a)(6)(i) of this section, when measured by and packaged in ½-liquid pint, 1-liquid pint, 1-liquid quart, ½-gallon, and 1-gallon measured-containers, as defined in the "Measure Container Code

of National Bureau of Standards Handbook 44," Specifications, Tolerances, and Other Technical Requirements for Weighing and Measuring Devices, Sec. 4.45 "Measure-Containers," which is incorporated by reference, are exempt from the requirement of § 101.105(f) of this chapter that the declaration of net contents be located within the bottom 30 percent of the principal display panel. Copies are available from the Center for Food Safety and Applied Nutrition (HFS-150), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, or available for inspection at the Office of the Federal Register, 800 North Capitol Street NW., suite 700, Washington, DC.

(7)(i) Milk, cream, light cream, coffee or table cream, whipping cream, light whipping cream, heavy or heavy whipping cream, sour or cultured sour cream, half-and-half, sour or cultured half-and-half, reconstituted or recombined milk and milk products, concentrated milk and milk products, skim or skimmed milk, vitamin D milk and milk products, fortified milk and milk products, homogenized milk, flavored milk and milk products, buttermilk, cultured buttermilk, cultured milk or cultured whole buttermilk, low-fat milk (0.5 to 2.0 percent butterfat), and acidified milk and milk products, when packaged in containers of 8- and 64-fluid-ounce capacity, are exempt from the requirements of § 101.105(b)(2) of this chapter to the extent that net contents of 8 fluid ounces and 64 fluid ounces (or 2 quarts) may be expressed as ½ pint and ½ gallon, respectively.

(ii) The products listed in paragraph (a)(7)(i) of this section, when packaged in glass or plastic containers of ½-pint, 1-pint, 1-quart, ½-gallon, and 1-gallon capacities are exempt from the placement requirement of § 101.105(f) of this chapter that the declaration of net contents be located within the bottom 30 percent of the principal display panel, provided that other required label information is conspicuously displayed on the cap or outside closure and the required net quantity of contents declaration is conspicuously blown, formed, or molded into or permanently applied to that part of the

glass or plastic container that is at or above the shoulder of the container.

(iii) The products listed in paragraph (a)(7)(i) of this section, when packaged in containers of 1-pint, 1-quart, and ½-gallon capacities are exempt from the dual net-contents declaration requirement of § 101.105(j) of this chapter.

(8) Wheat flour products, as defined by §§ 137.105, 137.155, 137.160, 137.165, 137.170, 137.175, 137.180, 137.185, 137.200, and 137.205 of this chapter, packaged:

(i) In conventional 2-, 5-, 10-, 25-, 50-, and 100-pound packages are exempt from the placement requirement of § 101.105(f) of this chapter that the declaration of net contents be located within the bottom 30 percent of the area of the principal display panel of the label; and

(ii) In conventional 2-pound packages are exempt from the dual net-contents declaration requirement of § 101.105(j) of this chapter provided the quantity of contents is expressed in pounds.

(9)(i) Twelve shell eggs packaged in a carton designed to hold 1 dozen eggs and designed to permit the division of such carton by the retail customer at the place of purchase into two portions of one-half dozen eggs each are exempt from the labeling requirements of this part with respect to each portion of such divided carton if the carton, when undivided, is in conformance with the labeling requirements of this part.

(ii) Twelve shell eggs packaged in a carton designed to hold 1 dozen eggs are exempt from the placement requirements for the declaration of contents prescribed by § 101.105(f) of this chapter if the required content declaration is otherwise placed on the principal display panel of such carton and if, in the case of such cartons designed to permit division by retail customers into two portions of one-half dozen eggs each, the required content declaration is placed on the principal display panel in such a manner that the context of the content declaration is destroyed upon division of the carton.

(10) Butter as defined in 42 Stat. 1500 (excluding whipped butter):

(i) In 8-ounce and in 1-pound packages is exempt from the requirements of § 101.105(f) of this chapter that the net contents declaration be placed

within the bottom 30 percent of the area of the principal display panel;

(ii) In 1-pound packages is exempt from the requirements of § 101.105(j)(1) of this chapter that such declaration be in terms of ounces and pounds, to permit declaration of "1-pound" or "one pound"; and

(iii) In 4-ounce, 8-ounce, and 1-pound packages with continuous label copy wrapping is exempt from the requirements of §§ 101.3 and 101.105(f) of this chapter that the statement of identity and net contents declaration appear in lines generally parallel to the base on which the package rests as it is designed to be displayed, provided that such statement and declaration are not so positioned on the label as to be misleading or difficult to read as the package is customarily displayed at retail.

(11) Margarine as defined in § 166.110 of this chapter and imitations thereof in 1-pound rectangular packages, except for packages containing whipped or soft margarine or packages that contain more than four sticks, are exempt from the requirement of § 101.105(f) of this chapter that the declaration of the net quantity of contents appear within the bottom 30 percent of the principal display panel and from the requirement of § 101.105(j)(1) of this chapter that such declaration be expressed both in ounces and in pounds to permit declaration of "1-pound" or "one pound," provided an accurate statement of net weight appears conspicuously on the principal display panel of the package.

(12) Corn flour and related products, as they are defined by §§ 137.211, 137.215, and §§ 137.230 through 137.290 of this chapter, packaged in conventional 5-, 10-, 25-, 50-, and 100-pound bags are exempt from the placement requirement of § 101.105(f) of this chapter that the declaration of net contents be located within the bottom 30 percent of the area of the principal display panel of the label.

(13)(i) Single strength and less than single strength fruit juice beverages, imitations thereof, and drinking water when packaged in glass or plastic containers of ½-pint, 1-pint, 1-quart, ½-gallon, and 1-gallon capacities are exempt from the placement requirement of § 101.105(f) of this chapter that the

declaration of net contents be located within the bottom 30 percent of the principal display panel: *Provided*, That other required label information is conspicuously displayed on the cap or outside closure and the required net quantity of contents declaration is conspicuously blown, formed, or molded into or permanently applied to that part of the glass or plastic container that is at or above the shoulder of the container.

(ii) Single strength and less than single strength fruit juice beverages, imitations thereof, and drinking water when packaged in glass, plastic, or paper (fluid milk type) containers of 1-pint, 1-quart, and ½-gallon capacities are exempt from the dual net-contents declaration requirement of § 101.105(j) of this chapter.

(iii) Single strength and less than single strength fruit juice beverages, imitations thereof, and drinking water when packaged in glass, plastic, or paper (fluid milk type) containers of 8- and 64-fluid-ounce capacity, are exempt from the requirements of § 101.105(b)(2) of this chapter to the extent that net contents of 8 fluid ounces and 64 fluid ounces (or 2 quarts) may be expressed as ½ pint (or half pint) and ½ gallon (or half gallon), respectively.

(14) The unit containers in a multi-unit or multicomponent retail food package shall be exempt from regulations of section 403 (e)(1), (g)(2), (i)(2), (k), and (q) of the act with respect to the requirements for label declaration of the name and place of business of the manufacturer, packer, or distributor; label declaration of ingredients; and nutrition information when:

(i) The multiunit or multicomponent retail food package labeling meets all the requirements of this part;

(ii) The unit containers are securely enclosed within and not intended to be separated from the retail package under conditions of retail sale; and

(iii) Each unit container is labeled with the statement "This Unit Not Labeled For Retail Sale" in type size not less than one-sixteenth of an inch in height. The word "Individual" may be used in lieu of or immediately preceding the word "Retail" in the statement.

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(b) *Drugs*. Liquid over-the-counter veterinary preparations intended for injection shall be exempt from the declaration of net quantity of contents in terms of the U.S. gallon of 231 cubic inches and quart, pint, and fluid-ounce subdivisions thereof as required by §201.62 (b), (i), and (j) of this chapter, and from the dual declaration requirements of §201.62(i) of this chapter, if such declaration of net quantity of contents is expressed in terms of the liter and milliliter, or cubic centimeter, with the volume expressed at 68 °F (20 °C).

(c) *Cosmetics*. Cosmetics in packages containing less than one-fourth ounce avoirdupois or one-eighth fluid ounce shall be exempt from compliance with the requirements of section 602(b)(2) of the Federal Food, Drug, and Cosmetic Act and section 4(a)(2) of the Fair Packaging and Labeling Act:

(1) When such cosmetics are affixed to a display card labeled in conformance with all labeling requirements of this part; or

(2) When such cosmetics are sold at retail as part of a cosmetic package consisting of an inner and outer container and the inner container is not for separate retail sale and the outer container is labeled in conformance with all labeling requirements of this part.

[42 FR 15553, Mar. 22, 1977, as amended at 47 FR 946, Jan. 8, 1982; 47 FR 32421, July 27, 1982; 49 FR 13339, Apr. 4, 1984; 54 FR 9033, Mar. 3, 1989; 58 FR 2174, Jan. 6, 1993; 61 FR 14478, Apr. 2, 1996; 66 FR 56035, Nov. 6, 2001]

### Subparts C–D [Reserved]

### Subpart E—Imports and Exports

#### § 1.83 Definitions.

For the purposes of regulations prescribed under section 801(a), (b), and (c) of the Federal Food, Drug, and Cosmetic Act:

(a) The term *owner* or *consignee* means the person who has the rights of a consignee under the provisions of sections 483, 484, and 485 of the Tariff Act of 1930, as amended (19 U.S.C. 1483, 1484, 1485).

(b) The term *district director* means the director of the district of the Food and Drug Administration having juris-

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diction over the port of entry through which an article is imported or offered for import, or such officer of the district as he may designate to act in his behalf in administering and enforcing the provisions of section 801 (a), (b), and (c).

#### § 1.90 Notice of sampling.

When a sample of an article offered for import has been requested by the district director, the collector of customs having jurisdiction over the article shall give to the owner or consignee prompt notice of delivery of, or intention to deliver, such sample. Upon receipt of the notice, the owner or consignee shall hold such article and not distribute it until further notice from the district director or the collector of customs of the results of examination of the sample.

#### § 1.91 Payment for samples.

The Food and Drug Administration will pay for all import samples which are found to be in compliance with the requirements of the Federal Food, Drug, and Cosmetic Act. Billing for reimbursement should be made by the owner or consignee to the Food and Drug Administration district headquarters in whose territory the shipment was offered for import. Payment for samples will not be made if the article is found to be in violation of the act, even though subsequently brought into compliance under the terms of an authorization to bring the article into compliance or rendered not a food, drug, device, or cosmetic as set forth in §1.95.

#### § 1.94 Hearing on refusal of admission.

(a) If it appears that the article may be subject to refusal of admission, the district director shall give the owner or consignee a written notice to that effect, stating the reasons therefor. The notice shall specify a place and a period of time during which the owner or consignee shall have an opportunity to introduce testimony. Upon timely request giving reasonable grounds therefor, such time and place may be changed. Such testimony shall be confined to matters relevant to the admissibility of the article, and may be introduced orally or in writing.

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(b) If such owner or consignee submits or indicates his intention to submit an application for authorization to relabel or perform other action to bring the article into compliance with the act or to render it other than a food, drug, device, or cosmetic, such testimony shall include evidence in support of such application. If such application is not submitted at or prior to the hearing, the district director shall specify a time limit, reasonable in the light of the circumstances, for filing such application.

### **§ 1.95 Application for authorization to relabel and recondition.**

Application for authorization to relabel or perform other action to bring the article into compliance with the act or to render it other than a food, drug, device or cosmetic may be filed only by the owner or consignee, and shall:

(a) Contain detailed proposals for bringing the article into compliance with the act or rendering it other than a food, drug, device, or cosmetic.

(b) Specify the time and place where such operations will be carried out and the approximate time for their completion.

### **§ 1.96 Granting of authorization to relabel and recondition.**

(a) When authorization contemplated by § 1.95 is granted, the district director shall notify the applicant in writing, specifying:

(1) The procedure to be followed;

(2) The disposition of the rejected articles or portions thereof;

(3) That the operations are to be carried out under the supervision of an officer of the Food and Drug Administration or the U.S. Customs Service, as the case may be;

(4) A time limit, reasonable in the light of the circumstances, for completion of the operations; and

(5) Such other conditions as are necessary to maintain adequate supervision and control over the article.

(b) Upon receipt of a written request for extension of time to complete such operations, containing reasonable grounds therefor, the district director may grant such additional time as he deems necessary.

(c) An authorization may be amended upon a showing of reasonable grounds therefor and the filing of an amended application for authorization with the district director.

(d) If ownership of an article covered by an authorization changes before the operations specified in the authorization have been completed, the original owner will be held responsible, unless the new owner has executed a bond and obtained a new authorization. Any authorization granted under this section shall supersede and nullify any previously granted authorization with respect to the article.

[42 FR 15553, Mar. 22, 1977, as amended at 54 FR 9033, Mar. 3, 1989]

### **§ 1.97 Bonds.**

(a) The bonds required under section 801(b) of the act may be executed by the owner or consignee on the appropriate form of a customs single-entry or term bond, containing a condition for the redelivery of the merchandise or any part thereof upon demand of the collector of customs and containing a provision for the performance of conditions as may legally be imposed for the relabeling or other action necessary to bring the article into compliance with the act or rendering it other than a food, drug, device, or cosmetic, in such manner as is prescribed for such bond in the customs regulations in force on the date of request for authorization. The bond shall be filed with the collector of customs.

(b) The collector of customs may cancel the liability for liquidated damages incurred under the above-mentioned provisions of such a bond, if he receives an application for relief therefrom, upon the payment of a lesser amount or upon such other terms and conditions as shall be deemed appropriate under the law and in view of the circumstances, but the collector shall not act under this regulation in any case unless the district director is in full agreement with the action.

### **§ 1.99 Costs chargeable in connection with relabeling and reconditioning inadmissible imports.**

The cost of supervising the relabeling or other action in connection with an

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import of food, drugs, devices, or cosmetics which fails to comply with the Federal Food, Drug, and Cosmetic Act shall be paid by the owner or consignee who files an application requesting such action and executes a bond, pursuant to section 801(b) of the act, as amended. The cost of such supervision shall include, but not be restricted to, the following:

(a) Travel expenses of the supervising officer.

(b) Per diem in lieu of subsistence of the supervising officer when away from his home station, as provided by law.

(c) The charge for the services of the supervising officer, which shall include administrative support, shall be computed at a rate per hour equal to 266 percent of the hourly rate of regular pay of a grade GS-11/4 employee, except that such services performed by a customs officer and subject to the provisions of the act of February 13, 1911, as amended (sec. 5, 36 Stat. 901, as amended (19 U.S.C. 267)), shall be calculated as provided in that act.

(d) The charge for the service of the analyst, which shall include administrative and laboratory support, shall be computed at a rate per hour equal to 266 percent of the hourly rate of regular pay of a grade GS-12/4 employee. The rate per hour equal to 266 percent of the equivalent hourly rate of regular pay of the supervising officer (GS-11/4) and the analyst (GS-12/4) is computed as follows:

	Hours
Gross number of working hours in 52 40-hr weeks	2,080
Less:	
9 legal public holidays—New Years Day, Washington's Birthday, Memorial Day, Independence Day, Labor Day, Columbus Day, Veterans Day, Thanksgiving Day, and Christmas Day .....	72
Annual leave—26 d .....	208
Sick leave—13 d .....	104
Total .....	384
Net number of working hours .....	1,696
Gross number of working hours in 52 40-hr weeks ..	2,080
Working hour equivalent of Government contributions for employee retirement, life insurance, and health benefits computed at 8½ pct. of annual rate of pay of employee .....	176
Equivalent annual working hours .....	2,256
Support required to equal to 1 man-year .....	2,256
Equivalent gross annual working hours charged to Food and Drug appropriation ....	4,512

NOTE: Ratio of equivalent gross annual number of working hours charged to Food and Drug appropriation to net number of annual working hours 4,512/1,696=266 pct.

(e) The minimum charge for services of supervising officers and of analysts shall be not less than the charge for 1 hour, and time after the first hour shall be computed in multiples of 1 hour, disregarding fractional parts less than ½ hour.

§ 1.101 Notification and recordkeeping.

(a) *Scope.* This section pertains to notifications and records required for human drug, biological product, device, animal drug, food, and cosmetic exports under sections 801 or 802 of the Federal Food, Drug, and Cosmetic Act (the act) or (21 U.S.C. 381 and 382) or section 351 of the Public Health Service Act (42 U.S.C. 262).

(b) *Recordkeeping requirements for human drugs, biological products, devices, animal drugs, foods, and cosmetics exported under or subject to section 801(e)(1) of the act.* Persons exporting an article under section 801(e)(1) of the act or an article otherwise subject to section 801(e)(1) of the act shall maintain records as enumerated in paragraphs (b)(1) through (b)(4) of this section demonstrating that the product meets the requirements of section 801(e)(1) of the act. Such records shall be maintained for the same period of time as required for records subject to good manufacturing practice or quality systems regulations applicable to the product, except that records pertaining to the export of foods and cosmetics under section 801(e)(1) of the act shall be kept for 3 years after the date of exportation. The records shall be made available to the Food and Drug Administration (FDA), upon request, during an inspection for review and copying by FDA.

(1) Records demonstrating that the product meets the foreign purchaser's specifications: The records must contain sufficient information to match the foreign purchaser's specifications to a particular export;

(2) Records demonstrating that the product does not conflict with the laws of the importing country: This may consist of either a letter from appropriate foreign government agency,

department, or other authorized body stating that the product has marketing approval from the foreign government or does not conflict with that country's laws, or a notarized certification by a responsible company official in the United States that the product does not conflict with the laws of the importing country and that includes a statement acknowledging that he or she is subject to the provisions of 18 U.S.C. 1001;

(3) Records demonstrating that the product is labeled on the outside of the shipping package that it is intended for export: This may consist of copies of any labels or labeling statements, such as "For export only," that are placed on the shipping packages or, if the exported product does not have a shipping package or container, on shipping invoices or other documents accompanying the exported product; and

(4) Records demonstrating that the product is not sold or offered for sale in the United States: This may consist of production and shipping records for the exported product and promotional materials.

(c) *Additional recordkeeping requirements for partially processed biological products exported under section 351(h) of the Public Health Service Act.* In addition to the requirements in paragraph (b) of this section, persons exporting a partially processed biological product under section 351(h) of the Public Health Service Act shall maintain, for the same period of time as required for records subject to good manufacturing practice or quality systems regulations applicable to the product, and make available to FDA, upon request, during an inspection for review and copying by FDA, the following records:

(1) Records demonstrating that the product for export is a partially processed biological product and not in a form applicable to the prevention, treatment, or cure of diseases or injuries of man;

(2) Records demonstrating that the partially processed biological product was manufactured in conformity with current good manufacturing practice requirements;

(3) Records demonstrating the distribution of the exported partially processed biological products; and

(4) Copies of all labeling that accompanies the exported partially processed biological product and other records demonstrating that the exported partially processed biological product is intended for further manufacture into a final dosage form outside the United States; this may include a container label with the statement, "Caution: For Further Manufacturing Use Only" and any package insert.

(d) *Notification requirements for drugs, biological products, and devices exported under section 802 of the act.* (1) Persons exporting a human drug, biological product, or device under section 802 of the act, other than a drug, biological product, or device for investigational use exported under section 802(c) of the act, or a drug, biological product, or device exported in anticipation of marketing authorization under section 802(d) of the act, shall provide written notification to FDA. The notification shall identify:

(i) The product's trade name;

(ii) If the product is a drug or biological product, the product's abbreviated or proper name or, if the product is a device, the type of device;

(iii) If the product is a drug or biological product, a description of the product's strength and dosage form or, if the product is a device, the product's model number; and

(iv) If the export is to a country not listed in section 802(b)(1) of the act, the country that is to receive the exported article. The notification may, but is not required to, identify countries listed in section 802(b)(1) of the act or state that the export is intended for a listed country without identifying the listed country.

(2) The notification shall be sent to the following addresses:

(i) For biological products and devices regulated by the Center for Biologics Evaluation and Research—Division of Case Management (HFM-610), Office of Compliance and Biologics Quality, Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, rm. 200N, Rockville, MD 20852-1448;

(ii) For human drug products—Division of Labeling and Nonprescription Drug Compliance (HFD-310), Center for Drug Evaluation and Research, Food

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and Drug Administration, 7520 Standish Pl., Rockville, MD 20855-2737;

(iii) For devices—Division of Program Operations (HFZ-305), Center for Devices and Radiological Health, Food and Drug Administration, 2094 Gaither Rd., Rockville, MD 20850.

(e) *Recordkeeping requirements for products subject to section 802(g) of the act.* (1) Any person exporting a product under any provision of section 802 of the act shall maintain records of all drugs, biological products, and devices exported and the countries to which the products were exported. In addition to the requirements in paragraph (b) of this section, such records include, but are not limited to, the following:

(i) The product's trade name;

(ii) If the product is a drug or biological product, the product's abbreviated or proper name or, if the product is a device, the type of device;

(iii) If the product is a drug or biological product, a description of its strength and dosage form and the product's lot or control number or, if the product is a device, the product's model number;

(iv) The consignee's name and address; and

(v) The date on which the product was exported and the quantity of product exported.

(2) These records shall be kept at the site from which the products were exported or manufactured, and be maintained for the same period of time as required for records subject to good manufacturing practice or quality systems regulations applicable to the product. The records shall be made available to FDA, upon request, during an inspection for review and copying by FDA.

[66 FR 65447, Dec. 19, 2001]

### Subparts F–G [Reserved]

### Subpart H—Registration of Food Facilities

SOURCE: 68 FR 58960, Oct. 10, 2003, unless otherwise noted.

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### GENERAL PROVISIONS

#### § 1.225 Who must register under this subpart?

(a) You must register your facility under this subpart if you are the owner, operator, or agent in charge of either a domestic or foreign facility, as defined in this subpart, and your facility is engaged in the manufacturing/processing, packing, or holding of food for consumption in the United States, unless your facility qualifies for one of the exemptions in § 1.226.

(b) If you are an owner, operator, or agent in charge of a domestic facility, you must register your facility whether or not the food from the facility enters interstate commerce.

(c) If you are the owner, operator, or agent in charge of a facility, you may authorize an individual to register your facility on your behalf.

#### § 1.226 Who does not have to register under this subpart?

This subpart does not apply to the following facilities:

(a) A foreign facility, if food from such facility undergoes further manufacturing/processing (including packaging) by another facility outside the United States. A facility is not exempt under this provision if the further manufacturing/processing (including packaging) conducted by the subsequent facility consists of adding labeling or any similar activity of a *de minimis* nature;

(b) Farms;

(c) Retail food establishments;

(d) Restaurants;

(e) Nonprofit food establishments in which food is prepared for, or served directly to, the consumer;

(f) Fishing vessels, including those that not only harvest and transport fish but also engage in practices such as heading, eviscerating, or freezing intended solely to prepare fish for holding on board a harvest vessel. However, those fishing vessels otherwise engaged in processing fish are subject to this subpart. For the purposes of this section, "processing" means handling, storing, preparing, shucking, changing into different market forms, manufacturing, preserving, packing, labeling, dockside unloading, holding, or heading, eviscerating, or freezing other

than solely to prepare fish for holding on board a harvest vessel;

(g) Facilities that are regulated exclusively, throughout the entire facility, by the U.S. Department of Agriculture under the Federal Meat Inspection Act (21 U.S.C. 601 *et seq.*), the Poultry Products Inspection Act (21 U.S.C. 451 *et seq.*), or the Egg Products Inspection Act (21 U.S.C. 1031 *et seq.*);

**§ 1.227 What definitions apply to this subpart?**

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

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

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

(2) *Facility* means any establishment, structure, or structures under one ownership at one general physical location, or, in the case of a mobile facility, traveling to multiple locations, that manufactures/processes, packs, or holds food for consumption in the United States. Transport vehicles are not facilities if they hold food only in the usual course of business as carriers. A facility may consist of one or more contiguous structures, and a single building may house more than one distinct facility if the facilities are under separate ownership. The private residence of an individual is not a facility. Nonbottled water drinking water collection and distribution establishments and their structures are not facilities.

(i) *Domestic facility* means any facility located in any State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico that manufactures/processes, packs, or holds food for consumption in the United States.

(ii) *Foreign facility* means a facility other than a domestic facility that manufactures/processes, packs, or holds food for consumption in the United States.

(3) *Farm* means a facility in one general physical location devoted to the growing and harvesting of crops, the raising of animals (including seafood), or both. Washing, trimming of outer leaves of, and cooling produce are considered part of harvesting. The term “farm” includes:

(i) Facilities that pack or hold food, provided that all food used in such activities is grown, raised, or consumed on that farm or another farm under the same ownership; and

(ii) Facilities that manufacture/process food, provided that all food used in such activities is consumed on that farm or another farm under the same ownership.

(4) *Food* has the meaning given in section 201(f) of the act (21 U.S.C. 321(f)),

(i) Except for purposes of this subpart, it does not include:

(A) *Food* contact substances as defined in section 409(h)(6) of the act (21 U.S.C. 348(h)(6)), or

(B) Pesticides as defined in 7 U.S.C. 136(u).

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

(5) *Holding* means storage of food. Holding facilities include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks.

(6) *Manufacturing/processing* means making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food, including food crops or ingredients. Examples of manufacturing/processing activities are cutting, peeling, trimming, washing, waxing, eviscerating, rendering, cooking, baking, freezing, cooling, pasteurizing, homogenizing, mixing, formulating, bottling, milling, grinding, extracting juice, distilling, labeling, or packaging.

(7) *Nonprofit food establishment* means a charitable entity that prepares or serves food directly to the consumer or otherwise provides food or meals for consumption by humans or animals in the United States. The term includes central food banks, soup kitchens, and nonprofit food delivery services. To be

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considered a nonprofit food establishment, the establishment must meet the terms of section 501(c)(3) of the U.S. Internal Revenue Code (26 U.S.C. 501(c)(3)).

(8) *Packaging* (when used as a verb) means placing food into a container that directly contacts the food and that the consumer receives.

(9) *Packing* means placing food into a container other than packaging the food.

(10) *Restaurant* means a facility that prepares and sells food directly to consumers for immediate consumption. “Restaurant” does not include facilities that provide food to interstate conveyances, central kitchens, and other similar facilities that do not prepare and serve food directly to consumers.

(i) Entities in which food is provided to humans, such as cafeterias, lunchrooms, cafes, bistros, fast food establishments, food stands, saloons, taverns, bars, lounges, catering facilities, hospital kitchens, day care kitchens, and nursing home kitchens are restaurants; and

(ii) Pet shelters, kennels, and veterinary facilities in which food is provided to animals are restaurants.

(11) *Retail food establishment* means an establishment that sells food products directly to consumers as its primary function. A retail food establishment may manufacture/process, pack, or hold food if the establishment’s primary function is to sell from that establishment food, including food that it manufactures/processes, packs, or holds, directly to consumers. A retail food establishment’s primary function is to sell food directly to consumers if the annual monetary value of sales of food products directly to consumers exceeds the annual monetary value of sales of food products to all other buyers. The term “consumers” does not include businesses. A “retail food establishment” includes grocery stores, convenience stores, and vending machine locations.

(12) *Trade name* means the name or names under which the facility conducts business, or additional names by which the facility is known. A trade name is associated with a facility, and

a brand name is associated with a product.

(13) *U.S. agent* means a person (as defined in section 201(e) of the act (21 U.S.C. 321(e))) residing or maintaining a place of business in the United States whom a foreign facility designates as its agent for purposes of this subpart. A U.S. agent cannot be in the form of a mailbox, answering machine or service, or other place where an individual acting as the foreign facility’s agent is not physically present.

(i) The U.S. agent acts as a communications link between FDA and the foreign facility for both emergency and routine communications. The U.S. agent will be the person FDA contacts when an emergency occurs, unless the registration specifies under §1.233(e) another emergency contact.

(ii) FDA will treat representations by the U.S. agent as those of the foreign facility, and will consider information or documents provided to the U.S. agent the equivalent of providing the information or documents to the foreign facility.

(iii) Having a single U.S. agent for the purposes of this subpart does not preclude facilities from having multiple agents (such as foreign suppliers) for other business purposes. A firm’s commercial business in the United States need not be conducted through the U.S. agent designated for purposes of this subpart.

(14) *You* or *registrant* means the owner, operator, or agent in charge of a facility that manufactures/processes, packs, or holds food for consumption in the United States.

### PROCEDURES FOR REGISTRATION OF FOOD FACILITIES

#### § 1.230 When must you register?

The owner, operator, or agent in charge of a facility that manufactures/processes, packs or holds food for consumption in the United States must register the facility no later than December 12, 2003. The owner, operator, or agent in charge of a facility that begins to manufacture/process, pack, or hold food for consumption in the United States on or after December 12, 2003, must register before the facility

begins such activities. An owner, operator, or agent in charge of a facility may authorize an individual to register the facility on its behalf.

**§ 1.231 How and where do you register?**

(a) *Electronic registration.* (1) To register electronically, you must register at <http://www.fda.gov/furls>, which is available for registration 24 hours a day, 7 days a week. This website is available from wherever the Internet is accessible, including libraries, copy centers, schools, and Internet cafes. An individual authorized by the owner, operator, or agent in charge of a facility may also register a facility electronically.

(2) FDA strongly encourages electronic registration for the benefit of both FDA and the registrant.

(3) Once you complete your electronic registration, FDA will automatically provide you with an electronic confirmation of registration and a permanent registration number.

(4) You will be considered registered once FDA electronically transmits your confirmation and registration number.

(b) *Registration by mail or fax.* If, for example, you do not have reasonable access to the Internet through any of the methods described in paragraph (a) of this section, you may register by mail or fax.

(1) You must register using Form 3537. You may obtain a copy of this form by writing to the U.S. Food and Drug Administration (HFS-681), 5600 Fishers Lane, Rockville, MD 20857 or by requesting the form by phone at 1-877-FDA-3882 (1-877-332-3882).

(2) When you receive the form, you must fill it out completely and legibly and either mail it to the address in paragraph (b)(1) of this section or fax it to 301-210-0247.

(3) If any required information on the form is incomplete or illegible when FDA receives it, FDA will return the form to you for revision, provided that your mailing address or fax number is legible and valid. When returning a registration form for revision, FDA will use the means by which the form was received by the agency (*i.e.*, by mail or fax).

(4) FDA will enter complete and legible mailed and faxed registration submissions into its registration system, along with CD-ROM submissions, as soon as practicable, in the order FDA receives them.

(5) FDA will then mail to the address or fax to the fax number on the registration form a copy of the registration as entered, confirmation of registration, and your registration number. When responding to a registration submission, FDA will use the means by which the registration was received by the agency (*i.e.*, by mail or fax).

(6) If any information you previously submitted was incorrect at the time of submission, you must immediately update your facility's registration as specified in § 1.234.

(7) Your facility is considered registered once FDA enters your facility's registration data into the registration system and the system generates a registration number.

(c) *Registration by CD-ROM for multiple submissions.* If, for example, you do not have reasonable access to the Internet through any of the methods provided under paragraph (a) of this section, you may register by CD-ROM.

(1) Registrants submitting their registrations in CD-ROM format must use ISO 9660 (CD-R or CD-RW) data format.

(2) These files must be submitted on a portable document format (PDF) rendition of the registration form (Form 3537) and be accompanied by one signed copy of the certification statement that appears on the registration form (Form 3537).

(3) Each submission on the CD-ROM must contain the same preferred mailing address in the appropriate block on Form 3537.

(4) A CD-ROM may contain registrations for as many facilities as needed up to the CD-ROM's capacity.

(5) The registration on the CD-ROM for each separate facility must have a unique file name up to 32 characters long, the first part of which may be used to identify the parent company.

(6) You must mail the CD-ROM to the U.S. Food and Drug Administration (HFS-681), 5600 Fishers Lane, Rockville, MD 20857.

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(7) If FDA receives a CD-ROM that does not comply with these specifications, it will return the CD-ROM to the submitter unprocessed.

(8) FDA will enter CD-ROM submissions that comply with these specifications into its registration system, along with the complete and legible mailed and faxed submissions, as soon as practicable, in the order FDA receives them.

(9) For each facility on the CD-ROM, FDA will mail to the preferred mailing address a copy of the registration(s) as entered, confirmation of registration, and each facility's assigned registration number.

(10) If any information you previously submitted was incorrect at the time of submission, you must immediately update your facility's registration as specified in § 1.234.

(11) Your facility is considered registered once FDA enters your facility's registration data into the registration system and the system generates a registration number.

(d) *Fees.* No registration fee is required.

(e) *Language.* You must submit all registration information in the English language except an individual's name, the name of a company, the name of a street, and a trade name may be submitted in a foreign language. All information, including these items, must be submitted using the Latin (Roman) alphabet.

### § 1.232 What information is required in the registration?

Each registrant must submit the following information through one of the methods described in § 1.231:

(a) The name, full address, and phone number of the facility;

(b) The name, address, and phone number of the parent company, if the facility is a subsidiary of the parent company;

(c) For domestic and foreign facilities, the names, addresses, and phone numbers of the owner, operator, and agent in charge.

(d) For a foreign facility, the name, address, phone number, and emergency contact phone number of its U.S. agent (if there is no other emergency contact designated under § 1.233(c));

(e) For a domestic facility, an emergency contact phone number;

(f) All trade names the facility uses;

(g) Applicable food product categories as identified in § 170.3 of this chapter, unless you check either "most/all human food product categories," according to § 1.233(e), or "none of the above mandatory categories" because your facility manufactures/processes, packs, or holds a food that is not identified in § 170.3 of this chapter;

(h) The name, address, and phone number for the owner, operator, or agent in charge;

(i) A statement in which the owner, operator, or agent in charge certifies that the information submitted is true and accurate. If the individual submitting the form is not the owner, operator, or agent in charge of the facility, the registration must also include a statement in which the individual certifies that the information submitted is true and accurate, certifies that he/she is authorized to submit the registration, and identifies by name, address, and telephone number, the individual who authorized submission of the registration. Each registration must include the name of the individual registering the facility submitting the registration, and the individual's signature (for the paper and CD-ROM options).

### § 1.233 What optional items are included in the registration form?

FDA encourages, but does not require, you to submit the following items in your facility's registration. These data will enable FDA to communicate more quickly with facilities that may be the target of a terrorist threat or attack, or otherwise affected by an outbreak of foodborne illness. This information includes:

(a) Fax number and e-mail address of the facility;

(b) Preferred mailing address, if different from that of the facility;

(c) Fax number and e-mail address of the parent company, if the facility is a subsidiary of the parent company;

(d) For a domestic facility, emergency contact name, title, and e-mail address;

(e) For a foreign facility, an emergency contact name, title, phone number and e-mail address. FDA will consider the facility's U.S. agent the facility's emergency contact unless the facility chooses to designate another person to serve as an emergency contact under this section;

(f) For a foreign facility, title, fax number, and e-mail address of the U.S. agent;

(g) Type of activity conducted at the facility (e.g., manufacturing/processing or holding);

(h) Food categories not identified in §170.3 of this chapter, which are provided in Form 3537 sections 11a (e.g., infant formula, animal byproducts and extracts) and 11b (e.g., grain products, amino acids);

(i) Type of storage, if the facility is primarily a holding facility;

(j) A food product category of "most/all human food product categories," if the facility manufactures/processes, packs, or holds foods in most or all of the categories identified in §170.3 of this chapter;

(k) Approximate dates of operation, if the facility's business is seasonal;

(l) The fax number and e-mail address of the owner, operator, or agent in charge; and

(m) The fax number and e-mail address of the individual who authorized submission of the registration.

**§ 1.234 How and when do you update your facility's registration information?**

(a) *Update requirements.* The owner, operator, or agent in charge must submit an update to a facility's registration within 60 calendar days of any change to any of the information previously submitted under §1.232 (e.g., change of operator, agent in charge, or U.S. agent), except a change of the owner. The owner, operator, or agent in charge may authorize an individual to update a facility's registration.

(b) *Cancellation due to ownership changes.* If the reason for the update is that the facility has a new owner, the former owner must cancel the facility's registration as specified in §1.235 within 60 calendar days of the change and the new owner must re-register the facility as specified in §1.231. The former

owner may authorize an individual to cancel a facility's registration.

(c) *Electronic update.* (1) To update your registration electronically, you must update at <http://www.fda.gov/furls>.

(2) Once you complete your electronic update, FDA will automatically provide you with an electronic confirmation of your update.

(3) Your registration will be considered updated once FDA transmits your update confirmation, unless notified otherwise.

(d) *Update by mail or fax.* If, for example, you do not have reasonable access to the Internet through any of the methods described in §1.231(a), you may update your facility's registration by mail or by fax:

(1) You must update your registration using Form 3537. You may obtain a copy of this form by writing to the U.S. Food and Drug Administration (HFS-681), 5600 Fishers Lane, Rockville, MD 20857 or by requesting the form by phone at 1-877-FDA-3882 (1-877-332-3882).

(2) When you receive the form, you must legibly fill out the sections of the form reflecting your updated information and either mail it to the address in paragraph (d)(1) of this section or fax it to 301-210-0247.

(3) If the information on the form is incomplete or illegible when FDA receives it, FDA will return the form to you for revision, provided that your mailing address or fax number is legible and valid. When returning a registration form for revision, FDA will use the means by which the registration was received by the agency (i.e., by mail or fax).

(4) FDA will enter complete and legible updates into its registration system, along with CD-ROM submissions, as soon as practicable, in the order FDA receives them.

(5) FDA will then mail to the address or fax to the fax number on the registration form a copy of the update as entered and confirmation of the update. When responding to an update submission, FDA will use the means by which the form was received by the agency (i.e., by mail or fax).

(6) If any update information you previously submitted was incorrect at

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the time of submission, you must immediately resubmit your update.

(7) Your registration will be considered updated once FDA enters your facility's update data into the registration system and the system generates an update confirmation.

(e) *Update by CD-ROM for multiple submissions.* If, for example, you do not have reasonable access to the Internet through any of the methods provided under § 1.231(a), you may update your facilities' registrations by CD-ROM.

(1) Registrants submitting their updates in CD-ROM format must use ISO 9660 (CD-R or CD-RW) data format.

(2) Update files must be submitted on a PDF rendition of FDA's registration form (Form 3537) and be accompanied by one signed copy of the certification statement on the registration form (Form 3537).

(3) Each submission on the CD-ROM must contain the same preferred mailing address in the appropriate block on Form 3537.

(4) The CD-ROM may contain updates for as many facilities as needed up to the CD-ROM's capacity.

(5) The update for each facility on the CD-ROM must have a unique file name up to 32 characters long, the first part of which may be used to identify the parent company.

(6) You must mail the CD-ROM to U.S. Food and Drug Administration (HFS-681), 5600 Fishers Lane, Rockville, MD 20857.

(7) If FDA receives an update CD-ROM that does not comply with these specifications, it will return the CD-ROM to the registrant unprocessed.

(8) FDA will enter CD-ROM update submissions into its registration system, along with the complete and legible mailed and faxed update submissions, as soon as practicable, in the order FDA receives them.

(9) For each facility on the CD-ROM, FDA will mail to the preferred mailing address a copy of the update(s) as entered and confirmation of the update.

(10) If any update information you previously submitted was incorrect at the time of submission, you must immediately resubmit your update.

(11) Your registration will be considered updated once FDA enters your facility's update data into the registra-

tion system and the system generates an update confirmation.

### § 1.235 How and when do you cancel your facility's registration information?

(a) *Notification of registration cancellation.* A facility canceling its registration must do so within 60 calendar days of the reason for cancellation (*e.g.*, facility ceases operations, ceases providing food for consumption in the United States, or the facility is sold to a new owner).

(b) *Cancellation requirements.* The cancellation of a facility's registration must include the following information:

(1) The facility's registration number;

(2) Whether the facility is domestic or foreign;

(3) The facility name and address;

(4) The name, address, and e-mail address (if available) of the individual submitting the cancellation; and

(5) A statement certifying that the information submitted is true and accurate, and that the person submitting the cancellation is authorized by the facility to cancel its registration.

(c) *Electronic cancellation.* (1) To cancel your registration electronically, you must cancel at <http://www.fda.gov/furls>.

(2) Once you complete your electronic cancellation, FDA will automatically provide you with an electronic confirmation of your cancellation.

(3) Your registration will be considered cancelled once FDA transmits your cancellation confirmation.

(d) *Cancellation by mail or fax.* If, for example, you do not have reasonable access to the Internet through any of the methods described in § 1.231(a), you may cancel your facility's registration by mail or fax.

(1) You must cancel your registration using Form 3537a. You may obtain a copy of this form by writing to the U.S. Food and Drug Administration (HFS-681), 5600 Fishers Lane, Rockville, MD 20857, or by requesting the form by phone at 1-877-FDA-3882 (1-877-332-3882).

(2) When you receive the form, you must completely and legibly fill out

the form and either mail it to the address in paragraph (d)(1) of this section or fax it to 301-210-0247.

(3) If the information on the form is incomplete or illegible when FDA receives it, FDA will return the form to you for revision, provided that your mailing address or fax number is legible and valid. When returning a cancellation form for revision, FDA will use the means by which the cancellation was received by the agency (*i.e.*, by mail or fax).

(4) FDA will enter complete and legible mailed and faxed cancellations into its registration system, along with CD-ROM cancellations, as soon as practicable, in the order FDA receives them.

(5) FDA will then mail to the address or fax to the fax number on the cancellation form a copy of the cancellation as entered and confirmation of the cancellation. When responding to a cancellation, FDA will use the means by which the form was received by the agency (*i.e.*, by mail or fax).

(6) If any information you previously submitted was incorrect at the time of submission, you must immediately re-submit your cancellation.

(7) Your registration will be considered cancelled once FDA enters your facility's cancellation data into the registration system and the system generates a confirmation.

(e) *Cancellation by CD-ROM for multiple submissions.* If, for example, you do not have reasonable access to the Internet through any of the methods described in §1.231(a), you may cancel your facilities' registrations using a CD-ROM.

(1) Registrants submitting their cancellations in CD-ROM format must use ISO 9660 (CD-R or CD-RW) data format.

(2) Cancellation files must be submitted on a PDF rendition of the cancellation form (Form 3537a) and be accompanied by one signed copy of the certification statement on the cancellation form.

(3) Each submission on the CD-ROM must contain the same preferred mailing address in the appropriate block on Form 3537.

(4) The CD-ROM may contain cancellations for as many facilities as needed up to the CD-ROM's capacity.

(5) The cancellation for each facility on the CD-ROM must have a unique file name up to 32 characters long, the first part of which may be used to identify the parent company.

(6) You must mail the CD-ROM to U.S. Food and Drug Administration (HFS-681), 5600 Fishers Lane, Rockville, MD 20857.

(7) If FDA receives a CD-ROM that does not comply with these specifications, it will return the CD-ROM to the registrant unprocessed.

(8) FDA will enter CD-ROM submissions that meet the specifications into its registration system, along with complete and legible mailed and faxed submissions, as soon as practicable, in the order FDA receives them.

(9) For each facility on the CD-ROM, FDA will mail to the preferred mailing address a copy of the cancellation(s) as entered and confirmation of the cancellation.

(10) If any information you previously submitted was incorrect at the time of submission, you must immediately re-submit your cancellation.

(11) Your registration will be considered cancelled once FDA enters your facility's cancellation data into the registration system and the system generates a confirmation.

#### ADDITIONAL PROVISIONS

##### **§ 1.240 What other registration requirements apply?**

In addition to the requirements of this subpart, you must comply with the registration regulations found in part 108 of this chapter, related to emergency permit control, and any other Federal, State, or local registration requirements that apply to your facility.

##### **§ 1.241 What are the consequences of failing to register, update, or cancel your registration?**

(a) Section 301 of the act (21 U.S.C. 331) prohibits the doing of certain acts or causing such acts to be done. Under section 302 of the act (21 U.S.C. 332), the United States can bring a civil action in Federal court to enjoin a person who commits a prohibited act. Under section 303 of the act (21 U.S.C. 333), the United States can bring a criminal action in Federal court to prosecute a

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person who is responsible for the commission of a prohibited act. Under section 306 of the act (21 U.S.C. 335a), FDA can seek debarment of any person who has been convicted of a felony relating to importation of food into the United States. Failure of an owner, operator, or agent in charge of a domestic or foreign facility to register its facility, to update required elements of its facility's registration, or to cancel its registration in accordance with the requirements of this subpart is a prohibited act under section 301(dd) of the act.

(b) FDA will cancel a registration if the agency independently verifies that the facility is no longer in business or has changed owners, and the owner, operator, or agent in charge of the facility fails to cancel the registration, or if FDA determines that the registration is for a facility that does not exist. If FDA cancels a facility's registration, FDA will mail a confirmation of the cancellation to the facility at the address provided in the facility's registration.

(c) If an article of food is imported or offered for import into the United States and a foreign facility that manufactured/processed, packed, or held that article of food has not registered in accordance with this subpart, the disposition of the article of food shall be governed by the procedures set out in subpart I of this part.

### § 1.242 What does assignment of a registration number mean?

Assignment of a registration number to a facility means that the facility is registered with FDA. Assignment of a registration number does not in any way convey FDA's approval or endorsement of a facility or its products.

### § 1.243 Is food registration information available to the public?

(a) The list of registered facilities and registration documents submitted under this subpart are not subject to disclosure under 5 U.S.C. 552 (the Freedom of Information Act). In addition, any information derived from such list or registration documents that would disclose the identity or location of a specific registered person, is not sub-

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ject to disclosure under 5 U.S.C. 552 (the Freedom of Information Act).

(b) Paragraph (a) of this section does not apply to any information obtained by other means or that has previously been disclosed to the public as defined in § 20.81 of this chapter.

### Subpart I—Prior Notice of Imported Food

SOURCE: 68 FR 59070, Oct. 10, 2003, unless otherwise noted.

#### GENERAL PROVISIONS

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

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

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

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

(2) *Country from which the article originates* means FDA Country of Production.

(3) *Country from which the article is shipped* means the country in which the article of food is loaded onto the conveyance that brings it to the United States or, in the case of food sent by international mail, the country from which the article is mail.

(4) *FDA Country of Production* means:

(i) For an article of food that is in its natural state, the country where the article of food was grown, including harvested or collected and readied for shipment to the United States. If an article of food is wild fish, including seafood that was caught or harvested outside the waters of the United States by a vessel that is not registered in the United States, the FDA Country of Production is the country in which the vessel is registered. If an article of food that is in its natural state was grown, including harvested or collected and readied for shipment, in a Territory, the FDA Country of Production is the United States.

(ii) For an article of food that is no longer in its natural state, the country where the article was made; except that, if an article of food is made from wild fish, including seafood, aboard a

vessel, the FDA Country of Production is the country in which the vessel is registered. If an article of food that is no longer in its natural state was made in a Territory, the FDA Country of Production is the United States.

(5) *Food* has the meaning given in section 201(f) of the act,

(i) Except for purposes of this subpart, it does not include:

(A) Food contact substances as defined in section 409(h)(6) of the act (21 U.S.C. 348(h)(6)); or

(B) Pesticides as defined in 7 U.S.C. 136(u).

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

(6) *Grower* means a person who engages in growing and harvesting or collecting crops (including botanicals), raising animals (including fish, which includes seafood), or both.

(7) *International mail* means foreign national mail services. International mail does not include express carriers, express consignment operators, or other private delivery services.

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

(9) *Port of arrival* means the water, air, or land port at which the article of food is imported or offered for import into the United States, *i.e.*, the port where the article of food first arrives in the United States. This port may be different than the port where consumption or warehouse entry or foreign trade zone admission documentation is presented to the United States Bureau of Customs and Border Protection (CBP).

(10) *Port of entry*, in sections 801(m) and 801(l) of the act, means the port of entry as defined in 19 CFR 101.1.

(11) *Registration number* refers to the registration number assigned by FDA under section 415 of the act (21 U.S.C. 350d) and 21 CFR part 1, subpart H.

(12) *Shipper* means the owner or exporter of the article of food who consigns and ships the article from a foreign country or the person who sends an article of food by international mail to the United States.

(13) *United States* means the Customs territory of the United States (*i.e.*, the 50 states, the District of Columbia, and the Commonwealth of Puerto Rico), but not the Territories.

(14) *You* means the person submitting the prior notice, *i.e.*, the submitter, or the person transmitting prior notice information on behalf of the submitter, *i.e.*, the transmitter.

[68 FR 59070, Oct. 10, 2003; 69 FR 4851, Feb. 2, 2004]

#### § 1.277 What is the scope of this subpart?

(a) This subpart applies to all food for humans and other animals that is imported or offered for import into the United States for use, storage, or distribution in the United States, including food for gifts and trade and quality assurance/quality control samples, food for transshipment through the United States to another country, food for future export, and food for use in a U.S. Foreign Trade Zone.

(b) Notwithstanding paragraph (a), this subpart does not apply to:

(1) Food for an individual's personal use when it is carried by or otherwise accompanies the individual when arriving in the United States;

(2) Food that was made by an individual in his/her personal residence and

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sent by that individual as a personal gift (*i.e.*, for non-business reasons) to an individual in the United States;

(3) Food that is imported then exported without leaving the port of arrival until export;

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

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

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

### REQUIREMENTS TO SUBMIT PRIOR NOTICE OF IMPORTED FOOD

#### § 1.278 Who is authorized to submit prior notice?

A prior notice for an article of food may be submitted by any person with knowledge of the required information. This person is the submitter. The submitter also may use another person to transmit the required information on his/her behalf. The person who transmits the information is the transmitter. The submitter and transmitter may be the same person.

#### § 1.279 When must prior notice be submitted to FDA?

(a) Except as provided in paragraph (c) of this section, you must submit the prior notice to FDA and the prior notice submission must be confirmed by FDA for review as follows:

(1) If the article of food is arriving by land by road, no less than 2 hours before arriving at the port of arrival;

(2) If the article of food is arriving by land by rail, no less than 4 hours before arriving at the port of arrival;

(3) If the article of food is arriving by air, no less than 4 hours before arriving at the port of arrival; or

(4) If the article of food is arriving by water, no less than 8 hours before arriving at the port of arrival.

(b) Except in the case of an article of food imported or offered for import by

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international mail, you may not submit prior notice more than 5 calendar days before the anticipated date of arrival of the food at the anticipated port of arrival.

(c) Notwithstanding paragraphs (a) and (b) of this section, if the article of food is arriving by international mail, you must submit the prior notice before the article of food is sent to the United States.

(d) FDA will notify you that your prior notice has been confirmed for review with a reply message that contains a Prior Notice (PN) Confirmation Number. Your prior notice will be considered submitted and the prior notice time will start when FDA has confirmed your prior notice for review.

(e) The PN Confirmation Number must accompany any article of food arriving by international mail. The PN Confirmation Number must appear on the Customs Declaration that accompanies the package.

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

(g) The PN Confirmation Number must accompany any article of food for which the prior notice was submitted through the FDA Prior Notice System Interface (FDA PN System Interface) when the article arrives in the United States and must be provided to CBP or FDA upon arrival.

[68 FR 59070, Oct. 10, 2003; 69 FR 4851, Feb. 2, 2004]

#### § 1.280 How must you submit prior notice?

(a) You must submit the prior notice electronically to FDA. You must submit all prior notice information in the English language, except that an individual's name, the name of a company, and the name of a street may be submitted in a foreign language. All information, including these items, must be submitted using the Latin (Roman) alphabet. Unless paragraphs (c) and (d) of this section apply, you must submit prior notice through:

(1) The CBP Automated Broker Interface of the Automated Commercial System (ABI/ACS); or

(2) The FDA PN System Interface at <http://www.access.fda.gov>. You must submit prior notice through the FDA PN System Interface for articles of food imported or offered for import by international mail, other transaction types that cannot be made through ABI/ACS, and articles of food that have been refused under section 801(m)(1) of the act and this subpart.

(b) If a custom broker's or self-filer's system is not working or if the ABI/ACS interface is not working, prior notice must be submitted through the FDA PN System Interface.

(c) If FDA determines that FDA PN System Interface is not working, FDA will issue notification at <http://www.access.fda.gov> or <http://www.cfsan.fda.gov/~furls/fisstat.html>, whichever FDA determines is available. Once FDA issues this notification, if you intended to use the FDA PN System Interface to submit a prior notice, you must submit prior notice information by e-mail or by fax to FDA. The location for receipt of submission by e-mail or fax will be listed at <http://www.access.fda.gov> or <http://www.cfsan.fda.gov/~furls/fisstat.html>, whichever FDA determines is available.

(d) If FDA determines that the Operational and Administration System for Import Support (OASIS) is not working, FDA will issue notification at <http://www.cfsan.fda.gov/~fulrs/fisstat.html>, on the FDA Web site at <http://www.fda.gov>, and through messages in ABI/ACS. Once FDA issues this notification, all prior notices must be submitted to FDA by e-mail or by fax. The location for receipt of submission by e-mail or fax will be listed at <http://www.access.fda.gov> or <http://www.cfsan.fda.gov/~furls/fisstat.html>, whichever FDA determines is available.

(e) Prior notice information will only be accepted at the listed e-mail or fax locations if FDA determines that the FDA PN System Interface or OASIS is not working.

[68 FR 59070, Oct. 10, 2003; 69 FR 4851, Feb. 2, 2003; 69 FR 8330, Feb. 24, 2004]

### § 1.281 What information must be in a prior notice?

(a) *General.* For each article of food that is imported or offered for import into the United States, except by international mail, you must submit the information for the article that is required in this paragraph.

(1) The name of the individual submitting the prior notice and his/her business address, and phone number, fax number, and e-mail address, and the name and address of the submitting firm, if applicable. If a registration number is provided, city and country may be provided instead of the full address;

(2) If different from the submitter, the name of the individual and firm, if applicable, transmitting the prior notice on behalf of the submitter and his/her business address, and phone number, fax number, and e-mail address. If a registration number is provided, city and country may be provided instead of the full address;

(3) The entry type;

(4) The CBP entry identifier (*e.g.*, CBP entry number or in-bond number), if available;

(5) The identity of the article of food being imported or offered for import, as follows:

(i) The complete FDA product code;

(ii) The common or usual name or market name;

(iii) The estimated quantity of food that will be shipped, described from largest container to smallest package size; and

(iv) The lot or code numbers or other identifier of the food if required by the act or FDA regulations, *e.g.*, low acid canned foods, by 21 CFR 113.60(c); acidified foods, by 21 CFR 114.80(b); and infant formula, by 21 CFR 106.90;

(6) For an article of food that is no longer in its natural state, the name and address of the manufacturer and the registration number assigned to the facility that is associated with the article of food. A registration number is not required for a facility associated with an article of food if the article is imported or offered for import for transshipment, storage and export, or further manipulation and export. If the article of food is sent by an individual as a personal gift (*i.e.*, for nonbusiness

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reasons) to an individual in the United States, you may provide the name and address of the firm that appears on the label under 21 CFR 101.5 instead of the name, address, and registration number of the manufacturer. If a registration number is provided, city and country may be provided instead of the full address;

(7) For an article of food that is in its natural state, the name and growing location address of the grower, if known. If the submitter does not know the identity of the grower or, if the article has been consolidated and the submitter does not know the identity of any of the growers, you may provide the name and address of the firm that has consolidated the articles of food from different growers or different growing locations;

(8) The FDA Country of Production;

(9) The name and address of the shipper and, if the shipper is required to register under 21 CFR part 1, subpart H, the registration number assigned to the shipper's facility that is associated with the article of food. A registration number is not required for a facility associated with an article of food if the article is imported or offered for import for transshipment, storage and export, or further manipulation and export. If a registration number is provided, city and country may be provided instead of the full address;

(10) The country from which the article is shipped;

(11) Anticipated arrival information about the article of food being imported or offered for import, as follows:

(i) The anticipated port of arrival and, if the anticipated port of arrival has more than one border crossing, the specific anticipated border crossing where the food will be brought into the United States;

(ii) The anticipated date on which the article of food will arrive at the anticipated port of arrival; and

(iii) The anticipated time of that arrival;

(12) The name and address of the importer. If a registration number is provided, city and country may be provided instead of the full address. The identity of the importer is not required for an article of food that is imported or offered for import for transshipment

through the United States under a Transportation and Exportation entry;

(13) The name and address of the owner if different from the importer or ultimate consignee. If a registration number is provided, city and country may be provided instead of the full address. The identity of the owner is not required for an article of food that is imported or offered for import for transshipment through the United States under a Transportation and Exportation entry;

(14) The name and address of the ultimate consignee. If a registration number is provided, city and country may be provided instead of the full address. The identity of the ultimate consignee is not required for an article of food that is imported or offered for import for transshipment through the United States under a Transportation and Exportation entry;

(15) The mode of transportation;

(16) The Standard Carrier Abbreviation Code (SCAC) or International Air Transportation Association (IATA) code of the carrier which is, or will be, carrying the article of food from the country from which the article is shipped to the United States, or if codes are not applicable, then the name and country of the carrier;

(17) Planned shipment information, as applicable:

(i) The Airway Bill number(s) or Bill of Lading number(s). This information is not required for an article of food when carried by or otherwise accompanying an individual when entering the United States;

(ii) For food arriving by ocean vessel, the vessel name and voyage number;

(iii) For food arriving by air carrier, the flight number;

(iv) For food arriving by truck, bus, or rail, the trip number;

(v) For food arriving as containerized cargo by water, air, or land, the container number(s). This information is not required for an article of food when carried by or otherwise accompanying an individual when entering the United States;

(vi) For food arriving by rail, the car number. This information is not required for an article of food when carried by or otherwise accompanying an individual;

(vii) For food arriving by privately owned vehicle, the license plate number and State or province; and

(viii) The 6-digit Harmonized Tariff Schedule (HTS) code.

(b) *Articles arriving by international mail.* For each article of food that is imported or offered for import into the United States by international mail, you must submit the information for the article that is required in this paragraph.

(1) The name of the individual submitting the prior notice and his/her business address, and phone number, fax number, and e-mail address, and the name and address of the submitting firm, if applicable. If a registration number is provided, city and country may be provided instead of the full address;

(2) If different from the submitter, the name of the individual and firm, if applicable, transmitting the prior notice on behalf of the submitter and his/her business address and phone number, fax number, and e-mail address. If a registration number is provided, city and country may be provided instead of the full address;

(3) The entry type (which will be a mail entry);

(4) The identity of the article of food being imported or offered for import, as follows:

(i) The complete FDA product code;

(ii) The common or usual name or market name;

(iii) The estimated quantity of food that will be shipped, described from largest container to smallest package size; and

(iv) The lot or code numbers or other identifier of the food if required by the act or FDA regulations, *e.g.*, low acid canned foods, by 21 CFR 113.60(c); acidified foods, by 21 CFR 114.80(b); and infant formula, 21 CFR 106.90;

(5) For an article of food that is no longer in its natural state, the name and address of the manufacturer and the registration number assigned to the facility that is associated with the article of food. A registration number is not required for a facility associated with an article of food if the article is imported or offered for import for transshipment, storage and export, or further manipulation and export. If the

article of food is sent by an individual as a personal gift (*i.e.*, for non-business reasons) to an individual in the United States, you may provide the name and address of the firm that appears on the label under 21 CFR 101.5 instead of the name, address, and registration number of the manufacturer. If a registration number is provided, city and country may be provided instead of the full address;

(6) For an article of food that is in its natural state, the name and growing location address of the grower, if known. If the submitter does not know the identity of the grower or, if the article has been consolidated and the submitter does not know the identity of any of the growers, you may provide the name and address of the firm that has consolidated the articles of food from different growers or different growing locations;

(7) The FDA Country of Production;

(8) The name and address of the shipper and, if the shipper is required to register under 21 CFR part 1, subpart H, the registration number assigned to the shipper's facility that is associated with the article of food. A registration number is not required for a facility associated with an article of food if the article is imported or offered for import for transshipment, storage and export, or further manipulation and export. If a registration number is provided, city and country may be provided instead of the full address;

(9) The country from which the article is shipped (*i.e.*, mailed);

(10) The anticipated date of mailing; and

(11) The name and address of the U.S. recipient.

(c) *Refused articles.* If the article of food has been refused under section 801(m)(1) of the act and this subpart, you must submit the information for the article that is required in this paragraph. However, if the refusal is based on § 1.283(a)(1)(iii) (Untimely Prior Notice), you do not have to re-submit any information previously submitted unless it has changed or the article has been exported and the original prior notice was submitted through ABI/ACS. If the refusal is based on § 1.283(a)(1)(ii), you should cancel the

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previous submission per § 1.282(b) and (c).

(1) The name of the individual submitting the prior notice and his/her business address, and phone number, fax number, and e-mail address, and the name and address of the submitting firm, if applicable. If a registration number is provided, city and country may be provided instead of the full address;

(2) If different from the submitter, the name of the individual and firm, if applicable, transmitting the prior notice on behalf of the submitter and his/her business address, and phone number, fax number, and e-mail address. If the registration number is provided, city and country may be provided instead of the full address;

(3) The entry type;

(4) The CBP entry identifier (*e.g.*, CBP entry number or in-bond number), if available;

(5) The identity of the article of food being imported or offered for import, as follows:

(i) The complete FDA product code;

(ii) The common or usual name or market name;

(iii) The quantity of food that was shipped, described from largest container to smallest package size; and

(iv) The lot or code numbers or other identifier of the food if required by the act or FDA regulations, *e.g.*, low acid canned foods, by 21 CFR 113.60(c); acidified foods, by 21 CFR 114.80(b); and infant formula, by 21 CFR 106.90;

(6) For an article of food that is no longer in its natural state, the name and address of the manufacturer and the registration number assigned to the facility that is associated with the article of food. A registration number is not required for a facility associated with an article of food if the article is imported or offered for import for transshipment, storage and export, or further manipulation and export. If the article of food is sent by an individual as a personal gift (*i.e.*, for non-business reasons) to an individual in the United States, you may provide the name and address of the firm that appears on the label under 21 CFR 101.5 instead of the name, address, and registration number of the manufacturer. If a registration number is provided, city and coun-

try may be provided instead of the full address;

(7) For an article of food that is in its natural state, the name and growing location address of the grower, if known. If the submitter does not know the identity of the grower or, if the article has been consolidated and the submitter does not know any of the growers, you may provide the name and address of the firm that has consolidated the articles of food from different growers or different growing locations;

(8) The FDA Country of Production;

(9) The name and address of the shipper and, if the shipper is required to register under 21 CFR part 1, subpart H, the registration number assigned to the shipper's facility that is associated with the article of food. A registration number is not required for a facility associated with an article of food if the article is imported or offered for import for transshipment, storage and export, or further manipulation and export. If a registration number is provided, city and country may be provided instead of the full address;

(10) The country from which the article is shipped;

(11) The port of arrival;

(12) The name and address of the importer. If a registration number is provided, city and country may be provided instead of the full address. The identity of the importer is not required for an article of food that is imported or offered for import for transshipment through the United States under a Transportation and Exportation entry;

(13) The name and address of the owner, if different from the importer or ultimate consignee. If a registration number is provided, city and country may be provided instead of the full address. The identity of the importer is not required for an article of food that is imported or offered for import for transshipment through the United States under a Transportation and Exportation entry;

(14) The name and address of the ultimate consignee. If a registration number is provided, city and country may be provided instead of the full address. The identity of the ultimate consignee is not required for an article of food that is imported or offered for import

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for transshipment through the United States under a Transportation and Exportation entry;

(15) The mode of transportation;

(16) The Standard Carrier Abbreviation Code (SCAC) or International Air Transportation Association (IATA) code of the carrier which carried the article of food from the country from which the article is shipped to the United States, or if codes are not applicable, then the name and country of the carrier;

(17) Shipment information, as applicable:

(i) The Airway Bill number(s) or Bill of Lading number(s); however, this information is not required for an article of food when carried by or otherwise accompanying an individual when entering the United States;

(ii) For food that arrived by ocean vessel, the vessel name and voyage number;

(iii) For food that arrived by air carrier, the flight number;

(iv) For food that arrived by truck, bus, or rail, the trip number;

(v) For food that arrived as containerized cargo by water, air, or land, the container number(s); however, this information is not required for an article of food when carried by or otherwise accompanying an individual when entering the United States;

(vi) For food that arrived by rail, the car number; however, this information is not required for an article of food when carried by or otherwise accompanying an individual;

(vii) For food that arrived by privately owned vehicle, the license plate number and State or province;

(viii) The 6-digit HTS code; and

(18) The location and address where the article of refused food will be or is being held, the date the article has arrived or will arrive at that location, and identification of a contact at that location.

[68 FR 59070, Oct. 10, 2003; 69 FR 4851, Feb. 2, 2004]

### § 1.282 What must you do if information changes after you have received confirmation of a prior notice from FDA?

(a)(1) If any of the information required in § 1.281(a) except the information required in:

(i) § 1.281(a)(5)(iii) (quantity),

(ii) § 1.281(a)(11) (anticipated arrival information), or

(iii) § 1.281(a)(17) (planned shipment information) changes after you receive notice that FDA has confirmed your prior notice submission for review, you must resubmit prior notice in accordance with this subpart unless the article of food will not be offered for import or imported into the United States.

(2) If any of the information required in § 1.281(b), except the information required in § 1.281(b)(10) (the anticipated date of mailing), changes after you receive notice that FDA has confirmed your prior notice submission for review, you must resubmit prior notice in accordance with this subpart, unless the article of food will not be offered for import or imported into the United States.

(b) If you submitted the prior notice via the FDA PN System Interface, you should cancel the prior notice via the FDA PN System Interface.

(c) If you submitted the prior notice via ABI/ACS, you should cancel the prior notice via ACS by requesting that CBP delete the entry.

#### CONSEQUENCES

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

(a) For each article of food that is imported or offered for import into the United States, except for food arriving by international mail or food carried by or otherwise accompanying an individual, the consequences are:

(1) *Inadequate prior notice*—(i) *No prior notice*. If an article of food arrives at the port of arrival and no prior notice has been submitted and confirmed by FDA for review, the food is subject to refusal of admission under section 801(m)(1) of the act (21 U.S.C. 381(m)(1)). If an article of food is refused for lack of prior notice, unless CBP concurrence

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is obtained for export and the article is immediately exported from the port of arrival under CBP supervision, it must be held within the port of entry for the article unless directed by CBP or FDA.

(ii) *Inaccurate prior notice.* If prior notice has been submitted and confirmed by FDA for review, but upon review of the notice or examination of the article of food, the notice is determined to be inaccurate, the food is subject to refusal of admission under section 801(m)(1) of the act (21 U.S.C. 381(m)(1)). If the article of food is refused due to inaccurate prior notice, unless CBP concurrence is obtained for export and the article is immediately exported from the port of arrival under CBP supervision, it must be held within the port of entry for the article unless directed by CBP or FDA.

(iii) *Untimely prior notice.* If prior notice has been submitted and confirmed by FDA for review, but the full time that applies under § 1.279 of this subpart for prior notice has not elapsed when the article of food arrives, the food is subject to refusal of admission under section 801(m)(1) of the act (21 U.S.C. 381(m)(1)), unless FDA has already reviewed the prior notice, determined its response to the prior notice, and advised CBP of that response. If the article of food is refused due to untimely prior notice, unless CBP concurrence is obtained for export and the article is immediately exported from the port of arrival under CBP supervision, it must be held within the port of entry for the article unless directed by CBP or FDA.

(2) *Status and movement of refused food.* (i) An article of food that has been refused under section 801(m)(1) of the act and paragraph (a) of this section shall be considered general order merchandise as described in section 490 of the Tariff Act of 1930, as amended, 19 U.S.C. 1490.

(ii) Refused food must be moved under appropriate custodial bond. FDA must be notified of the location where the food has been or will be moved, within 24 hours of refusal. The refused food shall not be entered and shall not be delivered to any importer, owner, or ultimate consignee. The food must be taken directly to the designated location.

(3) *Segregation of refused foods.* If an article of food that is refused is part of a shipment that contains articles of food that have not been placed under hold, the refused article of food may be segregated from the rest of the shipment. This segregation must take place where the article is held. FDA or CBP may supervise segregation. If FDA or CBP determines that supervision is necessary, segregation must not take place without supervision.

(4) *Costs.* Neither FDA nor CBP are liable for transportation, storage, or other expenses resulting from refusal.

(5) *Export after refusal.* An article of food that has been refused under § 1.283(a) may be exported with CBP concurrence and under CBP supervision unless it is seized or administratively detained by FDA or CBP under other authority. If an article of food that has been refused admission under § 1.283(a) is exported, the prior notice should be cancelled within 5 business days of exportation.

(6) *No post-refusal submission or request for review.* If an article of food is refused under section 801(m)(1) and no prior notice is submitted or resubmitted, no request for FDA review is submitted in a timely fashion, or export has not occurred in accordance with paragraph (a)(5) of this section, the article of food shall be dealt with as set forth in CBP regulations relating to general order merchandise (19 CFR part 127), except that the article may only be sold for export or destroyed as agreed to by CBP and FDA.

(b) *Food carried by or otherwise accompanying an individual.* If food carried by or otherwise accompanying an individual arriving in the United States is not for personal use and does not have adequate prior notice or the individual cannot provide FDA or CBP with a copy of the PN confirmation, the food is subject to refusal of admission under section 801(m)(1) of the act. If before leaving the port, the individual does not arrange to have the food held at the port or exported, the article of food may be destroyed.

(c) *Post-Refusal Prior Notice Submissions.* (1) If an article of food is refused under § 1.283(a)(1)(i) (no prior notice)

and the food is not exported, prior notice must be submitted in accordance with §§ 1.280 and 1.281(c) of this subpart.

(2) If an article of food is refused under § 1.283(a)(1)(ii) (inaccurate prior notice) and the food is not exported, you should cancel the prior notice in accordance with § 1.282 and must resubmit prior notice in accordance with §§ 1.280 and 1.281(c).

(3) Once the prior notice has been submitted or resubmitted and confirmed by FDA for review, FDA will endeavor to review and respond to the prior notice submission within the timeframes set out in § 1.279.

(d) *FDA Review After Refusal.* (1) If an article of food has been refused admission under section 801(m)(1) of the act, a request may be submitted asking FDA to review whether the article is subject to the requirements of this subpart under § 1.276(b)(5) or § 1.277, or whether the information submitted in a prior notice is accurate. A request for review may not be used to submit prior notice or to resubmit an inaccurate prior notice.

(2) A request may be submitted only by the submitter, importer, owner, or ultimate consignee. A request must identify which one the requester is.

(3) A request must be submitted in writing to FDA and delivered by mail, express courier, fax, or e-mail. The location for receipt of a request is listed at <http://www.fda.gov>—see Prior Notice. A request must include all factual and legal information necessary for FDA to conduct its review. Only one request for review may be submitted for each refused article.

(4) The request must be submitted within 5 calendar days of the refusal. FDA will review and respond within 5 calendar days of receiving the request.

(5) If FDA determines that the article is not subject to the requirements of this subpart under § 1.276(b)(5) or § 1.277 or that the prior notice submission is accurate, it will notify the requester, the transmitter, and CBP that the food is no longer subject to refusal under section 801(m)(1) of the act.

(e) *International Mail.* If an article of food arrives by international mail with inadequate prior notice or the PN confirmation number is not affixed as required, the parcel will be held by CBP

for 72 hours for FDA inspection and disposition. If FDA refuses the article under section 801(m)(1) of the act and there is a return address, the parcel may be returned to sender stamped “No Prior Notice—FDA Refused.” If the article is refused and there is no return address or FDA determines that the article of food in the parcel appears to present a hazard, FDA may dispose of or destroy the parcel at its expense. If FDA does not respond within 72 hours of the CBP hold, CBP may return the parcel to the sender or, if there is no return address, destroy the parcel, at FDA expense.

(f) *Prohibitions on delivery and transfer.* (1) Notwithstanding section 801(b) of the act, an article of food refused under section 801(m)(1) of the act may not be delivered to the importer, owner, or ultimate consignee until prior notice is submitted to FDA in accordance with this subpart, FDA has examined the prior notice, FDA has determined that the prior notice is adequate, and FDA has notified CBP and the transmitter that the article of food is no longer refused admission under section 801(m)(1).

(2) During the time an article of food that has been refused under section 801(m)(1) of the act is held, the article may not be transferred by any person from the port or the secure facility until prior notice is submitted to FDA in accordance with this subpart, FDA has examined the prior notice, FDA has determined that the prior notice is adequate, and FDA has notified CBP and the transmitter that the article of food no longer is refused admission under section 801(m)(1). After this notification by FDA to CBP and transmitter, entry may be made in accordance with law and regulation.

(g) *Relationship to other admissibility decisions.* A determination that an article of food is no longer refused under section 801(m)(1) of the act is different than, and may come before, determinations of admissibility under other provisions of the act or other U.S. laws. A determination that an article of food is no longer refused under section 801(m)(1) does not mean that it will be

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granted admission under other provisions of the act or other U.S. laws.

[68 FR 59070, Oct. 10, 2003; 69 FR 4851, 4852, Feb. 2, 2004]

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

(a) The importing or offering for import into the United States of an article of food in violation of the requirements of section 801(m), including the requirements of this subpart, is a prohibited act under section 301(ee) of the act (21 U.S.C. 331(ee)).

(b) Section 301 of the act (21 U.S.C. 331) prohibits the doing of certain acts or causing such acts to be done.

(1) Under section 302 of the act (21 U.S.C. 332), the United States can bring a civil action in Federal court to enjoin persons who commit a prohibited act.

(2) Under section 303 of the act (21 U.S.C. 333), the United States can bring a criminal action in Federal court to prosecute persons who are responsible for the commission of a prohibited act.

(c) Under section 306 of the act (21 U.S.C. 335a), FDA can seek debarment of any person who has been convicted of a felony relating to importation of food into the United States or any person who has engaged in a pattern of importing or offering adulterated food that presents a threat of serious adverse health consequences or death to humans or animals.

[68 FR 59070, Oct. 10, 2003; 69 FR 4852, Feb. 2, 2004]

### **§ 1.285 What happens to food that is imported or offered for import from unregistered facilities that are required to register under 21 CFR part 1, subpart H?**

(a) If an article of food from a foreign manufacturer that is not registered as required under section 415 of the act (21 U.S.C. 350d) and subpart H is imported or offered for import into the United States, the food is subject to refusal of admission under section 801(m)(1) of the act and § 1.283 for failure to provide adequate prior notice. The failure to provide the correct registration number of the foreign manufacturer, if registration is required under section 415

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of the act and 21 CFR part 1, subpart H, renders the identity of that facility incomplete for purposes of prior notice.

(b) Unless CBP concurrence is obtained for export and the article is immediately exported from the port of arrival, if an article of food is imported or offered for import from a foreign facility that is not registered as required under section 415 of the act and is placed under hold under section 801(l) of the act, it must be held within the port of entry for the article unless directed by CBP or FDA.

(c) *Status and movement of held food.*

(1) An article of food that has been placed under hold under section 801(l) of the act shall be considered general order merchandise as described in section 490 of the Tariff Act of 1930, as amended (19 U.S.C. 1490).

(2) Food under hold under section 801(l) must be moved under appropriate custodial bond. FDA must be notified of the location where the food has been or will be moved, within 24 hours of the hold. The food subject to hold shall not be entered and shall not be delivered to any importer, owner, or ultimate consignee. The food must be taken directly to the designated facility.

(d) *Segregation of held foods.* If an article of food that has been placed under hold under section 801(l) of the act is part of a shipment that contains articles that have not been placed under hold, the food under hold may be segregated from the rest of the shipment. This segregation must take place where the article is held, if different. FDA or CBP may supervise segregation. If FDA or CBP determine that supervision is necessary, segregation must not take place without supervision.

(e) *Costs.* Neither FDA nor CBP will be liable for transportation, storage, or other expenses resulting from any hold.

(f) *Export after hold.* An article of food that has been placed under hold under section 801(l) of the act may be exported with CBP concurrence and under CBP supervision unless it is seized or administratively detained by FDA or CBP under other authority.

(g) *No Registration or Request for Review.* If an article of food is placed under hold under section 801(l) of the act and no registration or request for

FDA review is submitted in a timely fashion or export has not occurred in accordance with subsection (f), the food shall be dealt with as set forth in CBP regulations relating to general order merchandise, except that the article may only be sold for export or destroyed as agreed to by CBP and FDA.

(h) *Food carried by or otherwise accompanying an individual.* If an article of food carried by or otherwise accompanying an individual arriving in the United States is placed under hold under section 801(l) of the act because it is from a foreign facility that is not registered as required under section 415 of the act, 21 U.S.C. 350d, and subpart H, the individual may arrange to have the food held at the port or exported. If such arrangements cannot be made, the article of food may be destroyed.

(i) *Post-refusal and post-hold submissions.* (1) Post-refusal. To resolve the refusal if an article of food is refused under §1.283(a) because the facility is not registered, the facility must be registered and after a registration number has been obtained, you should cancel the prior notice and must resubmit the prior notice in accordance with §1.283(c).

(2) Post-hold. To resolve a hold, if an article of food is held under §1.285(b) because it is from a foreign facility that is not registered, the facility must be registered and a registration number must be obtained.

(i) FDA must be notified of the applicable registration number in writing. The notification must provide the name and contact information for the person submitting the information. The notification may be delivered to FDA by mail, express courier, fax, or e-mail. The location for receipt of a notification of registration number associated with an article of food under hold is listed at <http://www.fda.gov>—see Food Facility Registration. The notification should include the applicable CBP identifier.

(ii) If FDA determines that the article is no longer subject to hold, it will notify the person who provided the registration information and CBP that the food is no longer subject to hold under section 801(l) of the act.

(j) *FDA review after hold.* (1) If an article of food has been placed under hold

under section 801(l) of the act, a request may be submitted asking FDA to review whether the facility associated with the article is subject to the requirements of section 415 of the act. A request for review may not be submitted to obtain a registration number.

(2) A request may be submitted only by the prior notice submitter, importer, owner, or ultimate consignee of the article. A request must identify which one the requestor is.

(3) A request must be submitted in writing to FDA and delivered by mail, express courier, fax or e-mail. The location for receipt of a request is listed at <http://www.fda.gov>—see Food Facility Registration. A request must include all factual and legal information necessary for FDA to conduct its review. Only one request for review may be submitted for each article under hold.

(4) The request must be submitted within 5 calendar days of the hold. FDA will review and respond within 5 calendar days of receiving the request.

(5) If FDA determines that the article is not from a facility subject to the requirements of section 415, it will notify the requestor and CBP that the food is no longer subject to hold under section 801(l) of the act.

(k) *International mail.* If an article of food is that arrives by international mail is from a foreign facility that is not registered as required under section 415 of the act (21 U.S.C. 350d) and subpart H, the parcel will be held by CBP for 72 hours for FDA inspection and disposition. If the article is held under section 801(l) of the act and there is a return address, the parcel may be returned to sender stamped “No Registration—No Admission Permitted.” If the article is under hold and there is no return address or FDA determines that the article of food is in the parcel appears to present a hazard, FDA may dispose of or destroy the parcel at its expense. If FDA does not respond within 72 hours of the CBP hold, CBP may return the parcel to the sender stamped “No Registration—No Admission Permitted” or, if there is no return address, destroy the parcel, at FDA expense.

**Pt. 2**

(1) *Prohibitions on delivery and transfer.* (1) Notwithstanding section 801(b) of the act (21 U.S.C. 381(b)), an article of food that has been placed under hold section 801(l) of the act may not be delivered to the importer, owner, or ultimate consignee until prior notice is submitted to FDA in accordance with this subpart, FDA has examined the prior notice, FDA has determined that the prior notice is adequate, and FDA has notified CBP and the transmitter that the article of food is no longer subject to hold under section 801(l) of the act.

(2) During the time an article of food that has been refused under section 801(m)(1) of the act is held, the article may not be transferred by any person from the port or the secure facility location until prior notice is submitted to FDA in accordance with this subpart, FDA has examined the prior notice, FDA has determined that the prior notice is adequate, and FDA has notified CBP and the transmitter that the article of food is no longer refused admission under section 801(m)(1) of the act. After this notification by FDA to CBP and transmitter, entry may be made in accordance with law and regulation.

(m) *Relationship to other admissibility provisions.* A determination that an article of food is no longer subject to hold under section 801(l) of the act is different than, and may come before, determinations of admissibility under other provisions of the act or other U.S. laws. A determination that an article of food is no longer under hold under section 801(l) does not mean that it will be granted admission under other provisions of the act or other U.S. laws.

[68 FR 59070, Oct. 10, 2003; 69 FR 4852, Feb. 2, 2004]

**PART 2—GENERAL ADMINISTRATIVE RULINGS AND DECISIONS**

**Subpart A—General Provisions**

Sec.

- 2.5 Imminent hazard to the public health.
- 2.10 Examination and investigation samples.
- 2.19 Methods of analysis.

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**Subpart B—Human and Animal Foods**

- 2.25 Grain seed treated with poisonous substances; color identification to prevent adulteration of human and animal food.
- 2.35 Use of secondhand containers for the shipment or storage of food and animal feed.

**Subparts C–E [Reserved]**

**Subpart F—Caustic Poisons**

- 2.110 Definition of ammonia under Federal Caustic Poison Act.

**Subpart G—Provisions Applicable to Specific Products Subject to the Federal Food, Drug, and Cosmetic Act**

- 2.125 Use of ozone-depleting substances in foods, drugs, devices, or cosmetics.

AUTHORITY: 15 U.S.C. 402, 409; 21 U.S.C. 321, 331, 335, 342, 343, 346a, 348, 351, 352, 355, 360b, 361, 362, 371, 372, 374; 42 U.S.C. 7671 *et seq.*

SOURCE: 42 FR 15559, Mar. 22, 1977, unless otherwise noted.

**Subpart A—General Provisions**

**§2.5 Imminent hazard to the public health.**

(a) Within the meaning of the Federal Food, Drug, and Cosmetic Act an imminent hazard to the public health is considered to exist when the evidence is sufficient to show that a product or practice, posing a significant threat of danger to health, creates a public health situation (1) that should be corrected immediately to prevent injury and (2) that should not be permitted to continue while a hearing or other formal proceeding is being held. The *imminent hazard* may be declared at any point in the chain of events which may ultimately result in harm to the public health. The occurrence of the final anticipated injury is not essential to establish that an *imminent hazard* of such occurrence exists.

(b) In exercising his judgment on whether an *imminent hazard* exists, the Commissioner will consider the number of injuries anticipated and the nature, severity, and duration of the anticipated injury.