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SUBCHAPTER A—GENERAL

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Subpart Q—Administrative Detention of Drugs Intended for Human or Animal Use

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AUTHORITY: 15 U.S.C. 1333, 1453, 1454, 1455, 4402; 19 U.S.C. 1490, 1491; 21 U.S.C. 321, 331, 332, 333, 334, 335a, 342, 343, 350c, 350d, 350e, 350j, 350k, 352, 355, 360b, 360ccc, 360ccc–1, 360ccc–2, 362, 371, 373, 374, 379j–31, 381, 382, 384a, 384b, 384d, 387, 387a, 387c, 393; 42 U.S.C. 216, 241, 243, 262, 264, 271; Pub. L. 107–188, 116 Stat. 594, 668–69; Pub. L. 111–353, 124 Stat. 3885, 3889.

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 also to the causing of such act to be done.

(b) The definitions and interpretations of terms contained in sections 201 and 900 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 and 387) 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 §§ 101.7(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 §§ 101.7(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 §§ 101.7(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 §§ 101.7(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; 75 FR 73953, Nov. 30, 2010; 78 FR 69543, Nov. 20, 2013; 81 FR 59131, Aug. 29, 2016]

§ 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 consumer 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, 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.

In the regulations specified in § 1.1(c) of this chapter, 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 § 101.7(f) applicable to such unit containers is waived if the units are in compliance with all the other requirements of this part.

[42 FR 15553, Mar. 22, 1977, as amended at 75 FR 73953, Nov. 30, 2010; 78 FR 69543, Nov. 20, 2013; 81 FR 59131, Aug. 29, 2016]

§ 1.21 Failure to reveal material facts.

(a) Labeling of a food, drug, device, cosmetic, or tobacco product 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, cosmetics, or tobacco products under the Federal Food, Drug, and Cosmetic 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.

[42 FR 15553, Mar. 22, 1977, as amended at 77 FR 5176, Feb. 2, 2012]

§ 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 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 § 101.7(j) of this chapter, bearing labels 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 § 101.7

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 § 101.7(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 § 101.7(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, 5001 Campus Dr., College Park, MD 20740, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

(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, 5001 Campus Dr., College Park, MD 20740, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

(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 § 101.7(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, 5001 Campus Dr., College Park, MD 20740, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

(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 § 101.7(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 § 101.7(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 § 101.7(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 § 101.7(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 § 101.7(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 § 101.7(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 § 101.7(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 101.7(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 § 101.7(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 § 101.7(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 § 101.7(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 § 101.7(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 § 101.7(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 § 101.7(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 multiunit 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.

(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; 81 FR 49895, July 29, 2016; 81 FR 59131, Aug. 29, 2016]

Subpart C [Reserved]

Subpart D—Electronic Import Entries

SOURCE: 81 FR 85870, Nov. 29, 2016, unless otherwise noted.

§ 1.70 Scope.

This subpart specifies the data elements that are required by the Food and Drug Administration (FDA) to be included in an electronic import entry submitted in the Automated Commercial Environment (ACE) system or any other U.S. Customs and Border Protection (CBP)-authorized electronic data interchange (EDI) system, which contains an article that is being imported or offered for import into the United States and that is regulated by FDA.

§ 1.71 Definitions.

For purposes of subpart D:

ACE filer means the person who is authorized to submit an electronic import entry for an FDA-regulated product in the Automated Commercial Environment or any other CBP-authorized EDI system.

Acidified food means acidified food, as defined in § 114.3(b) of this chapter, and subject to the requirements in parts 108 and 114 of this chapter.

Automated Commercial Environment or *ACE* means the automated and electronic system for processing commercial importations that is operated by U.S. Customs and Border Protection in accordance with the National Customs Automation Program established in Subtitle B of Title VI—Customs Modernization, in the North American Free Trade Agreement Implementation Act (Pub. L. 103–182, 107 Stat. 2057, 2170, December 8, 1993) (Customs Modernization Act), or any other CBP-authorized EDI system.

Biological product means a biological product as defined in section 351(i)(1) of the Public Health Service Act.

Cosmetic means a cosmetic as defined in section 201(i) of the Federal Food, Drug, and Cosmetic Act.

CBP or U.S. Customs and Border Protection means the Federal Agency that is primarily responsible for maintaining the integrity of the borders and ports of entry of the United States.

Drug means those articles meeting the definition of a drug in section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act.

FDA or Agency means the U.S. Food and Drug Administration.

Food means food as defined in section 201(f) of the Federal Food, Drug, and Cosmetic Act.

Food contact substance means any substance, as defined in section 409(h)(6) of the Federal Food, Drug, and Cosmetic Act, that is intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding food if such use is not intended to have any technical effect in such food.

HCT/Ps means human cells, tissues, or cellular or tissue-based products, as defined in § 1271.3(d) of this chapter.

Low-acid canned food means a thermally processed low-acid food (as defined in § 113.3(n) of this chapter) in a hermetically sealed container (as defined in § 113.3(j) of this chapter), and subject to the requirements in parts 108 and 113 of this chapter.

Medical device means a device as defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act, that is intended for use in humans.

Radiation-emitting electronic product means an electronic product as defined in section 531 of the Federal Food, Drug, and Cosmetic Act.

Tobacco product means a tobacco product as defined in section 201(rr) of the Federal Food, Drug, and Cosmetic Act.

§ 1.72 Data elements that must be submitted in ACE for articles regulated by FDA.

General. When filing an entry in ACE, the ACE filer shall submit the following information for food contact substances, drugs, biological products, HCT/Ps, medical devices, radiation-emitting electronic products, cosmetics, and tobacco products.

(a) *Product identifying information* for the article that is being imported or offered for import. This consists of:

(1) *FDA Country of Production,* which is the country where the article was last manufactured, processed, or grown (including harvested, or collected and readied for shipment to the United States). The FDA Country of Production for an article that has undergone any manufacturing or processing is the country where that activity occurred provided that the manufacturing or

processing had more than a minor, negligible, or insignificant effect on the article.

(2) *The Complete FDA Product Code*, which must be consistent with the invoice description of the product.

(3) *The Full Intended Use Code*.

(b) *Importer of record contact information*, which is the telephone and email address of the importer of record.

§ 1.73 Food.

(a) *Food contact substances*. An ACE filer must submit the information specified in § 1.72 at the time of filing entry in ACE for food that is a food contact substance.

(b) *Low-acid canned food*. For an article of food that is a low-acid canned food, the ACE filer must submit at the time of filing entry the Food Canning Establishment Number and the Submission Identifier, and can dimensions or volume, except that the ACE filer does not need to submit this information in ACE at the time of entry if the article is being imported or offered for import for laboratory analysis only and will not be taste tested or otherwise ingested.

(c) *Acidified food*. For an article of food that is an acidified food, the ACE filer must submit at the time of filing entry the Food Canning Establishment Number and the Submission Identifier, and can dimensions or volume, except that the ACE filer does not need to submit this information in ACE at the time of entry if the article is being imported or offered for import for laboratory analysis only and will not be taste tested or otherwise ingested.

§ 1.74 Human drugs.

In addition to the data required to be submitted in § 1.72, an ACE filer must submit the following information at the time of filing entry in ACE for drugs, including biological products, intended for human use that are regulated by the FDA Center for Drug Evaluation and Research.

(a) *Registration and listing*. For a drug intended for human use, the Drug Registration Number and the Drug Listing Number if the foreign establishment where the human drug was manufactured, prepared, propagated, compounded, or processed before being imported or offered for import into the United States is required to register and list the drug under part 207 of this chapter. For the purposes of this section, the Drug Registration Number that must be submitted at the time of entry in ACE is the unique facility identifier of the foreign establishment where the human drug was manufactured, prepared, propagated, compounded, or processed before being imported or offered for import into the United States. The unique facility identifier is the identifier submitted by a registrant in accordance with the system specified under section 510(b) of the Federal Food, Drug, and Cosmetic Act. For the purposes of this section, the Drug Listing Number is the National Drug Code number of the human drug article being imported or offered for import.

(b) *Drug application number*. For a drug intended for human use that is the subject of an approved application under section 505(b) or 505(j) of the Federal Food, Drug, and Cosmetic Act, the number of the new drug application or abbreviated new drug application. For a biological product regulated by the FDA Center for Drug Evaluation and Research that is required to have an approved new drug application or an approved biologics license application, the number of the applicable application.

(c) *Investigational new drug application number*. For a drug intended for human use that is the subject of an investigational new drug application under section 505(i) of the Federal Food, Drug, and Cosmetic Act, the number of the investigational new drug application.

§ 1.75 Animal drugs.

In addition to the data required to be submitted in § 1.72, an ACE filer must submit the following information at the time of filing entry in ACE for animal drugs:

(a) *Registration and listing*. For a drug intended for animal use, the Drug Registration Number and the Drug Listing Number if the foreign establishment where the drug was manufactured, prepared, propagated, compounded, or processed before being imported or offered for import into the United States is required to register and list the drug

under part 207 of this chapter. For the purposes of this section, the Drug Registration Number that must be submitted in ACE is the Unique Facility Identifier of the foreign establishment where the animal drug was manufactured, prepared, propagated, compounded, or processed before being imported or offered for import into the United States. The Unique Facility Identifier is the identifier submitted by a registrant in accordance with the system specified under section 510(b) of the Federal Food, Drug, and Cosmetic Act. For the purposes of this section, the Drug Listing Number is the National Drug Code number of the animal drug article being imported or offered for import.

(b) *New animal drug application number*. For a drug intended for animal use that is the subject of an approved application under section 512 of the Federal Food, Drug, and Cosmetic Act, the number of the new animal drug application or abbreviated new animal drug application. For a drug intended for animal use that is the subject of a conditionally approved application under section 571 of the Federal Food, Drug, and Cosmetic Act, the application number for the conditionally approved new animal drug.

(c) *Veterinary minor species index file number*. For a drug intended for use in animals that is the subject of an Index listing under section 572 of the Federal Food, Drug, and Cosmetic Act, the Minor Species Index File number of the new animal drug on the Index of Legally Marketed Unapproved New Animal Drugs for Minor Species.

(d) *Investigational new animal drug number*. For a drug intended for animal use that is the subject of an investigational new animal drug or generic investigational new animal drug application under part 511 of this chapter, the number of the investigational new animal drug or generic investigational new animal drug file.

§ 1.76 Medical devices.

In addition to the data required to be submitted in §1.72, an ACE filer must submit the following information at the time of filing entry in ACE for medical devices regulated by the FDA Center for Devices and Radiological Health.

(a) *Registration and listing*. For a medical device, the Registration Number for Foreign Manufacturers, Foreign Exporters, and/or Domestic Manufacturers, and the Device Listing Number, required under section 510 of the Federal Food, Drug, and Cosmetic Act and part 807 of this chapter.

(b) *Investigational devices*. For an investigational medical device that has an investigational device exemption granted under section 520(g) of the Federal Food, Drug, and Cosmetic Act, the Investigational Device Exemption Number. For an investigational medical device being imported or offered for import for use in a nonsignificant risk or exempt study, ''NSR'' to be entered in the Affirmation of Compliance for the ''investigational device exemption'' that identifies the device as being used in a nonsignificant risk or exempt study.

(c) *Premarket number*. For a medical device that has one, the Premarket Number. This is the Premarket Approval Number for those medical devices that have received premarket approval under section 515 of the Federal Food, Drug, and Cosmetic Act; the Product Development Protocol Number for those medical devices for which FDA has declared the product development protocol complete under section 515(f) of the Federal Food, Drug, and Cosmetic Act; the De Novo number for those medical devices granted marketing authorization under section 513(f)(2) of the Federal Food, Drug, and Cosmetic Act; the Premarket Notification Number for those medical devices that received premarket clearance under section 510(k) of the Federal Food, Drug, and Cosmetic Act; or the Humanitarian Device Exemption Number for those medical devices for which an exemption has been granted under section 520(m) of the Federal Food, Drug, and Cosmetic Act.

(d) *Component*. If applicable for a medical device, an affirmation identifying that the article being imported or offered for import is a component that requires further processing or inclusion into a finished medical device.

(e) *Lead wire/patient cable.* For electrode lead wires and patient cables intended for use with a medical device, an Affirmation of Compliance with the applicable performance standard under § 898.12 of this chapter.

(f) *Impact resistant lens.* For impact resistant lenses in eyeglasses and sunglasses, an Affirmation of Compliance with the applicable requirements of § 801.410 of this chapter.

(g) *Convenience kit.* If applicable for a medical device, an Affirmation of Compliance that the article imported or offered for import is a convenience kit or part of a convenience kit.

§ 1.77 Radiation-emitting electronic products.

In addition to the data required to be submitted in § 1.72, an ACE filer must submit all of the declarations required in Form FDA 2877 electronically in ACE at the time of filing entry for products subject to the standards under parts 1020–1050 of this chapter.

§ 1.78 Biological products, HCT/Ps, and related drugs and medical devices.

In addition to the data required to be submitted in § 1.72, an ACE filer must submit the following information at the time of filing entry in ACE for biological products, HCT/Ps, and related drugs and medical devices regulated by the FDA Center for Biologics Evaluation and Research.

(a) *Product name* which identifies the article being imported or offered for import by the name commonly associated with that article including the established name, trade name, brand name, proper name, or product description if the article does not have an established name, trade name, brand name, or proper name.

(b) *HCT/P registration and affirmation.* (1) For an HCT/P regulated solely under section 361 of the Public Health Service Act and the regulations in part 1271 of this chapter that is manufactured by an establishment that is required to be registered under part 1271 of this chapter, the HCT/P Registration Number; and

(2) For an HCT/P regulated solely under section 361 of the Public Health Service Act and the regulations in part 1271 of this chapter, an Affirmation of Compliance with the applicable requirements of part 1271 of this chapter.

(c) *Licensed biological products.* For a biological product that is the subject of an approved biologics license application under section 351 of the Public Health Service Act, the Submission Tracking Number of the biologics license application and/or the Biologics License Number.

(d) *Drug registration.* For a drug intended for human use, the Drug Registration Number if the foreign establishment where the human drug was manufactured, prepared, propagated, compounded, or processed before being imported or offered for import into the United States is required to register the drug under part 207 or part 607 of this chapter as applicable. For the purposes of this section, the Drug Registration Number that must be submitted at the time of entry in ACE is the unique facility identifier of the foreign establishment where the human drug was manufactured, prepared, propagated, compounded, or processed before being imported or offered for import into the United States. The unique facility identifier is the identifier submitted by a registrant in accordance with the system specified under section 510(b) of the Federal Food, Drug, and Cosmetic Act.

(e) *Drug application number.* For a drug intended for human use that is the subject of an approved application under section 505(b) or 505(j) of the Federal Food, Drug, and Cosmetic Act, the number of the new drug application or the abbreviated new drug application.

(f) *Investigational new drug application number.* For a drug intended for human use that is the subject of an investigational new drug application under section 505(i) of the Federal Food, Drug, and Cosmetic Act, the number of the investigational new drug application.

(g) *Medical device registration and listing.* For a medical device subject to the registration and listing procedures contained in part 807 of this chapter, the Registration Number for Foreign Manufacturers, Foreign Exporters, and/or Domestic Manufacturers, and the Device Listing Number, required under section 510 of the Federal Food, Drug, and Cosmetic Act and part 807 of this chapter.

(h) *Investigational devices*. For an investigational medical device that has an investigational device exemption granted under section 520(g) of the Federal Food, Drug, and Cosmetic Act, the Investigational Device Exemption Number. For an investigational medical device being imported or offered for import for use in a nonsignificant risk or exempt study, ''NSR'' to be entered in the Affirmation of Compliance for the ''investigational device exemption'' that identifies the device as being used in a nonsignificant risk or exempt study.

(i) *Medical device premarket number*. For a medical device that has one, the Premarket Number. This is the Premarket Approval Number for those medical devices that have received premarket approval under section 515 of the Federal Food, Drug, and Cosmetic Act; the Product Development Protocol Number for those medical devices for which FDA has declared the product development protocol complete under section 515(f) of the Federal Food, Drug, and Cosmetic Act; the De Novo number for those medical devices granted marketing authorization under section 513(f)(2) of the Federal Food, Drug, and Cosmetic Act; the Premarket Notification Number for those medical devices that received premarket clearance under section 510(k) of the Federal Food, Drug, and Cosmetic Act; or the Humanitarian Device Exemption Number for those medical devices for which an exemption has been granted under section 520(m) of the Federal Food, Drug, and Cosmetic Act.

(j) *Medical device component*. If applicable for a medical device, an affirmation identifying that the article being imported or offered for import is a component that requires further processing or inclusion into a finished medical device.

§ 1.79 Tobacco products.

In addition to the data required to be submitted in § 1.72, an ACE filer must submit the following information at the time of filing entry in ACE.

(a) *Brand name* of an article that is a tobacco product that is being imported or offered for import. If the article does not have a specific brand name, the ACE filer must submit a commercial name for the brand name. This data element is not applicable to those products solely intended either for further manufacturing or as investigational tobacco products.

(b) [Reserved]

§ 1.80 Cosmetics.

An ACE filer must submit the data specified in § 1.72 at the time of filing entry in ACE.

§ 1.81 Rejection of entry filing.

FDA may reject an entry filing for failure to provide complete and accurate information that is required pursuant to this subpart.

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 makes entry under the provisions of section 484 of the Tariff Act of 1930, as amended (19 U.S.C. 1484), namely, the ''importer of record.''

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

[42 FR 15553, Mar. 22, 1977, as amended at 81 FR 85872, Nov. 29, 2016]

§ 1.90 Notice of sampling.

When a sample of an article offered for import has been requested by the district director, FDA shall provide 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 U.S. Customs and Border Protection of the results of examination of the sample.

[81 FR 85872, Nov. 29, 2016]

§ 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 or destruction.

(a) If it appears that the article may be subject to refusal of admission, or that the article is a drug that may be subject to destruction under section 801(a) of the Federal Food, Drug, and Cosmetic Act, the district director shall give the owner or consignee a written or electronic 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 or destruction of the article, and may be introduced orally or in writing.

(b) If such owner or consignee submits or indicates his or her intention to submit an application for authorization to relabel or perform other action to bring the article into compliance with the Federal Food, Drug, and Cosmetic 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 on refusal of admission, the district director shall specify a time limit, reasonable in the light of the circumstances, for filing such application.

(c) If the article is a drug that may be subject to destruction under section 801(a) of the Federal Food, Drug, and Cosmetic Act, the district director may give the owner or consignee a single written or electronic notice that provides the notice of refusal of admission and the notice of destruction of an article described in paragraph (a) of this section. The district director may also combine the hearing on refusal of admission with the hearing on destruction of the article described in paragraph (a) of this section into a single proceeding.

[80 FR 55242, Sept. 15, 2015, as amended at 81 FR 85873, Nov. 29, 2016]

§ 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 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

	Hours
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, cosmetic, and tobacco product exports under sections 801 or 802 of the Federal Food, Drug, and Cosmetic 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, cosmetics, and tobacco products exported under or subject to section 801(e)(1) of the Federal Food, Drug, and Cosmetic 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 an 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—Food and Drug Administration, Center for Biologics Evaluation and Research, Document Control Center, 10903 New Hampshire Ave., Bldg. 71, Rm. G112, Silver Spring, MD 20993–0002.

(ii) For human drug products, biological products, and devices regulated by the Center for Drug Evaluation and Research—Division of New Drugs and Labeling Compliance, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002.

(iii) For devices—Food and Drug Administration, Center for Devices and Radiological Health, Division of Program Operations, 10903 New Hampshire Ave., Bldg. 66, rm. 5429, Silver Spring, MD 20993–0002.

(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, as amended at 69 FR 48774, Aug. 11, 2004; 70 FR 14980, Mar. 24, 2005; 74 FR 13112, Mar. 26, 2009; 75 FR 20914, Apr. 22, 2010; 77 FR 5176, Feb. 2, 2012; 80 FR 18090, Apr. 3, 2015]

Subparts F–G [Reserved]

Subpart H—Registration of Food Facilities

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

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?

The definitions of terms in section 201 of the Federal Food, Drug, and Cosmetic Act apply to such terms when used in this subpart. In addition, for the purposes of this subpart:

Calendar day means every day shown on the calendar.

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.

(1) *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.

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

Farm means:

(1) Primary production farm. A primary production farm is an operation under one management in one general (but not necessarily contiguous) physical location devoted to the growing of crops, the harvesting of crops, the raising of animals (including seafood), or any combination of these activities. The term ''farm'' includes operations that, in addition to these activities:

(i) Pack or hold raw agricultural commodities;

(ii) Pack or hold processed food, provided that all processed food used in such activities is either consumed on that farm or another farm under the same management, or is processed food identified in paragraph (1)(iii)(B)(*1*) of this definition; and

(iii) Manufacture/process food, provided that:

(A) All food used in such activities is consumed on that farm or another farm under the same management; or

(B) Any manufacturing/processing of food that is not consumed on that farm or another farm under the same management consists only of:

(*1*) Drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins), and packaging and labeling such commodities, without additional manufacturing/processing (an example of additional manufacturing/processing is slicing);

(*2*) Treatment to manipulate the ripening of raw agricultural commodities (such as by treating produce with ethylene gas), and packaging and labeling treated raw agricultural commodities, without additional manufacturing/processing; and

(*3*) Packaging and labeling raw agricultural commodities, when these activities do not involve additional manufacturing/processing (an example of additional manufacturing/processing is irradiation); or

(2) Secondary activities farm. A secondary activities farm is an operation, not located on a primary production farm, devoted to harvesting (such as hulling or shelling), packing, and/or holding of raw agricultural commodities, provided that the primary production farm(s) that grows, harvests, and/or raises the majority of the raw agricultural commodities harvested, packed, and/or held by the secondary activities farm owns, or jointly owns, a majority interest in the secondary activities farm. A secondary activities farm may also conduct those additional activities allowed on a primary production farm as described in paragraphs (1)(ii) and (iii) of this definition.

Food has the meaning given in section 201(f) of the Federal Food, Drug, and Cosmetic Act:

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

(i) Food contact substances as defined in section 409(h)(6) of the Federal Food, Drug, and Cosmetic Act; or

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

(2) 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.

Harvesting applies to farms and farm mixed-type facilities and means activities that are traditionally performed on farms for the purpose of removing raw agricultural commodities from the place they were grown or raised and preparing them for use as food. Harvesting is limited to activities performed on raw agricultural commodities, or on processed foods created by drying/dehydrating a raw agricultural commodity without additional manufacturing/processing, on a farm. Harvesting does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food,

Drug, and Cosmetic Act. Examples of harvesting include cutting (or otherwise separating) the edible portion of the raw agricultural commodity from the crop plant and removing or trimming part of the raw agricultural commodity (*e.g.*, foliage, husks, roots or stems). Examples of harvesting also include cooling, field coring, filtering, gathering, hulling, shelling, sifting, threshing, trimming of outer leaves of, and washing raw agricultural commodities grown on a farm.

Holding means storage of food and also includes activities performed incidental to storage of a food (*e.g.*, activities performed for the safe or effective storage of that food, such as fumigating food during storage, and drying/dehydrating raw agricultural commodities when the drying/dehydrating does not create a distinct commodity (such as drying/dehydrating hay or alfalfa)). Holding also includes activities performed as a practical necessity for the distribution of that food (such as blending of the same raw agricultural commodity and breaking down pallets), but does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act. Holding facilities could include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks.

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 include: Baking, boiling, bottling, canning, cooking, cooling, cutting, distilling, drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins), evaporating, eviscerating, extracting juice, formulating, freezing, grinding, homogenizing, irradiating, labeling, milling, mixing, packaging (including modified atmosphere packaging), pasteurizing, peeling, rendering, treating to manipulate ripening, trimming, washing, or waxing. For farms and farm mixed-type facilities, manufacturing/processing does not include activities that are part of harvesting, packing, or holding.

Mixed-type facility means an establishment that engages in both activities that are exempt from registration under section 415 of the Federal Food, Drug, and Cosmetic Act and activities that require the establishment to be registered. An example of such a facility is a ''farm mixed-type facility,'' which is an establishment that is a farm, but also conducts activities outside the farm definition that require the establishment to be registered.

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 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)).

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

Packing means placing food into a container other than packaging the food and also includes re-packing and activities performed incidental to packing or re-packing a food (*e.g.*, activities performed for the safe or effective packing or re-packing of that food (such as sorting, culling, grading, and weighing or conveying incidental to packing or re-packing)), but does not include activities that transform a raw agricultural commodity, as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act, into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act.

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.

(1) 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

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

Retail food establishment means an establishment that sells food products directly to consumers as its primary function. The term ''retail food establishment'' includes facilities that 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. A ''retail food establishment'' also includes certain farm-operated businesses selling food directly to consumers as their primary function.

(1) Sale of food directly to consumers from an establishment located on a farm includes sales by that establishment directly to consumers:

(i) At a roadside stand (a stand situated on the side of or near a road or thoroughfare at which a farmer sells food from his or her farm directly to consumers) or farmers' market (a location where one or more local farmers assemble to sell food from their farms directly to consumers);

(ii) Through a community supported agriculture program. Community supported agriculture (CSA) program means a program under which a farmer or group of farmers grows food for a group of shareholders (or subscribers) who pledge to buy a portion of the farmer's crop(s) for that season. This includes CSA programs in which a group of farmers consolidate their crops at a central location for distribution to shareholders or subscribers; and

(iii) At other such direct-to-consumer sales platforms, including door-to-door sales; mail, catalog and Internet order, including online farmers markets and online grocery delivery; religious or other organization bazaars; and State and local fairs.

(2) Sale of food directly to consumers by a farm-operated business includes the sale of food by that farm-operated business directly to consumers:

(i) At a roadside stand (a stand situated on the side of or near a road or thoroughfare at which a farmer sells food from his or her farm directly to consumers) or farmers' market (a location where one or more local farmers assemble to sell food from their farms directly to consumers);

(ii) Through a community supported agriculture program. Community supported agriculture (CSA) program means a program under which a farmer or group of farmers grows food for a group of shareholders (or subscribers) who pledge to buy a portion of the farmer's crop(s) for that season. This includes CSA programs in which a group of farmers consolidate their crops at a central location for distribution to shareholders or subscribers; and

(iii) At other such direct-to-consumer sales platforms, including door-to-door sales; mail, catalog and Internet order, including online farmers markets and online grocery delivery; religious or other organization bazaars; and State and local fairs.

(3) For the purposes of this definition, ''farm-operated business'' means a business that is managed by one or more farms and conducts manufacturing/processing not on the farm(s).

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.

U.S. agent means a person (as defined in section 201(e) of the Federal Food, Drug, and Cosmetic 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 may not 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.

(1) 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 another emergency contact.

(2) 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. FDA will consider the U.S. agent the equivalent of the registrant for purposes of sharing information and communications. The U.S. agent of a foreign facility may view the information submitted in the foreign facility's registration.

(3) 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.

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.

[80 FR 56141, Sept. 17, 2015, as amended at 81 FR 3715, Jan. 22, 2016; 81 FR 45950, July 14, 2016]

PROCEDURES FOR REGISTRATION OF FOOD FACILITIES

§ 1.230 When must you register or renew your registration?

(a) *Registration.* You must register before your facility begins to manufacture, process, pack, or hold food for consumption in the United States. You may authorize an individual to register the facility on your behalf.

(b) *Registration renewal.* You must submit a registration renewal containing the information required under § 1.232 every other year, during the period beginning on October 1 and ending on December 31 of each even-numbered year. You may authorize an individual to renew a facility's registration on your behalf. If the individual submitting the registration renewal is not the owner, operator, or agent in charge of the facility, the registration renewal 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 renewal, and identifies by name, address, and telephone number, the individual who authorized submission of the registration renewal. In addition, the registration renewal must also identify the individual who authorized submission of the registration renewal by email address, unless FDA has granted a waiver under § 1.245. Each registration renewal must include the name of the individual submitting the registration renewal, and the individual's signature (for the paper option). Each electronic registration renewal must include the name of the individual submitting the renewal.

(c) *Abbreviated registration renewal process.* If you do not have any changes to the information required under § 1.232 since you submitted the preceding registration, registration renewal, or update for your facility, you may use the abbreviated registration renewal process. If you use the abbreviated registration renewal process, you must confirm that no changes have been made to the information required under § 1.232 since you submitted the preceding registration, registration renewal or update, and you must certify that the information submitted is truthful and accurate. Each abbreviated registration renewal must include the name of the individual submitting the abbreviated renewal, and the individual's signature (for the paper option). Each electronic abbreviated registration renewal must include the name of the individual submitting the abbreviated renewal. For abbreviated registration renewals not submitted by the owner, operator, or agent in charge of the facility, the abbreviated renewal must provide the email address of the individual who authorized submission of the abbreviated renewal, unless FDA has granted a waiver under § 1.245. You must use

Form FDA 3537 to submit abbreviated registration renewals to FDA.

[81 FR 45950, July 14, 2016]

§ 1.231 How and where do you register or renew your registration?

(a) *Electronic registration and registration renewal.* (1) To register or renew a registration electronically, you must go to *http://www.fda.gov/furls*, which is available for registration 24 hours a day, 7 days a week. This Web site 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) Beginning on January 4, 2020, you must submit your registration or registration renewal to FDA electronically, unless FDA has granted you a waiver under § 1.245.

(3) After you submit your electronic registration, FDA will verify the accuracy of your unique facility identifier (UFI) recognized as acceptable by FDA and will also verify that the facility-specific address associated with the UFI is the same address associated with your registration. FDA will not confirm your registration or provide you with a registration number until FDA verifies the accuracy of your facility's UFI and verifies that the facility-specific address associated with the UFI is the same address associated with your registration. With respect to electronic registration renewals, after you submit your electronic registration renewal, FDA will provide you with an electronic confirmation of your registration renewal. When you update your facility's UFI as part of your electronic registration renewal, FDA will verify the accuracy of your facility's UFI and will also verify that the facility-specific address associated with the UFI is the same address associated with your registration. FDA will not provide you with a confirmation of your registration renewal until FDA verifies the accuracy of your UFI and verifies that the facility-specific address associated with the UFI is the same address associated with your registration.

(4) For electronic registrations not submitted by the owner, operator, or agent in charge of the facility, after submission of the registration, FDA will verify that the individual identified as having authorized submission of the registration in fact authorized the submission on behalf of the facility. FDA will not confirm the registration or provide a registration number until that individual confirms that he or she authorized the submission. With respect to electronic registration renewals, after completion of the electronic registration renewal, FDA will provide an electronic confirmation of the registration renewal. For electronic registration renewals not submitted by the owner, operator, or agent in charge of the facility, FDA will verify that the individual identified as having authorized submission of the registration renewal in fact authorized the submission on behalf of the facility. FDA will not provide an electronic confirmation of the registration renewal until that individual confirms that he or she authorized the submission.

(5) For a foreign facility, after you submit your electronic registration, FDA will verify that the person identified as the U.S. agent for your foreign facility has agreed to serve as your U.S. agent. FDA will not confirm your registration or provide you with a registration number until that person confirms that the person agreed to serve as your U.S. agent. With respect to electronic registration renewals, after you complete your electronic registration renewal, FDA will provide you with an electronic confirmation of your registration renewal. When you update information about your U.S. agent as part of your electronic registration renewal, FDA will verify that the person identified as the U.S. agent for your foreign facility has agreed to serve as your U.S. agent. FDA will not provide you with an electronic confirmation of your registration renewal until that person confirms that the person agreed to serve as your U.S. agent.

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

(b) *Registration or registration renewal by mail or fax*. Beginning January 4, 2020, you must submit your registration or registration renewal to FDA electronically, unless FDA has granted you a waiver under §1.245. If FDA has granted you a waiver under §1.245, you may register or renew a registration by mail or by fax.

(1) You must register or renew a registration (including abbreviated registration renewals) using Form FDA 3537. You may obtain a copy of this form by writing to the U.S. Food and Drug Administration, Center for Food Safety and Applied Nutrition, 5001 Campus Dr. (HFS–681), College Park, MD 20740 or by requesting the form by phone at 1–800–216–7331 or 301–575–0156.

(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 301–436–2804.

(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, as soon as practicable, in the order FDA receives them.

(5) After you submit your registration, FDA will verify the accuracy of your facility's UFI and will also verify that the facility-specific address associated with the UFI is the same address associated with your registration. FDA will not confirm your registration or provide you with a registration number until FDA verifies the accuracy of your facility's UFI and verifies that the facility-specific address associated with the UFI is the same address associated with your registration. With respect to registration renewals, after you submit your registration renewal by mail or fax, FDA will provide you with a confirmation of your registration renewal. When you update your facility's UFI as part of your registration renewal, FDA will verify the accuracy of your facility's UFI and will also verify that the facility-specific address associated with the UFI is the same address associated with your registration. FDA will not provide you with a confirmation of your registration renewal until FDA verifies the accuracy of your UFI and verifies that the facility-specific address associated with the UFI is the same address associated with your registration.

(6) For registrations not submitted by the owner, operator, or agent in charge of the facility, after submission of the registration by mail or fax, FDA will verify that the individual identified as having authorized submission of the registration in fact authorized the submission on behalf of the facility. FDA will not confirm the registration or provide a registration number until that individual confirms that he or she authorized the submission. With respect to registration renewals, after completion of the registration renewal by mail or fax, FDA will provide a confirmation of the registration renewal. For registration renewals not submitted by the owner, operator, or agent in charge of the facility, FDA will verify that the individual identified as having authorized submission of the registration renewal in fact authorized the submission on behalf of the facility. FDA will not provide a confirmation of the registration renewal until that individual confirms that he or she authorized the submission.

(7) For a foreign facility, after you submit your registration by mail or fax, FDA will verify that the person identified as the U.S. agent for your foreign facility has agreed to serve as your U.S. agent. FDA will not confirm your registration or provide you with a registration number until that person confirms that the person agreed to serve as your U.S. agent. With respect to registration renewals, after you complete your registration renewal by mail or fax, FDA will provide you with a confirmation of your registration renewal. When you update information about your U.S. agent as part of your registration renewal, FDA will verify

that the person identified as the U.S. agent for your foreign facility has agreed to serve as your U.S. agent. FDA will not provide you with a confirmation of your registration renewal until that person confirms that the person agreed to serve as your U.S. agent.

(8) FDA will mail or fax you 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).

(9) 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.

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

(d) *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.

[81 FR 45950, July 14, 2016]

§ 1.232 What information is required in the registration?

(a) For a domestic and foreign facility, the following information is required:

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

(2) Beginning October 1, 2020, the facility's UFI recognized as acceptable by FDA;

(3) The preferred mailing address, if different from that of the facility;

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

(5) All trade names the facility uses;

(6) The name, full address, and phone number of the owner, operator, or agent in charge of the facility. In addition, the email address of the owner, operator, or agent in charge is required, unless FDA has granted you a waiver under § 1.245;

(7) The applicable food product categories of any food manufactured/processed, packed, or held at the facility as identified on Form FDA 3537;

(8) The type of activity conducted at the facility for each food product category identified. You may select more than one activity type for each food product category identified. The activity type options are as follows:

(i) Ambient human food storage warehouse/holding facility;

(ii) Refrigerated human food warehouse/holding facility;

(iii) Frozen human food warehouse/holding facility;

(iv) Interstate conveyance caterer/catering point;

(v) Contract sterilizer;

(vi) Labeler/relabeler;

(vii) Manufacturer/processor;

(viii) Acidified food processor;

(ix) Low-acid food processor;

(x) Farm mixed-type facility;

(xi) Packer/repacker;

(xii) Salvage operator (reconditioner);

(xiii) Animal food warehouse/holding facility;

(xiv) Other activity.

(9) A statement in which the owner, operator, or agent in charge provides an assurance that FDA will be permitted to inspect the facility at the times and in the manner permitted by the Federal Food, Drug, and Cosmetic Act;

(10) 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. In addition, the registration must identify the individual who authorized submission of the registration by email address, unless FDA

has granted a waiver under § 1.245. Each registration must include the name of the individual submitting the registration, and the individual's signature (for the paper option).

(b) For a domestic facility, the following additional information is required:

(1) The email address for the contact person of the facility;

(2) An emergency contact phone number and email address if different from the email address for the contact person in paragraph (b)(1) of this section.

(c) For a foreign facility, the following additional information is required:

(1) The name, full address, phone number, and email address of the foreign facility's U.S. agent;

(2) An emergency contact phone number and email address.

[81 FR 45951, July 14, 2016]

§ 1.233 Are there optional items included in the registration form?

Yes. FDA encourages, but does not require, you to submit items that are indicated as optional on the Form FDA 3537 that you submit.

[81 FR 45952, July 14, 2016]

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

(a) *Update requirements*. You must update 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. You may authorize an individual to update a facility's registration on your behalf. For updates not submitted by the owner, operator, or agent in charge of the facility, the update must provide the email address of the individual who authorized submission of the update, unless FDA has granted a waiver under § 1.245.

(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 submit a new registration for 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) After you submit your electronic update, FDA will provide you with an electronic confirmation of your update. When updating UFI information, FDA will verify the accuracy of your facility's UFI and will also verify that the facility-specific address associated with the UFI is the same address associated with your registration. FDA will not provide you with an electronic confirmation of your registration update until FDA verifies the accuracy of your facility's UFI and verifies that the facility-specific address associated with the UFI is the same address associated with your registration. For foreign facilities, when updating information about your U.S. agent, FDA will verify that the person identified as the U.S. agent for your foreign facility has agreed to serve as your U.S. agent. FDA will not provide you with an electronic confirmation of your registration update until that person confirms that the person agreed to serve as your U.S. agent.

(3) For electronic updates not submitted by the owner, operator, or agent in charge of the facility, after submission of the electronic update, FDA will verify that the individual identified as having authorized submission of the update in fact authorized the submission on behalf of the facility. FDA will not confirm the update to the registration until that individual confirms that he or she authorized the submission.

(4) Your registration will be considered updated once FDA sends you your update confirmation, unless notified otherwise.

(d) *Update by mail or fax*. Beginning January 4, 2020, you must submit your update electronically, unless FDA has granted you a waiver under § 1.245. If FDA has granted you a waiver under § 1.245, you may update your facility's registration by mail or by fax.

(1) You must update your registration using Form FDA 3537. You may

obtain a copy of this form by writing to the U.S. Food and Drug Administration, Center for Food Safety and Applied Nutrition, 5001 Campus Dr. (HFS–681), College Park, MD 20740 or by requesting the form by phone at 1–800–216–7331 or 301–575–0156.

(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 301–436–2804.

(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 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). After you submit your update by mail or fax, FDA will verify the accuracy of your facility's UFI and will also verify that the facility-specific address associated with the UFI is the same address associated with your registration. FDA will not provide a confirmation of your registration update until FDA verifies the accuracy of your facility's UFI and verifies that the facility-specific address associated with the UFI is the same address associated with your registration. For foreign facilities, when updating information about your U.S. agent, FDA will verify that the person identified as the U.S. agent for your foreign facility has agreed to serve as your U.S. agent. FDA will not provide you with a confirmation of your registration update until that person confirms that the person agreed to serve as your U.S. agent.

(6) For registration updates not submitted by the owner, operator, or agent in charge of the facility, after submission of the registration update by mail or fax, FDA will verify that the individual identified as having authorized submission of the update in fact authorized the submission on behalf of the facility. FDA will not confirm the registration update until that individual confirms that he or she authorized the update.

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

(8) 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.

[81 FR 45952, July 14, 2016]

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

(a) *Notification of registration cancellation.* You must cancel a registration within 60 calendar days of the reason for cancellation (e.g., your facility ceases operations, ceases providing food for consumption in the United States, or 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 email address (if available) of the individual submitting the cancellation;

(5) For registration cancellations not submitted by the owner, operator, or agent in charge of the facility, the email address of the individual who authorized submission of the registration cancellation, unless FDA has granted a waiver under § 1.245; and

(6) 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 provide you with an electronic confirmation of your cancellation.

(3) For registration cancellations not submitted by the owner, operator, or agent in charge of the facility, after submission of the registration cancellation, FDA will verify that the individual identified as having authorized submission of the cancellation in fact authorized the submission on behalf of the facility. FDA will not confirm the registration cancellation until that individual confirms that he or she authorized the registration cancellation.

(4) Your registration will be considered cancelled once FDA sends you your cancellation confirmation.

(d) *Cancellation by mail or fax.* Beginning January 4, 2020, you must cancel your registration electronically, unless FDA has granted you a waiver under § 1.245. If FDA has granted a waiver under § 1.245, you may cancel your facility's registration by mail or fax.

(1) You must cancel your registration using Form FDA 3537a. You may obtain a copy of this form by writing to the U.S. Food and Drug Administration, Center for Food Safety and Applied Nutrition, 5001 Campus Dr. (HFS–681), College Park, MD 20740 or by requesting the form by phone at 1–800–216–7331 or 301–575–0156.

(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 301–436–2804.

(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 as soon as practicable, in the order FDA receives them.

(5) FDA will 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) For registration cancellations not submitted by the owner, operator, or agent in charge of the facility, after submission of the registration cancellation by mail or fax, FDA will verify that the individual identified as having authorized submission of the cancellation in fact authorized the submission on behalf of the facility. FDA will not confirm the registration cancellation until that individual confirms that he or she authorized the registration cancellation.

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

[81 FR 45952, July 14, 2016]

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, renew, or cancel your registration?

(a) Section 301 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331) prohibits the doing of certain acts or causing such acts to be done. Under section 302 of the Federal Food, Drug, and Cosmetic 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 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 333), the United States can bring a criminal action in Federal court to prosecute a person who is responsible for the commission of a prohibited act. Under section 306 of the Federal Food, Drug, and Cosmetic 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, renew the registration of its facility, update required elements of its facility's registration, or cancel its registration in accordance with the requirements of this subpart is a prohibited act under section 301(dd) of the Federal Food, Drug, and Cosmetic Act.

(b) FDA will consider a registration for a food facility to be expired if the registration is not renewed, as required by § 1.230(b). Thus, if you previously submitted a registration to FDA, but do not submit a registration renewal to FDA during the period beginning on October 1 and ending on December 31 of each even-numbered year, FDA will consider the registration for the facility to be expired. FDA will consider a food facility with an expired registration to have failed to register in accordance with section 415 of the Federal Food, Drug, and Cosmetic Act.

(c) FDA will cancel a registration if FDA 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, is not required to register, or where the information about the facility's address was not updated in a timely manner in accordance with § 1.234(a) or the registration was submitted by a person not authorized to submit the registration under § 1.225. Also, FDA will cancel a registration if the facility's registration has expired because the facility has failed to renew its registration in accordance with § 1.230(b). If FDA cancels a facility's registration, FDA will send a confirmation of the cancellation using contact information submitted by the facility in the registration database.

(d) 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.

[81 FR 45953, July 14, 2016]

§ 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 subject 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.

§ 1.245 Waiver request.

Under §§ 1.231(a)(2) and (b), 1.234(d), and 1.235(d), beginning January 4, 2020, you must submit your registration, registration renewal, updates, and cancellations to FDA electronically unless FDA has granted a waiver from such requirement. Under § 1.232(a)(6), you must provide the email address of the owner, operator, or agent in charge of the facility unless FDA has granted a waiver from such requirement. In addition, under §§ 1.230(b) and (c), 1.232(a)(10), 1.234(a), and 1.235(b)(5), registration renewals, abbreviated registration renewals, registrations, updates, and cancellations not submitted by the owner, operator, or agent in charge must include the email address for the individual who authorized the submission, unless FDA has granted a waiver. To request a waiver from these requirements, you must submit a written request to FDA that explains why it is not reasonable for you to submit your registration, registration renewal,

update, or cancellation to FDA electronically or to provide the email address of the owner, operator, or agent in charge of the facility. You must submit your request to: U.S. Food and Drug Administration, Center for Food Safety and Applied Nutrition, 5001 Campus Dr. (HFS–681), College Park, MD 20740.

[81 FR 45953, July 14, 2016]

Subpart I—Prior Notice of Imported Food

SOURCE: 73 FR 66402, Nov. 7, 2008, 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 in this section.

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

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

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

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

(ii) For an article of food that is no longer in its natural state, the country where the article was made; except that, if an article of food is made from wild fish, including seafood, aboard a vessel, the FDA Country of Production is the country in which the vessel is registered. If an article of food that is no longer in its natural state was made in a Territory, the FDA Country of Production is the United States.

(5) *Food* has the meaning given in section 201(f) of the act, except as provided in paragraph (b)(5)(i) of this section.

(i) For purposes of this subpart, food does not include:

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

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

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

(6) *Full address* means the facility's street name and number; suite/unit number, as appropriate; city; Province or State as appropriate; mail code as appropriate; and country.

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

(8) *International mail* means foreign national mail services. International mail does not include express consignment operators or carriers or other private delivery services unless such service is operating under contract as an agent or extension of a foreign mail service.

(9) *Manufacturer* means the last facility, as that word is defined in § 1.227, that manufactured/processed the food. A facility is considered the last facility even if the food undergoes further manufacturing/processing that consists of adding labeling or any similar activity

of a *de minimis* nature. If the food undergoes further manufacturing/processing that exceeds an activity of a *de minimis* nature, then the subsequent facility that performed the additional manufacturing/processing is considered the manufacturer.

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

(11) *Port of arrival* means the water, air, or land port at which the article of food is imported or offered for import into the United States. For an article of food arriving by water or air, this is the port of unloading. For an article of food arriving by land, this is the port where the article of food first crosses the border into the United States. The port of arrival may be different than the port where consumption or warehouse entry or foreign trade zone admission documentation is presented to the U.S. Customs and Border Protection (CBP).

(12) *Port of entry*, in section 801(m) and (l) of the act (21 U.S.C. 381(m) and (l)), means the port of entry as defined in 19 CFR 101.1.

(13) *Registration number* means the registration number assigned to a facility by FDA under section 415 of the act (21 U.S.C. 350d) and subpart H of this part.

(14) *Shipper* means the owner or exporter of the article of food who consigns and ships the article from a foreign country or the person who sends an article of food by international mail or express consignment operators or carriers or other private delivery service to the United States.

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

(16) *You* means the person submitting the prior notice, i.e., the submitter or the transmitter, if any.

[73 FR 66402, Nov. 7, 2008, as amended at 80 FR 56143, Sept. 17, 2015]

§ 1.277 What is the scope of this subpart?

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

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

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

(2) Food that was made by an individual in his/her personal residence and sent by that individual as a personal gift (i.e., for nonbusiness reasons) to an individual in the United States;

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

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

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

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

(7) Articles of food subject to Article 27(3) of The Vienna Convention on Diplomatic Relations (1961), i.e., shipped as baggage or cargo constituting the diplomatic bag.

REQUIREMENTS TO SUBMIT PRIOR NOTICE OF IMPORTED FOOD

§ 1.278 Who is authorized to submit prior notice?

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

§ 1.279 When must prior notice be submitted to FDA?

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

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

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

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

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

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

(1) If prior notice is submitted via the Automated Broker Interface/Automated Commercial Environment/International Trade Data System (ABI/ACE/ITDS), you may not submit prior notice more than 30-calendar days before the anticipated date of arrival.

(2) If prior notice is submitted via the FDA Prior Notice System Interface (FDA PNSI), you may not submit prior notice more than 15-calendar days before the anticipated date of arrival.

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

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

(e) The PN Confirmation Number must accompany any article of food arriving by international mail. The PN Confirmation Number must appear on the Customs Declaration (e.g., CN22 or CN23 or U.S. equivalent) that accompanies the package.

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

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

[73 FR 66402, Nov. 7, 2008, as amended at 82 FR 15629, Mar. 30, 2017]

§ 1.280 How must you submit prior notice?

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

(1) The U.S. Customs and Border Protection (CBP) Automated Broker Interface/Automated Commercial Environment/International Trade Data System (ABI/ACE/ITDS); or

(2) The FDA PNSI at *https://www.access.fda.gov/*. You must submit prior notice through the FDA Prior Notice System Interface (FDA PNSI) for articles of food imported or offered for import by international mail, and other transaction types that cannot be made through ABI/ACE/ITDS.

(b) If a customhouse broker's or self-filer's system is not working or if the ABI/ACE/ITDS interface is not working, prior notice must be submitted through the FDA PNSI.

(c) If FDA determines that FDA PNSI or the Operational and Administration System for Import Support (OASIS) is not working, FDA will post prominent notification and instructions at *http://www.fda.gov*. FDA will accept prior notice submissions in the format it deems appropriate during the system(s) outage.

[73 FR 66402, Nov. 7, 2008, as amended at 82 FR 15629, Mar. 30, 2017]

§ 1.281 What information must be in a prior notice?

(a) *General*. For each article of food that is imported or offered for import into the United States, except by international mail, you must submit the information for the article that is required in paragraphs (a)(1) through (18) of this section:

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

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

(3) The entry type;

(4) The U.S. Customs and Border Protection (CBP) entry identifier (e.g., CBP entry number or in-bond number), if available;

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

(i) The complete FDA product code;

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

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

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

(6) For an article of food that is no longer in its natural state, the identity of the manufacturer, as follows:

(i) The name of the manufacturer; and

(ii) Either the registration number, city, and country of the manufacturer or both the full address of the manufacturer and the reason the registration number is not provided;

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

(8) The FDA Country of Production;

(9) If the shipper is different from the manufacturer, the identity of the shipper, as follows:

(i) The name of the shipper; and

(ii) The full address of the shipper. If the address of the shipper is a registered facility, you also may submit the registration number of the shipper's registered facility;

(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;

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

(iii) The anticipated time of that arrival; and

(iv) Notwithstanding paragraphs (a)(11) introductory text and (a)(11)(i) through (iii) of this section, if the article of food is arriving by express consignment operator or carrier, the express consignment operator or carrier tracking number may be submitted in lieu of the information required in paragraphs (a)(11) introductory text and (a)(11)(i) through (iii) of this section.

(12) The name and full address of the importer. If the business address of the importer is a registered facility, you also may submit the registration number of the importer's registered facility. The identity of the importer is not required for an article of food that is imported or offered for import for transshipment through the United States under a Transportation and Exportation entry;

(13) The name and full address of the owner if different from the importer or ultimate consignee. If the business address of the owner is a registered facility, you also may submit the registration number of the owner's registered facility. The identity of the owner is not required for an article of food that is imported or offered for import for transshipment through the United States under a Transportation and Exportation entry;

(14) The name and full address of the ultimate consignee. If the business address of the ultimate consignee is a registered facility, you also may submit the registration number of the ultimate consignee's registered facility. The identity of the ultimate consignee is not required for an article of food that is imported or offered for import for transshipment through the United States under a Transportation and Exportation entry;

(15) The mode of transportation;

(16) The Standard Carrier Abbreviation Code (SCAC) or International Air Transportation Association (IATA) code of the carrier which is, or will be, carrying the article of food from the country from which the article is shipped to the United States to the port of arrival, or if this code is not applicable, then the name of the carrier. If the carrier is a privately owned vehicle, the license plate number of the vehicle and the State or Province that issued the license plate number;

(17) Planned shipment information, as applicable to the mode of transportation and when it exists:

(i) The Airway Bill number(s) or Bill of Lading number(s), as applicable. This information is not required for an article of food when carried by or otherwise accompanying an individual when entering the United States. If the article of food is arriving by express consignment operator or carrier, the express consignment operator or carrier tracking number may by submitted in lieu of the Airway Bill number(s) or Bill of Lading number(s), as applicable;

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

(iii) For food arriving by air carrier, the flight number. If the article of food is arriving by express consignment operator or carrier, the express consignment operator or carrier tracking number may be submitted in lieu of 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; and

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

(18) Any country to which the article has been refused entry.

(b) *Articles arriving by international mail.* For each article of food that is imported or offered for import into the United States by international mail, you must submit the information for the article that is required in paragraphs (b)(1) through (12) of this section:

(1) The name of the individual submitting the prior notice and his/her business address, phone number, and e-mail address, and the name and address

of the submitting firm, if applicable. If the business address of the individual submitting the prior notice is a registered facility, then the facility's registration number, city, and country may be provided instead of the facility's full address;

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

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

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

(i) The complete FDA product code;

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

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

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

(5) For an article of food that is no longer in its natural state, the identity of the manufacturer, as follows:

(i) The name of the manufacturer; and

(ii) Either the registration number, city, and country of the manufacturer or both the full address of the manufacturer and the reason the registration number is not provided;

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

(7) The FDA Country of Production;

(8) If the shipper is different from the manufacturer, the identity of the shipper, as follows:

(i) The name of the shipper; and

(ii) The full address of the shipper. If the address of the shipper is a registered facility, you also may submit the registration number of the shipper's registered facility;

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

(10) The anticipated date of mailing; and

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

(12) Any country to which the article has been refused entry.

(c) *Refused articles.* If the article of food has been refused under section 801(m)(1) of the act and under this subpart, you must submit the information for the article that is required in paragraphs (c)(1) through (19) of this section. However, if the refusal is based on § 1.283(a)(1)(iii) (Untimely Prior Notice), you do not have to resubmit any information previously submitted unless it has changed or the article has been exported and the original prior notice was submitted through ABI/ACE/ITDS. If the refusal is based on § 1.283(a)(1)(ii), you should cancel the previous submission per § 1.282(b) and (c).

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

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

(3) The entry type;

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

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

(i) The complete FDA product code;

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

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

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

(6) For an article of food that is no longer in its natural state, the identity of the manufacturer, as follows:

(i) The name of the manufacturer; and

(ii) Either the registration number, city, and country of the manufacturer or both the full address of the manufacturer and the reason the registration number is not provided;

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

(8) The FDA Country of Production;

(9) If the shipper is different from the manufacturer, the identity of the shipper, as follows:

(i) The name of the shipper; and

(ii) The full address of the shipper. If the address of the shipper is a registered facility, you also may submit the registration number of the shipper's registered facility;

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

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

(i) The port of arrival; and

(ii) The date on which the article of food arrived at the port of arrival.

(iii) Notwithstanding paragraphs (c)(11) introductory text and (c)(11)(i) and (ii) of this section, if the article of food arrived by express consignment operator or carrier, the express consignment operator or carrier tracking number may be submitted in lieu of the information required in paragraphs (c)(11) introductory text and (c)(11)(i) and (ii) of this section.

(12) The name and full address of the importer. If the business address of the importer is a registered facility, you also may submit the registration number of the importer's registered facility. The identity of the importer is not required for an article of food that is imported or offered for import for transshipment through the United States under a Transportation and Exportation entry;

(13) The name and full address of the owner, if different from the importer or ultimate consignee. If the business address of the owner is a registered facility, you also may submit the registration number of the importer's registered facility. The identity of the owner is not required for an article of food that is imported or offered for import for transshipment through the United States under a Transportation and Exportation entry;

(14) The name and full address of the ultimate consignee. If the business address of the ultimate consignee is a registered facility, you also may submit the registration number of the ultimate consignee's registered facility. The identity of the ultimate consignee is not required for an article of food that is imported or offered for import for transshipment through the United States under a Transportation and Exportation entry;

(15) The mode of transportation;

(16) The SCAC or IATA code of the carrier which carried the article of food from the country from which the article is shipped to the United States to the port of arrival, or if this code is not applicable, then the name of the carrier. If the carrier is a privately owned vehicle, the license plate number of the vehicle and the State or Province that issued the license plate number;

(17) Shipment information, as applicable to the mode of transportation and when it exists:

(i) The Airway Bill number(s) or Bill of Lading number(s), as applicable; however, this information is not required for an article of food when carried by or otherwise accompanying an individual when entering the United States. If the article of food arrived by express consignment operator or carrier, the express consignment operator or carrier tracking number may be submitted in lieu of the Airway Bill number(s) or Bill of Lading number(s), as applicable;

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

(iii) For food that arrived by air carrier, the flight number. If the article of food arrived by express consignment operator or carrier, the express consignment operator or carrier tracking number may be submitted in lieu of 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; and

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

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

(19) Any country to which the article has been refused entry.

[73 FR 66402, Nov. 7, 2008, as amended at 76 FR 25545, May 5, 2011; 82 FR 15629, Mar. 30, 2017]

§ 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) Section 1.281(a)(5)(iii) (quantity),

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

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

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

(b) If you submitted the prior notice via the FDA PNSI, you should cancel the prior notice via the FDA PNSI.

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

[73 FR 66402, Nov. 7, 2008, as amended at 82 FR 15629, Mar. 30, 2017]

CONSEQUENCES

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

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

(1) *Inadequate prior notice*—(i) *No prior notice.* If an article of food arrives at the port of arrival and no prior notice has been submitted and confirmed by FDA for review, the food is subject to refusal of admission under section 801(m)(1) of the act (21 U.S.C. 381(m)(1)). If an article of food is refused for lack of prior notice, unless U.S. Customs and Border Protection (CBP) concurrence is obtained for export and the article is immediately exported from the port of arrival under CBP supervision, it must be held within the port of entry

for the article unless directed by CBP or FDA.

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

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

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

(ii) Refused food must be moved under appropriate custodial bond unless immediately exported under CBP supervision. If the food is to be held at the port, FDA must be notified of the location where the food is held at that port before the food is moved there. If the food is to be held at a secure facility outside the port, FDA must be notified of the location of the secure facility before the food is moved there. The refused food shall not be entered and shall not be delivered to any importer, owner, or ultimate consignee. If the food is to be held at a secure facility outside a port, the food must be taken directly to that secure facility.

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

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

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

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

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

food held at the port or exported, FDA or CBP may destroy the article of food.

(c) *Post-Refusal prior notice submissions.* (1) If an article of food is refused under paragraph (a)(1)(i) of this section (no prior notice) and the food is not exported, prior notice must be submitted in accordance with §§1.280 and 1.281(c).

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

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

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

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

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

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

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

(e) *International mail.* If an article of food arrives by international mail with inadequate prior notice or the PN confirmation number is not affixed as required, the parcel will be held by CBP for 72 hours for FDA inspection and disposition. If FDA refuses the article under section 801(m)(1) of the act and there is a return address, the parcel may be returned to sender marked ''No Prior Notice—FDA Refused.'' If the article is refused and there is no return address or FDA determines that the article of food in the parcel appears to present a hazard, FDA may dispose of or destroy the parcel at its expense. If FDA does not respond within 72 hours of the CBP hold, CBP may return the parcel to the sender or, if there is no return address, destroy the parcel, at FDA expense.

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

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

(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) of the act does not mean that it will be granted admission under other provisions of the act or other U.S. laws.

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

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

(b) Section 301 of the act 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 sections 301 and 303 of the act (21 U.S.C. 331 and 333), the United States can bring a criminal action in Federal court to prosecute persons who are responsible for the commission of a prohibited act.

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

§ 1.285 What happens to food that is imported or offered for import from unregistered facilities that are required to register under subpart H of this part?

(a) *Consequences.* If an article of food from a foreign facility that is not registered as required under section 415 of the act (21 U.S.C. 350d) and subpart H of this part is imported or offered for import into the United States, the food is subject to being held under section 801(l) of the act (21 U.S.C. 381(l)).

(b) *Hold.* Unless CBP concurrence is obtained for export and the article is immediately exported from the port of arrival, if an article of food has been placed under hold under section 801(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) of the act must be moved under appropriate custodial bond unless immediately exported under CBP supervision. If the food is to be held at the port, FDA must be notified of the location where the food is held at the port before the food is moved there. If the food is to be held at a secure facility outside the port, FDA must be notified of the location of the secure facility before the food is moved there. The food subject to hold shall not be entered and shall not be delivered to any importer, owner, or ultimate consignee. If the food is to be held at a secure facility outside a port, the food must be taken directly to that secure facility.

(d) *Segregation of held foods.* If an article of food that has been placed under hold under section 801(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. 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 number or request for FDA review is submitted in accordance with paragraph (j) of this section or export has not occurred in accordance with paragraph (f) of this section, the food shall be dealt with as set forth in CBP regulations relating to general order merchandise, except that, unless otherwise agreed to by CBP and FDA, the article may only be sold for export or destroyed.

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

(i) *Post-hold submissions.* (1) To resolve a hold, if an article of food is held under paragraph (b) of this section because it is from a foreign facility that is not registered, the facility must be registered and a registration number must be obtained.

(2) The FDA Division of Food Defense Targeting must be notified of the applicable registration number in writing. The notification must provide the name and contact information for the person submitting the information. The notification may be delivered to FDA by fax or e-mail. The contact information for these delivery methods is listed at *http://www.fda.gov*—see Prior Notice. The notification should include the applicable CBP entry identifier.

(3) If FDA determines that the article is no longer subject to hold, it will notify the person who provided the registration information and CBP that the food is no longer subject to hold under section 801(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 carrier, submitter, importer, owner, or ultimate consignee of the article. A request must identify which one the requestor is.

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

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

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

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

(l) *Prohibitions on delivery and transfer.* Notwithstanding section 801(b) of the act, while an article of food is under hold under section 801(l) of the act, it may not be delivered to the importer, owner, or ultimate consignee. If an article of food is no longer subject to hold under section 801(l) of the act,

entry may be made in accordance with law and regulation.

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

[73 FR 66402, Nov. 7, 2008, as amended at 82 FR 15629, Mar. 30, 2017]

Subpart J—Establishment, Maintenance, and Availability of Records

SOURCE: 69 FR 71651, Dec. 9, 2004, unless otherwise noted.

GENERAL PROVISIONS

§ 1.326 Who is subject to this subpart?

(a) Persons who manufacture, process, pack, transport, distribute, receive, hold, or import food in the United States are subject to the regulations in this subpart, unless you qualify for one of the exclusions in § 1.327. If you conduct more than one type of activity at a location, you are required to keep records with respect to those activities covered by this subpart, but are not required by this subpart to keep records with respect to activities that fall within one of the exclusions in § 1.327.

(b) Persons subject to the regulations in this subpart must keep records whether or not the food is being offered for or enters interstate commerce.

§ 1.327 Who is excluded from all or part of the regulations in this subpart?

(a) Farms are excluded from all of the requirements in this subpart.

(b) Restaurants are excluded from all of the requirements in this subpart. A restaurant/retail facility is excluded from all of the requirements in this subpart if its sales of food it prepares and sells to consumers for immediate consumption are more than 90 percent of its total food sales.

(c) 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, are excluded from all of the requirements in this subpart, except §§ 1.361 and 1.363. However, those fishing vessels otherwise engaged in processing fish are subject to all of the requirements in 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.

(d) Persons who distribute food directly to consumers are excluded from the requirements in § 1.345 to establish and maintain records to identify the nontransporter and transporter immediate subsequent recipients as to those transactions. The term ''consumers'' does not include businesses.

(e) Persons who operate retail food establishments that distribute food to persons who are not consumers are subject to all of the requirements in this subpart. However, the requirements in § 1.345 to establish and maintain records to identify the nontransporter and transporter immediate subsequent recipients that are not consumers applies as to those transactions only to the extent the information is reasonably available.

(1) For purposes of this section, retail food establishment is defined to mean an establishment that sells food products directly to consumers as its primary function. The term ''consumers'' does not include businesses.

(2) 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.

(3) 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.

(4) A ''retail food establishment'' includes grocery stores, convenience stores, and vending machine locations.

(f) Retail food establishments that employ 10 or fewer full-time equivalent employees are excluded from all of the requirements in this subpart, except §§ 1.361 and 1.363. The exclusion is based on the number of full-time equivalent employees at each retail food establishment and not the entire business, which may own numerous retail stores.

(g) Persons who manufacture, process, pack, transport, distribute, receive, hold, or import food in the United States that is within the exclusive jurisdiction of the U.S. Department of Agriculture (USDA) under the Federal Meat Inspection Act (21 U.S.C. 601 *et seq.*), the Poultry Products Inspection Act (21 U.S.C. 451 *et seq.*), or the Egg Products Inspection Act (21 U.S.C. 1031 *et seq.*) are excluded from all of the requirements in this subpart with respect to that food while it is under the exclusive jurisdiction of USDA.

(h) Foreign persons, except for foreign persons who transport food in the United States, are excluded from all of the requirements of this subpart.

(i) Persons who manufacture, process, pack, transport, distribute, receive, hold, or import food are subject to §§ 1.361 and 1.363 with respect to its packaging (the outer packaging of food that bears the label and does not contact the food). All other persons who manufacture, process, pack, transport, distribute, receive, hold, or import packaging are excluded from all of the requirements of this subpart.

(j) Persons who manufacture, process, pack, transport, distribute, receive, hold, or import food contact substances other than the finished container that directly contacts food are excluded from all of the requirements of this subpart, except §§ 1.361 and 1.363.

(k) Persons who place food directly in contact with its finished container are subject to all of the requirements of this subpart as to the finished container that directly contacts that food. All other persons who manufacture, process, pack, transport, distribute, receive, hold, or import the finished container that directly contacts the food are excluded from the requirements of this subpart as to the finished container, except §§ 1.361 and 1.363.

(l) Nonprofit food establishments are excluded from all of the requirements in this subpart, except §§ 1.361 and 1.363.

(m) Persons who manufacture, process, pack, transport, distribute, receive, hold, or import food for personal consumption are excluded from all of the requirements of this subpart.

(n) Persons who receive or hold food on behalf of specific individual consumers and who are not also parties to the transaction and who are not in the business of distributing food are excluded from all of the requirements of this subpart.

§ 1.328 What definitions apply to this subpart?

The definitions of terms in section 201 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321) apply to such terms when used in this subpart. In addition, for the purposes of this subpart:

Farm means:

(1) *Primary production farm.* A primary production farm is an operation under one management in one general (but not necessarily contiguous) physical location devoted to the growing of crops, the harvesting of crops, the raising of animals (including seafood), or any combination of these activities. The term ''farm'' includes operations that, in addition to these activities:

(i) Pack or hold raw agricultural commodities;

(ii) Pack or hold processed food, provided that all processed food used in such activities is either consumed on that farm or another farm under the same management, or is processed food identified in paragraph (1)(iii)(B)(*1*) of this definition; and

(iii) Manufacture/process food, provided that:

(A) All food used in such activities is consumed on that farm or another farm under the same management; or

(B) Any manufacturing/processing of food that is not consumed on that farm or another farm under the same management consists only of:

(*1*) Drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins), and packaging and labeling such commodities, without additional manufacturing/processing (an example of additional manufacturing/processing is slicing);

(*2*) Treatment to manipulate the ripening of raw agricultural commodities (such as by treating produce with ethylene gas), and packaging and labeling treated raw agricultural commodities, without additional manufacturing/processing; and

(*3*) Packaging and labeling raw agricultural commodities, when these activities do not involve additional manufacturing/processing (an example of additional manufacturing/processing is irradiation); or

(2) *Secondary activities farm.* A secondary activities farm is an operation, not located on a primary production farm, devoted to harvesting (such as hulling or shelling), packing, and/or holding of raw agricultural commodities, provided that the primary production farm(s) that grows, harvests, and/or raises the majority of the raw agricultural commodities harvested, packed, and/or held by the secondary activities farm owns, or jointly owns, a majority interest in the secondary activities farm. A secondary activities farm may also conduct those additional activities allowed on a primary production farm as described in paragraphs (1)(ii) and (iii) of this definition.

Food has the meaning given in section 201(f) of the Federal Food, Drug, and Cosmetic Act. Examples of food include, but are not limited to 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 and additives, including substances that migrate into food from the finished container and other articles that contact food; dietary supplements and dietary ingredients; infant formula; beverages, including alcoholic beverages and bottled water; live food animals; bakery goods; snack foods; candy; and canned foods.

Full-time equivalent employee means all individuals employed by the person claiming the exemption. The number of full-time equivalent employees is determined by dividing the total number of hours of salary or wages paid directly to employees of the person and of all of its affiliates by the number of hours of work in 1 year, 2,080 hours (i.e., 40 hours × 52 weeks).

Harvesting applies to farms and farm mixed-type facilities and means activities that are traditionally performed on farms for the purpose of removing raw agricultural commodities from the place they were grown or raised and preparing them for use as food. Harvesting is limited to activities performed on raw agricultural commodities, or on processed foods created by drying/dehydrating a raw agricultural commodity without additional manufacturing/processing, on a farm. Harvesting does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act. Examples of harvesting include cutting (or otherwise separating) the edible portion of the raw agricultural commodity from the crop plant and removing or trimming part of the raw agricultural commodity (*e.g.*, foliage, husks, roots, or stems). Examples of harvesting also include cooling, field coring, filtering, gathering, hulling, shelling, sifting, threshing, trimming of outer leaves of, and washing raw agricultural commodities grown on a farm.

Holding means storage of food and also includes activities performed incidental to storage of a food (*e.g.*, activities performed for the safe or effective storage of that food, such as fumigating food during storage, and drying/dehydrating raw agricultural commodities when the drying/dehydrating does not create a distinct commodity (such as drying/dehydrating hay or alfalfa)). Holding also includes activities performed as a practical necessity for the distribution of that food (such as blending of the same raw agricultural commodity and breaking down pallets), but does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act. Holding facilities could include warehouses, cold

storage facilities, storage silos, grain elevators, and liquid storage tanks.

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 include: Baking, boiling, bottling, canning, cooking, cooling, cutting, distilling, drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins), evaporating, eviscerating, extracting juice, formulating, freezing, grinding, homogenizing, irradiating, labeling, milling, mixing, packaging (including modified atmosphere packaging), pasteurizing, peeling, rendering, treating to manipulate ripening, trimming, washing, or waxing. For farms and farm mixed-type facilities, manufacturing/processing does not include activities that are part of harvesting, packing, or holding.

Mixed-type facility means an establishment that engages in both activities that are exempt from registration under section 415 of the Federal Food, Drug, and Cosmetic Act and activities that require the establishment to be registered. An example of such a facility is a ''farm mixed-type facility,'' which is an establishment that is a farm, but also conducts activities outside the farm definition that require the establishment to be registered.

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 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)).

Nontransporter means a person who owns food or who holds, manufactures, processes, packs, imports, receives, or distributes food for purposes other than transportation.

Nontransporter immediate previous source means a person that last had food before transferring it to another nontransporter.

Nontransporter immediate subsequent recipient means a nontransporter that acquires food from another nontransporter.

Packaging (when used as a noun) means the outer packaging of food that bears the label and does not contact the food. Packaging does not include food contact substances as they are defined in section 409(h)(6) of the Federal Food, Drug, and Cosmetic Act.

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

Packing means placing food into a container other than packaging the food and also includes re-packing and activities performed incidental to packing or re-packing a food (*e.g.*, activities performed for the safe or effective packing or re-packing of that food (such as sorting, culling, grading, and weighing or conveying incidental to packing or re-packing)), but does not include activities that transform a raw agricultural commodity, as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act, into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act.

Person includes individual, partnership, corporation, and association.

Recipe means the formula, including ingredients, quantities, and instructions, necessary to manufacture a food product. Because a recipe must have all three elements, a list of the ingredients used to manufacture a product without quantity information and manufacturing instructions is not a recipe.

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.

(1) Facilities in which food is directly 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.

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

Transporter means a person who has possession, custody, or control of an article of food in the United States for the sole purpose of transporting the food, whether by road, rail, water, or air. Transporter also includes a foreign person that transports food in the United States, regardless of whether that foreign person has possession, custody, or control of that food for the sole purpose of transporting that food.

Transporter's immediate previous source means a person from whom a transporter received food. This source can be either another transporter or a nontransporter.

Transporter's immediate subsequent recipient means a person to whom a transporter delivered food. This recipient can be either another transporter or a nontransporter.

You means a person subject to this subpart under § 1.326.

[69 FR 71651, Dec. 9, 2004, as amended at 80 FR 56143, Sept. 17, 2015; 81 FR 3715, Jan. 22, 2016]

§ 1.329 Do other statutory provisions and regulations apply?

(a) In addition to the regulations in this subpart, you must comply with all other applicable statutory provisions and regulations related to the establishment and maintenance of records for foods except as described in paragraph (b) of this section. For example, the regulations in this subpart are in addition to existing recordkeeping regulations for low acid canned foods, juice, seafood, infant formula, color additives, bottled water, animal feed, and medicated animal feed.

(b) Records established or maintained to satisfy the requirements of this subpart that meet the definition of electronic records in § 11.3(b)(6) (21 CFR 11.3 (b)(6)) of this chapter are exempt from the requirements of part 11 of this chapter. Records that satisfy the requirements of this subpart but that are also required under other applicable statutory provisions or regulations remain subject to part 11 of this chapter.

§ 1.330 Can existing records satisfy the requirements of this subpart?

The regulations in this subpart do not require duplication of existing records if those records contain all of the information required by this subpart. If a covered person keeps records of all of the information as required by this subpart to comply with other Federal, State, or local regulations, or for any other reason, then those records may be used to meet these requirements. Moreover, persons do not have to keep all of the information required by this rule in one set of records. If they have records containing some of the required information, they may keep those existing records and keep, either separately or in a combined form, any new information required by this rule. There is no obligation to create an entirely new record or compilation of records containing both existing and new information, even if the records containing some of the required information were not created at the time the food was received or released.

Requirements for Nontransporters To Establish and Maintain Records To Identify the Nontransporter and Transporter Immediate Previous Sources of Food

§ 1.337 What information must nontransporters establish and maintain to identify the nontransporter and transporter immediate previous sources of food?

(a) If you are a nontransporter, you must establish and maintain the following records for all food you receive:

(1) The name of the firm, address, telephone number and, if available, the fax number and e-mail address of the nontransporter immediate previous source, whether domestic or foreign;

(2) An adequate description of the type of food received, to include brand name and specific variety (e.g., brand x cheddar cheese, not just cheese; or romaine lettuce, not just lettuce);

(3) The date you received the food;

(4) For persons who manufacture, process, or pack food, the lot or code number or other identifier of the food (to the extent this information exists);

(5) The quantity and how the food is packaged (e.g., 6 count bunches, 25 pound (lb) carton, 12 ounce (oz) bottle, 100 gallon (gal) tank); and

(6) The name of the firm, address, telephone number, and, if available, the fax number and e-mail address of the transporter immediate previous source (the transporter who transported the food to you).

REQUIREMENTS FOR NONTRANSPORTERS TO ESTABLISH AND MAINTAIN RECORDS TO IDENTIFY THE NONTRANSPORTER AND TRANSPORTER IMMEDIATE SUBSEQUENT RECIPIENTS OF FOOD

§ 1.345 What information must nontransporters establish and maintain to identify the nontransporter and transporter immediate subsequent recipients of food?

(a) If you are a nontransporter, you must establish and maintain the following records for food you release:

(1) The name of the firm, address, telephone number, and, if available, the fax number and e-mail address of the nontransporter immediate subsequent recipient, whether domestic or foreign;

(2) An adequate description of the type of food released, to include brand name and specific variety (e.g., brand x cheddar cheese, not just cheese; or romaine lettuce, not just lettuce);

(3) The date you released the food;

(4) For persons who manufacture, process, or pack food, the lot or code number or other identifier of the food (to the extent this information exists);

(5) The quantity and how the food is packaged (e.g., 6 count bunches, 25 lb carton, 12 oz bottle, 100 gal tank);

(6) The name of the firm, address, telephone number, and, if available, the fax number and e-mail address of the transporter immediate subsequent recipient (the transporter who transported the food from you); and

(b) Your records must include information reasonably available to you to identify the specific source of each ingredient used to make every lot of finished product.

REQUIREMENTS FOR TRANSPORTERS TO ESTABLISH AND MAINTAIN RECORDS

§ 1.352 What information must transporters establish and maintain?

If you are a transporter, you must establish and maintain the following records for each food you transport in the United States. You may fulfill this requirement by either:

(a) Establishing and maintaining the following records:

(1) Names of the transporter's immediate previous source and transporter's immediate subsequent recipient;

(2) Origin and destination points;

(3) Date shipment received and date released;

(4) Number of packages;

(5) Description of freight;

(6) Route of movement during the time you transported the food; and

(7) Transfer point(s) through which shipment moved; or

(b) Establishing and maintaining records containing the following information currently required by the Department of Transportation's Federal Motor Carrier Safety Administration (of roadway interstate transporters (49 CFR 373.101 and 373.103) as of December 9, 2004:

(1) Names of consignor and consignee;

(2) Origin and destination points;

(3) Date of shipment;

(4) Number of packages;

(5) Description of freight;

(6) Route of movement and name of each carrier participating in the transportation; and

(7) Transfer points through which shipment moved; or

(c) Establishing and maintaining records containing the following information currently required by the Department of Transportation's Surface Transportation Board of rail and water interstate transporters (49 CFR 1035.1 and 1035.2) as of December 9, 2004:

(1) Date received;

(2) Received from;

(3) Consigned to;

(4) Destination;

(5) State of;

(6) County of;

(7) Route;

(8) Delivering carrier;

(9) Car initial;

(10) Car no;

(11) Trailer initials/number;
(12) Container initials/number;
(13) No. packages; and
(14) Description of articles; or

(d) Establishing and maintaining records containing the following information currently required by the Warsaw Convention of international air transporters on air waybills:

(1) Shipper's name and address;
(2) Consignee's name and address;
(3) Customs reference/status;
(4) Airport of departure and destination;
(5) First carrier; and
(6) Description of goods; or

(e) Entering into an agreement with the nontransporter immediate previous source located in the United States and/or the nontransporter immediate subsequent recipient located in the United States to establish, maintain, or establish and maintain, the information in § 1.352(a), (b), (c), or (d). The agreement must contain the following elements:

(1) Effective date;
(2) Printed names and signatures of authorized officials;
(3) Description of the records to be established and/or maintained;
(4) Provision for the records to be maintained in compliance with § 1.360, if the agreement provides for maintenance of records;
(5) Provision for the records to be available to FDA as required by § 1.361, if the agreement provides for maintenance of records;
(6) Acknowledgement that the nontransporter assumes legal responsibility under § 1.363 for establishing and/or maintaining the records as required by this subpart; and
(7) Provision that if the agreement is terminated in writing by either party, responsibility for compliance with the applicable establishment, maintenance, and access provisions of this subpart reverts to the transporter as of the date of termination.

GENERAL REQUIREMENTS

§ 1.360 What are the record retention requirements?

(a) You must create the required records when you receive and release food, except to the extent that the information is contained in existing records.

(b) If you are a nontransporter, you must retain for 6 months after the dates you receive and release the food all required records for any food having a significant risk of spoilage, loss of value, or loss of palatability within 60 days after the date you receive or release the food.

(c) If you are a nontransporter, you must retain for 1 year after the dates you receive and release the food all required records for any food for which a significant risk of spoilage, loss of value, or loss of palatability occurs only after a minimum of 60 days, but within 6 months, after the date you receive or release the food.

(d) If you are a nontransporter, you must retain for 2 years after the dates you receive and release the food all required records for any food for which a significant risk of spoilage, loss of value, or loss of palatability does not occur sooner than 6 months after the date you receive or release the food, including foods preserved by freezing, dehydrating, or being placed in a hermetically sealed container.

(e) If you are a nontransporter, you must retain for 1 year after the dates you receive and release the food all required records for animal food, including pet food.

(f) If you are a transporter or nontransporter retaining records on behalf of a transporter, you must retain for 6 months after the dates you receive and release the food all required records for any food having a significant risk of spoilage, loss of value, or loss of palatability within 60 days after the date the transporter receives or releases the food. If you are a transporter, or nontransporter retaining records on behalf of a transporter, you must retain for 1 year after the dates you receive and release the food, all required records for any food for which a significant risk of spoilage, loss of value, or loss of palatability occurs only after a minimum of 60 days after the date the transporter receives or releases the food.

(g) You must retain all records at the establishment where the covered activities described in the records occurred (onsite) or at a reasonably accessible location.

(h) The maintenance of electronic records is acceptable. Electronic records are considered to be onsite if they are accessible from an onsite location.

§ 1.361 What are the record availability requirements?

When FDA has a reasonable belief that an article of food, and any other article of food that FDA reasonably believes is likely to be affected in a similar manner, is adulterated and presents a threat of serious adverse health consequences or death to humans or animals, or when FDA believes that there is a reasonable probability that the use of or exposure to an article of food, and any other article of food that FDA reasonably believes is likely to be affected in a similar manner, will cause serious adverse health consequences or death to humans or animals, any records and other information accessible to FDA under section 414 or 704(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350c and 374(a)) must be made readily available for inspection and photocopying or other means of reproduction. Such records and other information must be made available as soon as possible, not to exceed 24 hours from the time of receipt of the official request, from an officer or employee duly designated by the Secretary of Health and Human Services who presents appropriate credentials and a written notice.

[77 FR 10662, Feb. 23, 2012]

§ 1.362 What records are excluded from this subpart?

The establishment and maintenance of records as required by this subpart does not extend to recipes for food as defined in § 1.328; financial data, pricing data, personnel data, research data, or sales data (other than shipment data regarding sales).

§ 1.363 What are the consequences of failing to establish or maintain records or make them available to FDA as required by this subpart?

(a) The failure to establish or maintain records as required by section 414(b) of the Federal Food, Drug, and Cosmetic Act and this regulation or the refusal to permit access to or verification or copying of any such required record is a prohibited act under section 301 of the Federal Food, Drug, and Cosmetic Act.

(b) The failure of a nontransporter immediate previous source or a nontransporter immediate subsequent recipient who enters an agreement under § 1.352(e) to establish, maintain, or establish and maintain, records required under § 1.352(a), (b), (c), or (d), or the refusal to permit access to or verification or copying of any such required record, is a prohibited act under section 301 of the Federal Food, Drug, and Cosmetic Act.

(c) The failure of any person to make records or other information available to FDA as required by section 414 or 704(a) of the Federal Food, Drug, and Cosmetic Act and this regulation is a prohibited act under section 301 of the Federal Food, Drug, and Cosmetic Act.

[80 FR 56144, Sept. 17, 2015

COMPLIANCE DATES

§ 1.368 What are the compliance dates for this subpart?

The compliance date for the requirements in this subpart is December 9, 2005. However, the compliance dates for small and very small businesses are contained in paragraphs (a) and (b) of this section. The size of the business is determined using the total number of full-time equivalent employees in the entire business, not each individual location or establishment. A full-time employee counts as one full-time equivalent employee. Two part-time employees, each working half time, count as one full-time equivalent employee.

(a) The compliance date for the requirements in this subpart is June 9, 2006, for small businesses employing fewer that 500, but more than 10 full-time equivalent employees.

(b) The compliance date for the requirements in this subpart is December 11, 2006, for very small businesses that employ 10 or fewer full-time equivalent employees.

[69 FR 71651, Dec. 9, 2004, as amended at 70 FR 8727, Feb. 23, 2005]

Subpart K—Administrative Detention of Food for Human or Animal Consumption

SOURCE: 69 FR 31701, June 4, 2004, unless otherwise noted.

GENERAL PROVISIONS

§ 1.377 What definitions apply to this subpart?

The definitions of terms that appear in section 201 of the act (21 U.S.C. 321) apply when the terms are used in this subpart. In addition, for the purposes of this subpart:

Act means the Federal Food, Drug, and Cosmetic Act.

Authorized FDA representative means an FDA Division Director in whose division the article of food involved is located or an FDA official senior to such director.

Calendar day means every day shown on the calendar.

Food has the meaning given in section 201(f) of the act (21 U.S.C. 321(f)). Examples of food include, but are not limited to, fruits, vegetables, fish, dairy products, eggs, raw agricultural commodities for use as food or components of food, animal feed, including pet food, food and feed ingredients and additives, including substances that migrate into food from food packaging and other articles that contact food, dietary supplements and dietary ingredients, infant formula, beverages, including alcoholic beverages and bottled water, live food animals, bakery goods, snack foods, candy, and canned foods.

Perishable food means food that is not heat-treated; not frozen; and not otherwise preserved in a manner so as to prevent the quality of the food from being adversely affected if held longer than 7 calendar days under normal shipping and storage conditions.

We means the U.S. Food and Drug Administration (FDA).

Working day means any day from Monday through Friday, excluding Federal holidays.

You means any person who received the detention order or that person's representative.

[69 FR 31701, June 4, 2004, as amended at 85 FR 16550, Mar. 24, 2020]

§ 1.378 What criteria does FDA use to order a detention?

An officer or qualified employee of FDA may order the detention of any article of food that is found during an inspection, examination, or investigation under the act if the officer or qualified employee has reason to believe that the article of food is adulterated or misbranded.

[76 FR 25541, May 5, 2011]

§ 1.379 How long may FDA detain an article of food?

(a) FDA may detain an article of food for a reasonable period that may not exceed 20 calendar days after the detention order is issued. However, an article may be detained for 10 additional calendar days if a greater period of time is required to institute a seizure or injunction action. The authorized FDA representative may approve the additional 10-calendar day detention period at the time the detention order is issued, or at any time within the 20-calendar day period by amending the detention order.

(b) The entire detention period may not exceed 30 calendar days.

(c) An authorized FDA representative may, in accordance with § 1.384, terminate a detention order before the expiration of the detention period.

§ 1.380 Where and under what conditions must the detained article of food be held?

(a) You must hold the detained article of food in the location and under the conditions specified by FDA in the detention order.

(b) If FDA determines that removal to a secure facility is appropriate, the article of food must be removed to a secure facility. A detained article of food remains under detention before, during, and after movement to a secure facility. FDA will also state in the detention order any conditions of transportation applicable to the detained article.

(c) If FDA directs you to move the detained article of food to a secure facility, you must receive a modification of the detention order under § 1.381(c) before you move the detained article of food to a secure facility.

(d) You must ensure that any required tags or labels under § 1.382 accompany the detained article during and after movement. The tags or labels must remain with the article of food until FDA terminates the detention order or the detention period expires, whichever occurs first, unless otherwise permitted by the authorized FDA representative.

(e) The movement of an article of food in violation of a detention order issued under § 1.393 is a prohibited act under section 301 of the act (21 U.S.C. 331).

§ 1.381 May a detained article of food be delivered to another entity or transferred to another location?

(a) An article of food subject to a detention order under this subpart may not be delivered under the execution of a bond. Notwithstanding section 801(b) of the act (21 U.S.C. 381(b)), while any article of food is subject to a detention order under section 304(h) of the act (21 U.S.C. 334(h)), it may not be delivered to any of its importers, owners, or consignees. This section does not preclude movement at FDA's direction of imported food to a secure facility under an appropriate Customs' bond when that bond is required by Customs' law and regulation.

(b) Except as provided in paragraph (c) of this section, no person may transfer a detained article of food within or from the place where it has been ordered detained, or from the place to which it was removed, until an authorized FDA representative releases the article of food under § 1.384 or the detention period expires under § 1.379, whichever occurs first.

(c) The authorized FDA representative may approve, in writing, a request to modify a detention order to permit movement of a detained article of food for any of the following purposes:

(1) To destroy the article of food,

(2) To move the detained article of food to a secure facility under the terms of a detention order,

(3) To maintain or preserve the integrity or quality of the article of food, or

(4) For any other purpose that the authorized FDA representative believes is appropriate in the case.

(d) You must submit your request for modification of the detention order in writing to the authorized FDA representative who approved the detention order. You must state in your request the reasons for movement; the exact address of and location in the new facility (or the new location within the same facility) where the detained article of food will be transferred; an explanation of how the new address and location will be secure, if FDA has directed that the article be detained in a secure facility; and how the article will be held under any applicable conditions described in the detention order. If you are requesting modification of a detention order for the purpose of destroying the detained article of food, you also must submit a verified statement identifying the ownership or proprietary interest you have in the detained article of food, in accordance with Supplemental Rule C to the ''Federal Rules of Civil Procedure.''

(e) If FDA approves a request for modification of a detention order, the article may be transferred but remains under detention before, during, and after the transfer. FDA will state any conditions of transportation applicable to the detained article. You may not transfer a detained article of food without FDA supervision unless FDA has declined in writing to supervise the transfer. If FDA has declined in writing to supervise the transfer of a detained article, you must immediately notify in writing the authorized FDA representative who approved the modification of the detention order that the article of food has reached its new location, and the specific location of the detained article within the new location. Such written notification may be in the form of a fax, e-mail, or other form as agreed to by the authorized FDA representative.

(f) You must ensure that any required tags or labels under § 1.382 accompany the detained article during and after movement. The tags or labels must remain with the article of food until FDA terminates the detention order or the detention period expires, whichever occurs first, unless otherwise permitted by the authorized FDA

representative who approves the modification of a detention order under this section.

(g) The transfer of an article of food in violation of a detention order issued under § 1.393 is a prohibited act under section 301 of the act.

§ 1.382 What labeling or marking requirements apply to a detained article of food?

The officer or qualified employee of FDA issuing a detention order under § 1.393 may label or mark the detained article of food with official FDA tags or labels that include the following information:

(a) A statement that the article of food is detained by FDA in accordance with section 304(h) of the act;

(b) A statement that the article of food must not be consumed, moved, altered, or tampered with in any manner for the period shown, without the written permission of an authorized FDA representative;

(c) A statement that the violation of a detention order or the removal or alteration of the tag or label is a prohibited act, punishable by fine or imprisonment or both; and

(d) The detention order number, the date and hour of the detention order, the detention period, and the name of the officer or qualified employee of FDA who issued the detention order.

§ 1.383 What expedited procedures apply when FDA initiates a seizure action against a detained perishable food?

If FDA initiates a seizure action under section 304(a) of the act against a perishable food subject to a detention order under this subpart, FDA will send the seizure recommendation to the Department of Justice (DOJ) within 4 calendar days after the detention order is issued, unless extenuating circumstances exist. If the fourth calendar day is not a working day, FDA will advise the DOJ of its plans to recommend a seizure action on the last working day before the fourth calendar day and send the recommendation as soon as practicable on the first working day that follows. For purposes of this section, an extenuating circumstance includes, but is not limited to, instances when the results of confirmatory testing or other evidentiary development requires more than 4 calendar days to complete.

§ 1.384 When does a detention order terminate?

If FDA terminates a detention order or the detention period expires, an authorized FDA representative will issue a detention termination notice releasing the article of food to any person who received the detention order or that person's representative and will remove, or authorize in writing the removal of, the required labels or tags. If FDA fails to issue a detention termination notice and the detention period expires, the detention is deemed to be terminated.

How Does FDA Order a Detention?

§ 1.391 Who approves a detention order?

An authorized FDA representative must approve a detention order. If prior written approval is not feasible, prior oral approval must be obtained and confirmed in writing as soon as possible.

[69 FR 31701, June 4, 2004, as amended at 85 FR 16550, Mar. 24, 2020]

§ 1.392 Who receives a copy of the detention order?

(a) FDA must issue the detention order to the owner, operator, or agent in charge of the place where the article of food is located. If the owner of the article of food is different from the owner, operator, or agent in charge of the place where the article is detained, FDA must provide a copy of the detention order to the owner of the article of food if the owner's identity can be determined readily.

(b) If FDA issues a detention order for an article of food located in a vehicle or other carrier used to transport the detained article of food, FDA also must provide a copy of the detention order to the shipper of record and the owner and operator of the vehicle or other carrier, if their identities can be determined readily.

§ 1.393 What information must FDA include in the detention order?

(a) FDA must issue the detention order in writing, in the form of a detention notice, signed and dated by the officer or qualified employee of FDA who has reason to believe that such article of food is adulterated or misbranded.

(b) The detention order must include the following information:

(1) The detention order number;

(2) The date and hour of the detention order;

(3) Identification of the detained article of food;

(4) The period of the detention;

(5) A statement that the article of food identified in the order is detained for the period shown;

(6) A brief, general statement of the reasons for the detention;

(7) The address and location where the article of food is to be detained and the appropriate storage conditions;

(8) Any applicable conditions of transportation of the detained article of food;

(9) A statement that the article of food is not to be consumed, moved, altered, or tampered with in any manner during the detention period, unless the detention order is first modified under § 1.381(c);

(10) The text of section 304(h) of the act and §§ 1.401 and 1.402;

(11) A statement that any informal hearing on an appeal of a detention order must be conducted as a regulatory hearing under part 16 of this chapter, with certain exceptions described in § 1.403;

(12) The mailing address, telephone number, email address, fax number, and the name of the FDA Division Director in whose division the detained article of food is located;

(13) A statement indicating the manner in which approval of the detention order was obtained, *i.e.*, verbally or in writing; and

(14) The name and the title of the authorized FDA representative who approved the detention order.

[69 FR 31701, June 4, 2004, as amended at 76 FR 25541, May 5, 2011; 85 FR 16550, Mar. 24, 2020]

WHAT IS THE APPEAL PROCESS FOR A DETENTION ORDER?

§ 1.401 Who is entitled to appeal?

Any person who would be entitled to be a claimant for the article of food, if seized under section 304(a) of the act, may appeal a detention order as specified in § 1.402. Procedures for establishing entitlement to be a claimant for purposes of section 304(a) of the act are governed by Supplemental Rule C to the ''Federal Rules of Civil Procedure.''

§ 1.402 What are the requirements for submitting an appeal?

(a) If you want to appeal a detention order, you must submit your appeal in writing to the FDA Division Director in whose division the detained article of food is located, at the mailing address, email address, or fax number identified in the detention order according to the following applicable timeframes:

(1) *Perishable food:* If the detained article is a perishable food, as defined in § 1.377, you must file an appeal within 2 calendar days of receipt of the detention order.

(2) *Nonperishable food:* If the detained article is not a perishable food, as defined in § 1.377, you must file a notice of an intent to request a hearing within 4 calendar days of receipt of the detention order. If the notice of intent is not filed within 4 calendar days, you will not be granted a hearing. If you have not filed a timely notice of intent to request a hearing, you may file an appeal without a hearing request. Whether or not it includes a request for hearing, your appeal must be filed within 10 calendar days of receipt of the detention order.

(b) Your request for appeal must include a verified statement identifying your ownership or proprietary interest in the detained article of food, in accordance with Supplemental Rule C to the ''Federal Rules of Civil Procedure.''

(c) The process for the appeal of a detention order under this section terminates if FDA institutes either a seizure action under section 304(a) of the act or an injunction under section 302 of the act (21 U.S.C. 276) regarding the article of food involved in the detention order.

(d) As part of the appeals process, you may request an informal hearing. Your request for a hearing must be in writing and must be included in your request for an appeal specified in paragraph (a) of this section. If you request an informal hearing, and FDA grants your request, the hearing will be held within 2 calendar days after the date the appeal is filed.

[69 FR 31701, June 4, 2004, as amended at 85 FR 16550, Mar. 24, 2020]

§ 1.403 What requirements apply to an informal hearing?

If FDA grants a request for an informal hearing on an appeal of a detention order, FDA must conduct the hearing in accordance with part 16 of this chapter, except that:

(a) The detention order under § 1.393, rather than the notice under § 16.22(a) of this chapter, provides notice of opportunity for a hearing under this section and is part of the administrative record of the regulatory hearing under § 16.80(a) of this chapter;

(b) A request for a hearing under this section must be addressed to the FDA Division Director in whose division the article of food involved is located;

(c) The provision in § 16.22(b) of this chapter, providing that a person not be given less than 3 working days after receipt of notice to request a hearing, does not apply to a hearing under this subpart;

(d) The provision in § 16.24(e) of this chapter, stating that a hearing may not be required to be held at a time less than 2 working days after receipt of the request for a hearing, does not apply to a hearing under this subpart;

(e) Section 1.406, rather than § 16.24(f) of this chapter, describes the statement that will be provided to an appellant where a detention order is based on classified information;

(f) Section 1.404, rather than § 16.42(a) of this chapter, describes the FDA employees who preside at hearings under this subpart;

(g) The presiding officer may require that a hearing conducted under this section be completed within 1 calendar day, as appropriate;

(h) Section 16.60(e) and (f) of this chapter does not apply to a hearing under this subpart. The presiding officer must prepare a written report of the hearing. All written material presented at the hearing will be attached to the report. The presiding officer must include as part of the report of the hearing a finding on the credibility of witnesses (other than expert witnesses) whenever credibility is a material issue, and must include a proposed decision, with a statement of reasons. The hearing participant may review and comment on the presiding officer's report within 4 hours of issuance of the report. The presiding officer will then issue the final agency decision.

(i) Section 16.80(a)(4) of this chapter does not apply to a regulatory hearing under this subpart. The presiding officer's report of the hearing and any comments on the report by the hearing participant under § 1.403(h) are part of the administrative record.

(j) No party shall have the right, under § 16.119 of this chapter to petition the Commissioner of Food and Drugs for reconsideration or a stay of the presiding officer's final agency decision.

(k) If FDA grants a request for an informal hearing on an appeal of a detention order, the hearing must be conducted as a regulatory hearing pursuant to regulation in accordance with part 16 of this chapter, except that § 16.95(b) does not apply to a hearing under this subpart. With respect to a regulatory hearing under this subpart, the administrative record of the hearing specified in §§ 16.80(a)(1), (a)(2), (a)(3), and (a)(5), and 1.403(i) constitutes the exclusive record for the presiding officer's final decision on an administrative detention. For purposes of judicial review under § 10.45 of this chapter, the record of the administrative proceeding consists of the record of the hearing and the presiding officer's final decision.

[69 FR 31701, June 4, 2004, as amended at 82 FR 14144, Mar. 17, 2017; 85 FR 16550, Mar. 24, 2020]

§ 1.404 Who serves as the presiding officer for an appeal and for an informal hearing?

The presiding officer for an appeal, and for an informal hearing, must be

an Office of Regulatory Affairs Program Director or another FDA official senior to an FDA Division Director.

[85 FR 16550, Mar. 24, 2020]

§ 1.405 When does FDA have to issue a decision on an appeal?

(a) The presiding officer must issue a written report that includes a proposed decision confirming or revoking the detention by noon on the fifth calendar day after the appeal is filed; after your 4 hour opportunity for submitting comments under § 1.403(h), the presiding officer must issue a final decision within the 5-calendar day period after the appeal is filed. If FDA either fails to provide you with an opportunity to request an informal hearing, or fails to confirm or terminate the detention order within the 5-calendar day period, the detention order is deemed terminated.

(b) If you appeal the detention order, but do not request an informal hearing, the presiding officer must issue a decision on the appeal confirming or revoking the detention within 5 calendar days after the date the appeal is filed. If the presiding officer fails to confirm or terminate the detention order during such 5-calendar day period, the detention order is deemed terminated.

(c) If you appeal the detention order and request an informal hearing and your hearing request is denied, the presiding officer must issue a decision on the appeal confirming or revoking the detention within 5 calendar days after the date the appeal is filed. If the presiding officer fails to confirm or terminate the detention order during such 5-calendar day period, the detention order is deemed terminated.

(d) If the presiding officer confirms a detention order, the article of food continues to be detained until we terminate the detention under § 1.384 or the detention period expires under § 1.379, whichever occurs first.

(e) If the presiding officer terminates a detention order, or the detention period expires, FDA must terminate the detention order as specified under § 1.384.

(f) Confirmation of a detention order by the presiding officer is considered a final agency action for purposes of 5 U.S.C. 702.

§ 1.406 How will FDA handle classified information in an informal hearing?

Where the credible evidence or information supporting the detention order is classified under the applicable Executive order as requiring protection from unauthorized disclosure in the interest of national security (''classified information''), FDA will not provide you with this information. The presiding officer will give you notice of the general nature of the information and an opportunity to offer opposing evidence or information, if he or she may do so consistently with safeguarding the information and its source. If classified information was used to support the detention, then any confirmation of such detention will state whether it is based in whole or in part on that classified information.

Subpart L—Foreign Supplier Verification Programs for Food Importers

SOURCE: 80 FR 74340, Nov. 27, 2015, unless otherwise noted.

§ 1.500 What definitions apply to this subpart?

The following definitions apply to words and phrases as they are used in this subpart. Other definitions of these terms may apply when they are used in other subparts of this part.

Adequate means that which is needed to accomplish the intended purpose in keeping with good public health practice.

Audit means the systematic, independent, and documented examination (through observation, investigation, discussions with employees of the audited entity, records review, and, as appropriate, sampling and laboratory analysis) to assess an audited entity's food safety processes and procedures.

Dietary supplement has the meaning given in section 201(ff) of the Federal Food, Drug, and Cosmetic Act.

Dietary supplement component means any substance intended for use in the manufacture of a dietary supplement, including those that may not appear in the finished batch of the dietary supplement. Dietary supplement components include dietary ingredients (as

described in section 201(ff) of the Federal Food, Drug, and Cosmetic Act) and other ingredients.

Environmental pathogen means a pathogen capable of surviving and persisting within the manufacturing, processing, packing, or holding environment such that food may be contaminated and may result in foodborne illness if that food is consumed without treatment to significantly minimize the environmental pathogen. Examples of environmental pathogens for the purposes of this part include *Listeria monocytogenes* and *Salmonella* spp. but do not include the spores of pathogenic sporeforming bacteria.

Facility means a domestic facility or a foreign facility that is required to register under section 415 of the Federal Food, Drug, and Cosmetic Act, in accordance with the requirements of subpart H of this part.

Farm means farm as defined in § 1.227.

Farm mixed-type facility means an establishment that is a farm but that also conducts activities outside the farm definition that require the establishment to be registered under section 415 of the Federal Food, Drug, and Cosmetic Act.

Food has the meaning given in section 201(f) of the Federal Food, Drug, and Cosmetic Act, except that food does not include pesticides (as defined in 7 U.S.C. 136(u)).

Food allergen means a major food allergen as defined in section 201(qq) of the Federal Food, Drug, and Cosmetic Act.

Foreign supplier means, for an article of food, the establishment that manufactures/processes the food, raises the animal, or grows the food that is exported to the United States without further manufacturing/processing by another establishment, except for further manufacturing/processing that consists solely of the addition of labeling or any similar activity of a de minimis nature.

Good compliance standing with a foreign food safety authority means that the foreign supplier—

(1) Appears on the current version of a list, issued by the food safety authority of the country in which the foreign supplier is located and which has regulatory oversight of the supplier, of food producers that are in good compliance standing with the food safety authority; or

(2) Has otherwise been designated by such food safety authority as being in good compliance standing.

Harvesting applies to applies to farms and farm mixed-type facilities and means activities that are traditionally performed on farms for the purpose of removing raw agricultural commodities from the place they were grown or raised and preparing them for use as food. Harvesting is limited to activities performed on raw agricultural commodities, or on processed foods created by drying/dehydrating a raw agricultural commodity without additional manufacturing/processing, on a farm. Harvesting does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act. Examples of harvesting include cutting (or otherwise separating) the edible portion of the raw agricultural commodity from the crop plant and removing or trimming part of the raw agricultural commodity (*e.g.*, foliage, husks, roots, or stems). Examples of harvesting also include cooling, field coring, filtering, gathering, hulling, shelling, sifting, threshing, trimming of outer leaves of, and washing raw agricultural commodities grown on a farm.

Hazard means any biological, chemical (including radiological), or physical agent that is reasonably likely to cause illness or injury.

Hazard requiring a control means a known or reasonably foreseeable hazard for which a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would, based on the outcome of a hazard analysis (which includes an assessment of the probability that the hazard will occur in the absence of controls or measures and the severity of the illness or injury if the hazard were to occur), establish one or more controls or measures to significantly minimize or prevent the hazard in a food and components to manage those controls or measures (such as monitoring, corrections or corrective actions, verification, and records) as appropriate to the food, the facility, and the

nature of the control or measure and its role in the facility's food safety system.

Holding means storage of food and also includes activities performed incidental to storage of a food (*e.g.*, activities performed for the safe or effective storage of that food, such as fumigating food during storage, and drying/dehydrating raw agricultural commodities when the drying/dehydrating does not create a distinct commodity (such as drying/dehydrating hay or alfalfa)). Holding also includes activities performed as a practical necessity for the distribution of that food (such as blending of the same raw agricultural commodity and breaking down pallets), but does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act. Holding facilities could include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks.

Importer means the U.S. owner or consignee of an article of food that is being offered for import into the United States. If there is no U.S. owner or consignee of an article of food at the time of U.S. entry, the importer is the U.S. agent or representative of the foreign owner or consignee at the time of entry, as confirmed in a signed statement of consent to serve as the importer under this subpart.

Known or reasonably foreseeable hazard means a biological, chemical (including radiological), or physical hazard that is known to be, or has the potential to be, associated with a food or the facility in which it is manufactured/processed.

Lot means the food produced during a period of time and identified by an establishment's specific code.

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 include: Baking, boiling, bottling, canning, cooking, cooling, cutting, distilling, drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins), evaporating, eviscerating, extracting juice, extruding (of animal food), formulating, freezing, grinding, homogenizing, irradiating, labeling, milling, mixing, packaging (including modified atmosphere packaging), pasteurizing, peeling, pelleting (of animal food), rendering, treating to manipulate ripening, trimming, washing, or waxing. For farms and farm mixed-type facilities, manufacturing/processing does not include activities that are part of harvesting, packing, or holding.

Microorganisms means yeasts, molds, bacteria, viruses, protozoa, and microscopic parasites and includes species that are pathogens.

Packing means placing food into a container other than packaging the food and also includes re-packing and activities performed incidental to packing or re-packing a food (*e.g.*, activities performed for the safe or effective packing or re-packing of that food (such as sorting, culling, grading, and weighing or conveying incidental to packing or re-packing)), but does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act.

Pathogen means a microorganism of public health significance.

Qualified auditor means a person who is a qualified individual as defined in this section and has technical expertise obtained through education, training, or experience (or a combination thereof) necessary to perform the auditing function as required by §1.506(e)(1)(i) or §1.511(c)(5)(i)(A). Examples of potential qualified auditors include:

(1) A government employee, including a foreign government employee; and

(2) An audit agent of a certification body that is accredited in accordance with subpart M of this part.

Qualified individual means a person who has the education, training, or experience (or a combination thereof) necessary to perform an activity required under this subpart, and can read and understand the language of any records that the person must review in performing this activity. A qualified individual may be, but is not required to be, an employee of the importer. A

government employee, including a foreign government employee, may be a qualified individual.

Raw agricultural commodity has the meaning given in section 201(r) of the Federal Food, Drug, and Cosmetic Act.

Ready-to-eat food (RTE food) means any food that is normally eaten in its raw state or any food, including a processed food, for which it is reasonably foreseeable that the food will be eaten without further processing that would significantly minimize biological hazards.

Receiving facility means a facility that is subject to subparts C and G of part 117 of this chapter, or subparts C and E of part 507 of this chapter, and that manufactures/processes a raw material or other ingredient that it receives from a supplier.

U.S. owner or consignee means the person in the United States who, at the time of U.S. entry, either owns the food, has purchased the food, or has agreed in writing to purchase the food.

Very small importer means:

(1) With respect to the importation of human food, an importer (including any subsidiaries and affiliates) averaging less than $1 million per year, adjusted for inflation, during the 3-year period preceding the applicable calendar year, in sales of human food combined with the U.S. market value of human food imported, manufactured, processed, packed, or held without sale (*e.g.*, imported for a fee); and

(2) With respect to the importation of animal food, an importer (including any subsidiaries and affiliates) averaging less than $2.5 million per year, adjusted for inflation, during the 3-year period preceding the applicable calendar year, in sales of animal food combined with the U.S. market value of animal food imported, manufactured, processed, packed, or held without sale (*e.g.*, imported for a fee).

You means a person who is subject to some or all of the requirements in this subpart.

[80 FR 74340, Nov. 27, 2015, as amended at 81 FR 25327, Apr. 28, 2016]

§ 1.501 To what foods do the requirements in this subpart apply?

(a) *General*. Except as specified otherwise in this section, the requirements in this subpart apply to all food imported or offered for import into the United States and to the importers of such food.

(b) *Exemptions for juice and seafood*—(1) *Importers of certain juice and seafood products*. This subpart does not apply with respect to juice, fish, and fishery products that are imported from a foreign supplier that is required to comply with, and is in compliance with, the requirements in part 120 or part 123 of this chapter. If you import juice or fish and fishery products that are subject to part 120 or part 123, respectively, you must comply with the requirements applicable to importers of those products under § 120.14 or § 123.12 of this chapter, respectively.

(2) *Certain importers of juice or seafood raw materials or other ingredients subject to part 120 or part 123 of this chapter*. This subpart does not apply with respect to any raw materials or other ingredients that you import and use in manufacturing or processing juice subject to part 120 or fish and fishery products subject to part 123, provided that you are in compliance with the requirements in part 120 or part 123 with respect to the juice or fish or fishery product that you manufacture or process from the imported raw materials or other ingredients.

(c) *Exemption for food imported for research or evaluation*. This subpart does not apply to food that is imported for research or evaluation use, provided that such food:

(1) Is not intended for retail sale and is not sold or distributed to the public;

(2) Is labeled with the statement ''Food for research or evaluation use'';

(3) Is imported in a small quantity that is consistent with a research, analysis, or quality assurance purpose, the food is used only for this purpose, and any unused quantity is properly disposed of; and

(4) Is accompanied, when filing entry with U.S. Customs and Border Protection, by an electronic declaration that the food will be used for research or evaluation purposes and will not be sold or distributed to the public.

(d) *Exemption for food imported for personal consumption*. This subpart does not apply to food that is imported for personal consumption, provided that

such food is not intended for retail sale and is not sold or distributed to the public. Food is imported for personal consumption only if it is purchased or otherwise acquired by a person in a small quantity that is consistent with a non-commercial purpose and is not sold or distributed to the public.

(e) *Exemption for alcoholic beverages.* (1) This subpart does not apply with respect to alcoholic beverages that are imported from a foreign supplier that is a facility that meets the following two conditions:

(i) Under the Federal Alcohol Administration Act (27 U.S.C. 201 *et seq.*) or chapter 51 of subtitle E of the Internal Revenue Code of 1986 (26 U.S.C. 5001 *et seq.*), the facility is a foreign facility of a type that, if it were a domestic facility, would require obtaining a permit from, registering with, or obtaining approval of a notice or application from the Secretary of the Treasury as a condition of doing business in the United States; and

(ii) Under section 415 of the Federal Food, Drug, and Cosmetic Act, the facility is required to register as a facility because it is engaged in manufacturing/processing one or more alcoholic beverages.

(2) This subpart does not apply with respect to food that is not an alcoholic beverage that is imported from a foreign supplier described in paragraph (e)(1) of this section, provided such food:

(i) Is in prepackaged form that prevents any direct human contact with such food; and

(ii) Constitutes not more than 5 percent of the overall sales of the facility, as determined by the Secretary of the Treasury.

(3) This subpart does not apply with respect to raw materials and other ingredients that are imported for use in alcoholic beverages provided that:

(i) The imported raw materials and other ingredients are used in the manufacturing/processing, packing, or holding of alcoholic beverages;

(ii) Such manufacturing/processing, packing, or holding is performed by the importer;

(iii) The importer is required to register under section 415 of the Federal Food, Drug, and Cosmetic Act; and

(iv) The importer is exempt from the regulations in part 117 of this chapter in accordance with §117.5(i) of this chapter.

(f) *Inapplicability to food that is transshipped or imported for processing and export.* This subpart does not apply to food:

(1) That is transshipped through the United States to another country and is not sold or distributed to the public in the United States; or

(2) That is imported for processing and future export and that is not sold or distributed to the public in the United States.

(g) *Inapplicability to U.S. food returned.* This subpart does not apply to food that is manufactured/processed, raised, or grown in the United States, exported, and returned to the United States without further manufacturing/processing in a foreign country.

(h) *Inapplicability to certain meat, poultry, and egg products.* This subpart does not apply with respect to:

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

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

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

[80 FR 74340, Nov. 27, 2015, as amended at 81 FR 25327, Apr. 28, 2016]

§ 1.502 What foreign supplier verification program (FSVP) must I have?

(a) *General.* Except as specified in paragraph (b) of this section, for each food you import, you must develop, maintain, and follow an FSVP that provides adequate assurances that your foreign supplier is producing the food in compliance with processes and procedures that provide at least the same level of public health protection as those required under section 418 (regarding hazard analysis and risk-based

preventive controls for certain foods) or 419 (regarding standards for produce safety), if either is applicable, and the implementing regulations, and is producing the food in compliance with sections 402 (regarding adulteration) and 403(w) (if applicable) (regarding misbranding with respect to labeling for the presence of major food allergens) of the Federal Food, Drug, and Cosmetic Act.

(b) *Low-acid canned foods*—(1) *Importers of low-acid canned foods not subject to further manufacturing or processing*. With respect to those microbiological hazards that are controlled by part 113 of this chapter, if you import a thermally processed low-acid food packaged in a hermetically sealed container (low-acid canned food), you must verify and document that the food was produced in accordance with part 113. With respect to all matters that are not controlled by part 113, you must have an FSVP as specified in paragraph (a) of this section.

(2) *Certain importers of raw materials or other ingredients subject to part 113 of this chapter*. With respect to microbiological hazards that are controlled by part 113, you are not required to comply with the requirements of this subpart for raw materials or other ingredients that you import and use in the manufacturing or processing of low-acid canned food provided that you are in compliance with part 113 with respect to the low-acid canned food that you manufacture or process from the imported raw materials or other ingredients. With respect to all hazards other than microbiological hazards that are controlled by part 113, you must have an FSVP as specified in paragraph (a) of this section for the imported raw materials and other ingredients that you use in the manufacture or processing of low-acid canned foods.

(c) *Importers subject to section 418 of the Federal Food, Drug, and Cosmetic Act*. You are deemed to be in compliance with the requirements of this subpart for a food you import, except for the requirements in § 1.509, if you are a receiving facility as defined in § 117.3 or § 507.3 of this chapter and you are in compliance with the following requirements of part 117 or part 507 of this chapter, as applicable:

(1) You implement preventive controls for the hazards in the food in accordance with § 117.135 or § 507.34 of this chapter;

(2) You are not required to implement a preventive control under § 117.136 or § 507.36 of this chapter with respect to the food; or

(3) You have established and implemented a risk-based supply-chain program in compliance with subpart G of part 117 or subpart E of part 507 of this chapter with respect to the food.

§ 1.503 Who must develop my FSVP and perform FSVP activities?

(a) *Qualified individual*. A qualified individual must develop your FSVP and perform each of the activities required under this subpart. A qualified individual must have the education, training, or experience (or a combination thereof) necessary to perform their assigned activities and must be able to read and understand the language of any records that must be reviewed in performing an activity.

(b) *Qualified auditor*. A qualified auditor must conduct any audit conducted in accordance with § 1.506(e)(1)(i) or § 1.511(c)(5)(i)(A). A qualified auditor must have technical expertise obtained through education, training, or experience (or a combination thereof) necessary to perform the auditing function.

§ 1.504 What hazard analysis must I conduct?

(a) *Requirement for a hazard analysis*. Except as specified in paragraph (d) of this section, you must conduct a hazard analysis to identify and evaluate, based on experience, illness data, scientific reports, and other information, known or reasonably foreseeable hazards for each type of food you import to determine whether there are any hazards requiring a control. Your hazard analysis must be written regardless of its outcome.

(b) *Hazard identification*. (1) Your analysis of the known or reasonably foreseeable hazards in each food must include the following types of hazards:

(i) Biological hazards, including microbiological hazards such as parasites, environmental pathogens, and other pathogens;

(ii) Chemical hazards, including radiological hazards, pesticide and drug residues, natural toxins, decomposition, unapproved food or color additives, food allergens, and (in animal food) nutrient deficiencies or toxicities; and

(iii) Physical hazards (such as stones, glass, and metal fragments).

(2) Your analysis must include known or reasonably foreseeable hazards that may be present in a food for any of the following reasons:

(i) The hazard occurs naturally;

(ii) The hazard may be unintentionally introduced; or

(iii) The hazard may be intentionally introduced for purposes of economic gain.

(c) *Hazard evaluation.* (1) Your hazard analysis must include an evaluation of the hazards identified in paragraph (b) of this section to assess the probability that the hazard will occur in the absence of controls and the severity of the illness or injury if the hazard were to occur.

(2) The hazard evaluation required by paragraph (c)(1) of this section must include an evaluation of environmental pathogens whenever a ready-to-eat food is exposed to the environment before packaging and the packaged food does not receive a treatment or otherwise include a control or measure (such as a formulation lethal to the pathogen) that would significantly minimize the pathogen.

(3) Your hazard evaluation must consider the effect of the following on the safety of the finished food for the intended consumer:

(i) The formulation of the food;

(ii) The condition, function, and design of the establishment and equipment of a typical entity that manufactures/processes, grows, harvests, or raises this type of food;

(iii) Raw materials and other ingredients;

(iv) Transportation practices;

(v) Harvesting, raising, manufacturing, processing, and packing procedures;

(vi) Packaging and labeling activities;

(vii) Storage and distribution;

(viii) Intended or reasonably foreseeable use;

(ix) Sanitation, including employee hygiene; and

(x) Any other relevant factors, such as the temporal (*e.g.*, weather-related) nature of some hazards (*e.g.*, levels of natural toxins).

(d) *Review of another entity's hazard analysis.* If another entity (including your foreign supplier) has, using a qualified individual, analyzed the known or reasonably foreseeable hazards for the food to determine whether there are any hazards requiring a control, you may meet your requirement to determine whether there are any hazards requiring a control in a food by reviewing and assessing the hazard analysis conducted by that entity. You must document your review and assessment of that hazard analysis, including documenting that the hazard analysis was conducted by a qualified individual.

(e) *Hazards in raw agricultural commodities that are fruits or vegetables.* If you are importing a raw agricultural commodity that is a fruit or vegetable that is ''covered produce'' as defined in § 112.3 of this chapter, you are not required to determine whether there are any biological hazards requiring a control in such food because the biological hazards in such fruits or vegetables require a control and compliance with the requirements in part 112 of this chapter significantly minimizes or prevents the biological hazards. However, you must determine whether there are any other types of hazards requiring a control in such food.

(f) *No hazards requiring a control.* If you evaluate the known and reasonably foreseeable hazards in a food and determine that there are no hazards requiring a control, you are not required to conduct an evaluation for foreign supplier approval and verification under § 1.505 and you are not required to conduct foreign supplier verification activities under § 1.506. This paragraph (f) does not apply if the food is a raw agricultural commodity that is a fruit or vegetable that is ''covered produce'' as defined in § 112.3 of this chapter.

§ 1.505 What evaluation for foreign supplier approval and verification must I conduct?

(a) *Evaluation of a foreign supplier's performance and the risk posed by a food.* (1) Except as specified in paragraphs (d) and (e) of this section, in approving your foreign suppliers and determining the appropriate supplier verification activities that must be conducted for a foreign supplier of a type of food you import, you must consider the following:

(i) The hazard analysis of the food conducted in accordance with § 1.504, including the nature of the hazard requiring a control.

(ii) The entity or entities that will be significantly minimizing or preventing the hazards requiring a control or verifying that such hazards have been significantly minimized or prevented, such as the foreign supplier, the foreign supplier's raw material or other ingredient supplier, or another entity in your supply chain.

(iii) Foreign supplier performance, including:

(A) The foreign supplier's procedures, processes, and practices related to the safety of the food;

(B) Applicable FDA food safety regulations and information relevant to the foreign supplier's compliance with those regulations, including whether the foreign supplier is the subject of an FDA warning letter, import alert, or other FDA compliance action related to food safety (or, when applicable, the relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or determined to be equivalent to that of the United States, and information relevant to the supplier's compliance with those laws and regulations); and

(C) The foreign supplier's food safety history, including available information about results from testing foods for hazards, audit results relating to the safety of the food, and responsiveness of the foreign supplier in correcting problems.

(iv) Any other factors as appropriate and necessary, such as storage and transportation practices.

(2) You must document the evaluation you conduct under paragraph (a)(1) of this section.

(b) *Approval of foreign suppliers.* You must approve your foreign suppliers on the basis of the evaluation that you conducted under paragraph (a) of this section or that you review and assess under paragraph (d) of this section, and document your approval.

(c) *Reevaluation of a foreign supplier's performance and the risk posed by a food.* (1) Except as specified in paragraph (d) of this section, you must promptly reevaluate the concerns associated with the factors in paragraph (a)(1) of this section when you become aware of new information about these factors, and the reevaluation must be documented. If you determine that the concerns associated with importing a food from a foreign supplier have changed, you must promptly determine (and document) whether it is appropriate to continue to import the food from the foreign supplier and whether the supplier verification activities conducted under § 1.506 or § 1.511(c) need to be changed.

(2) If at the end of any 3-year period you have not reevaluated the concerns associated with the factors in paragraph (a)(1) of this section in accordance with paragraph (c)(1) of this section, you must reevaluate those concerns and take other appropriate actions, if necessary, in accordance with paragraph (c)(1). You must document your reevaluation and any subsequent actions you take in accordance with paragraph (c)(1).

(d) *Review of another entity's evaluation or reevaluation of a foreign supplier's performance and the risk posed by a food.* If an entity other than the foreign supplier has, using a qualified individual, performed the evaluation described in paragraph (a) of this section or the reevaluation described in paragraph (c) of this section, you may meet the requirements of the applicable paragraph by reviewing and assessing the evaluation or reevaluation conducted by that entity. You must document your review and assessment, including documenting that the evaluation or reevaluation was conducted by a qualified individual.

(e) *Inapplicability to certain circumstances.* You are not required to conduct an evaluation under this section or to conduct foreign supplier verification activities under § 1.506 if

one of the circumstances described in § 1.507 applies to your importation of a food and you are in compliance with that section.

§ 1.506 What foreign supplier verification and related activities must I conduct?

(a) *Use of approved foreign suppliers.* (1) You must establish and follow written procedures to ensure that you import foods only from foreign suppliers you have approved based on the evaluation conducted under § 1.505 (or, when necessary and appropriate, on a temporary basis from unapproved foreign suppliers whose foods you subject to adequate verification activities before importing the food). You must document your use of these procedures.

(2) You may rely on an entity other than your foreign supplier to establish the procedures and perform and document the activities required under paragraph (a)(1) of this section provided that you review and assess that entity's documentation of the procedures and activities, and you document your review and assessment.

(b) *Foreign supplier verification procedures.* You must establish and follow adequate written procedures for ensuring that appropriate foreign supplier verification activities are conducted with respect to the foods you import.

(c) *Requirement of supplier verification.* The foreign supplier verification activities must provide assurance that the hazards requiring a control in the food you import have been significantly minimized or prevented.

(d) *Determination of appropriate foreign supplier verification activities*—(1)(i) *General.* Except as provided in paragraphs (d)(2) and (3) of this section, before importing a food from a foreign supplier, you must determine and document which verification activity or activities listed in paragraphs (d)(1)(ii)(A) through (D) of this section, as well as the frequency with which the activity or activities must be conducted, are needed to provide adequate assurances that the food you obtain from the foreign supplier is produced in accordance with paragraph (c) of this section. Verification activities must address the entity or entities that are significantly minimizing or preventing the hazards or verifying that the hazards have been significantly minimized or prevented (*e.g.*, when an entity other than the grower of produce subject to part 112 of this chapter harvests or packs the produce and significantly minimizes or prevents the hazard or verifies that the hazard has been significantly minimized or prevented, or when the foreign supplier's raw material supplier significantly minimizes or prevents a hazard). The determination of appropriate supplier verification activities must be based on the evaluation of the food and foreign supplier conducted under § 1.505.

(ii) *Appropriate verification activities.* The following are appropriate supplier verification activities:

(A) Onsite audits as specified in paragraph (e)(1)(i) of this section;

(B) Sampling and testing of a food as specified in paragraph (e)(1)(ii) of this section;

(C) Review of the foreign supplier's relevant food safety records as specified in paragraph (e)(1)(iii) of this section; and

(D) Other appropriate supplier verification activities as specified in paragraph (e)(1)(iv) of this section.

(2) *Verification activities for certain serious hazards.* When a hazard in a food will be controlled by the foreign supplier and is one for which there is a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans or animals, you must conduct or obtain documentation of an onsite audit of the foreign supplier before initially importing the food and at least annually thereafter, unless you make an adequate written determination that, instead of such initial and annual onsite auditing, other supplier verification activities listed in paragraph (d)(1)(ii) of this section and/or less frequent onsite auditing are appropriate to provide adequate assurances that the foreign supplier is producing the food in accordance with paragraph (c) of this section, based on the determination made under § 1.505.

(3) *Reliance on a determination by another entity.* You may rely on a determination of appropriate foreign supplier verification activities in accordance with paragraph (d)(1) or (2) of this

section made by an entity other than the foreign supplier if you review and assess whether the entity's determination regarding appropriate activities (including the frequency with which such activities must be conducted) is appropriate. You must document your review and assessment, including documenting that the determination of appropriate verification activities was made by a qualified individual.

(e) *Performance of foreign supplier verification activities*—(1) *Verification activities*. Except as provided in paragraph (e)(2) of this section, based on the determination made in accordance with paragraph (d) of this section, you must conduct (and document) or obtain documentation of one or more of the supplier verification activities listed in paragraphs (e)(1)(i) through (iv) of this section for each foreign supplier before importing the food and periodically thereafter.

(i) *Onsite audit of the foreign supplier*. (A) An onsite audit of a foreign supplier must be performed by a qualified auditor.

(B) If the food is subject to one or more FDA food safety regulations, an onsite audit of the foreign supplier must consider such regulations and include a review of the supplier's written food safety plan, if any, and its implementation, for the hazard being controlled (or, when applicable, an onsite audit may consider relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or determined to be equivalent to that of the United States).

(C) If the onsite audit is conducted solely to meet the requirements of paragraph (e) of this section by an audit agent of a certification body that is accredited in accordance with subpart M of this part, the audit is not subject to the requirements in that subpart.

(D) You must retain documentation of each onsite audit, including the audit procedures, the dates the audit was conducted, the conclusions of the audit, any corrective actions taken in response to significant deficiencies identified during the audit, and documentation that the audit was conducted by a qualified auditor.

(E) The following inspection results may be substituted for an onsite audit, provided that the inspection was conducted within 1 year of the date by which the onsite audit would have been required to be conducted:

(*1*) The written results of an appropriate inspection of the foreign supplier for compliance with applicable FDA food safety regulations conducted by FDA, representatives of other Federal Agencies (such as the USDA), or representatives of State, local, tribal, or territorial agencies; or

(*2*) The written results of an inspection of the foreign supplier by the food safety authority of a country whose food safety system FDA has officially recognized as comparable or determined to be equivalent to that of the United States, provided that the food that is the subject of the onsite audit is within the scope of the official recognition or equivalence determination, and the foreign supplier is in, and under the regulatory oversight of, such country.

(ii) *Sampling and testing of the food*. You must retain documentation of each sampling and testing of a food, including identification of the food tested (including lot number, as appropriate), the number of samples tested, the test(s) conducted (including the analytical method(s) used), the date(s) on which the test(s) were conducted and the date of the report of the testing, the results of the testing, any corrective actions taken in response to detection of hazards, information identifying the laboratory conducting the testing, and documentation that the testing was conducted by a qualified individual.

(iii) *Review of the foreign supplier's relevant food safety records*. You must retain documentation of each record review, including the date(s) of review, the general nature of the records reviewed, the conclusions of the review, any corrective actions taken in response to significant deficiencies identified during the review, and documentation that the review was conducted by a qualified individual.

(iv) *Other appropriate activity*. (A) You may conduct (and document) or obtain documentation of other supplier

verification activities that are appropriate based on foreign supplier performance and the risk associated with the food.

(B) You must retain documentation of each activity conducted in accordance with paragraph (e)(1)(iv) of this section, including a description of the activity, the date on which it was conducted, the findings or results of the activity, any corrective actions taken in response to significant deficiencies identified, and documentation that the activity was conducted by a qualified individual.

(2) *Reliance upon performance of activities by other entities.* (i) Except as specified in paragraph (e)(2)(ii) of this section, you may rely on supplier verification activities conducted in accordance with paragraph (e)(1) of this section by another entity provided that you review and assess the results of these activities in accordance with paragraph (e)(3) of this section.

(ii) You may not rely on the foreign supplier itself or employees of the foreign supplier to perform supplier verification activities, except with respect to sampling and testing of food in accordance with paragraph (e)(1)(ii) of this section.

(3) *Review of results of verification activities.* You must promptly review and assess the results of the verification activities that you conduct or obtain documentation of under paragraph (e)(1) of this section, or that are conducted by other entities in accordance with paragraph (e)(2) of this section. You must document your review and assessment of the results of verification activities. If the results do not provide adequate assurances that the hazards requiring a control in the food you obtain from the foreign supplier have been significantly minimized or prevented, you must take appropriate action in accordance with §1.508(a). You are not required to retain documentation of supplier verification activities conducted by other entities, provided that you can obtain the documentation and make it available to FDA in accordance with §1.510(b).

(4) *Independence of qualified individuals conducting verification activities.* There must not be any financial conflicts of interests that influence the results of the verification activities set forth in paragraph (e)(1) of this section, and payment must not be related to the results of the activity.

§ 1.507 What requirements apply when I import a food that cannot be consumed without the hazards being controlled or for which the hazards are controlled after importation?

(a) *Circumstances.* You are not required to conduct an evaluation of a food and foreign supplier under §1.505 or supplier verification activities under §1.506 when you identify a hazard requiring a control (identified hazard) in a food and any of the following circumstances apply:

(1) You determine and document that the type of food (*e.g.*, raw agricultural commodities such as cocoa beans and coffee beans) could not be consumed without application of an appropriate control;

(2) You rely on your customer who is subject to the requirements for hazard analysis and risk-based preventive controls in subpart C of part 117 or subpart C of part 507 of this chapter to ensure that the identified hazard will be significantly minimized or prevented and you:

(i) Disclose in documents accompanying the food, in accordance with the practice of the trade, that the food is ''not processed to control [identified hazard]''; and

(ii) Annually obtain from your customer written assurance, subject to the requirements of paragraph (c) of this section, that the customer has established and is following procedures (identified in the written assurance) that will significantly minimize or prevent the identified hazard;

(3) You rely on your customer who is not subject to the requirements for hazard analysis and risk-based preventive controls in subpart C of part 117 or subpart C of part 507 of this chapter to provide assurance it is manufacturing, processing, or preparing the food in accordance with the applicable food safety requirements and you:

(i) Disclose in documents accompanying the food, in accordance with the practice of the trade, that the food is ''not processed to control [identified hazard]''; and

(ii) Annually obtain from your customer written assurance that it is manufacturing, processing, or preparing the food in accordance with applicable food safety requirements;

(4) You rely on your customer to provide assurance that the food will be processed to control the identified hazard by an entity in the distribution chain subsequent to the customer and you:

(i) Disclose in documents accompanying the food, in accordance with the practice of the trade, that the food is ''not processed to control [identified hazard]''; and

(ii) Annually obtain from your customer written assurance, subject to the requirements of paragraph (c) of this section, that your customer:

(A) Will disclose in documents accompanying the food, in accordance with the practice of the trade, that the food is ''not processed to control [identified hazard]''; and

(B) Will only sell the food to another entity that agrees, in writing, it will:

(*1*) Follow procedures (identified in a written assurance) that will significantly minimize or prevent the identified hazard (if the entity is subject to the requirements for hazard analysis and risk-based preventive controls in subpart C of part 117 or subpart C of part 507 of this chapter) or manufacture, process, or prepare the food in accordance with applicable food safety requirements (if the entity is not subject to the requirements for hazard analysis and risk-based preventive controls in subpart C of part 117 or subpart C of part 507); or

(*2*) Obtain a similar written assurance from the entity's customer, subject to the requirements of paragraph (c) of this section, as in paragraphs (a)(4)(ii)(A) and (B) of this section, as appropriate; or

(5) You have established, documented, and implemented a system that ensures control, at a subsequent distribution step, of the hazards in the food you distribute and you document your implementation of that system.

(b) *Written assurances.* Any written assurances required under this section must contain the following:

(1) Effective date;

(2) Printed names and signatures of authorized officials; and

(3) The assurance specified in the applicable paragraph.

(c) *Provision of assurances.* The customer or other subsequent entity in the distribution chain for a food that provides a written assurance under paragraph (a)(2), (3), or (4) of this section must act consistently with the assurance and document its actions taken to satisfy the written assurance.

§ 1.508 What corrective actions must I take under my FSVP?

(a) You must promptly take appropriate corrective actions if you determine that a foreign supplier of food you import does not produce the food in compliance with processes and procedures that provide at least the same level of public health protection as those required under section 418 or 419 of the Federal Food, Drug, and Cosmetic Act, if either is applicable, and the implementing regulations, or produces food that is adulterated under section 402 or misbranded under section 403(w) (if applicable) of the Federal Food, Drug, and Cosmetic Act. This determination could be based on a review of consumer, customer, or other complaints related to food safety, the verification activities conducted under § 1.506 or § 1.511(c), a reevaluation of the risks posed by the food and the foreign supplier's performance conducted under § 1.505(c) or (d), or any other relevant information you obtain. The appropriate corrective actions will depend on the circumstances but could include discontinuing use of the foreign supplier until the cause or causes of noncompliance, adulteration, or misbranding have been adequately addressed. You must document any corrective actions you take in accordance with this paragraph.

(b) If you determine, by means other than the verification activities conducted under § 1.506 or § 1.511(c) or a reevaluation conducted under § 1.505(c) or (d), that a foreign supplier of food that you import does not produce food in compliance with processes and procedures that provide at least the same level of public health protection as those required under section 418 or 419

of the Federal Food, Drug, and Cosmetic Act, if either is applicable, and the implementing regulations, or produces food that is adulterated under section 402 or misbranded under section 403(w) (if applicable) of the Federal Food, Drug, and Cosmetic Act, you must promptly investigate to determine whether your FSVP is adequate and, when appropriate, modify your FSVP. You must document any investigations, corrective actions, and changes to your FSVP that you undertake in accordance with this paragraph.

(c) This section does not limit your obligations with respect to other laws enforced by FDA, such as those relating to product recalls.

§ 1.509 How must the importer be identified at entry?

(a) You must ensure that, for each line entry of food product offered for importation into the United States, your name, electronic mail address, and unique facility identifier recognized as acceptable by FDA, identifying you as the importer of the food, are provided electronically when filing entry with U.S. Customs and Border Protection.

(b) Before an article of food is imported or offered for import into the United States, the foreign owner or consignee of the food (if there is no U.S. owner or consignee) must designate a U.S. agent or representative as the importer of the food for the purposes of the definition of ''importer'' in § 1.500.

§ 1.510 How must I maintain records of my FSVP?

(a) *General requirements for records.* (1) You must keep records as original records, true copies (such as photocopies, pictures, scanned copies, microfilm, microfiche, or other accurate reproductions of the original records), or electronic records.

(2) You must sign and date records concerning your FSVP upon initial completion and upon any modification of the FSVP.

(3) All records must be legible and stored to prevent deterioration or loss.

(b) *Record availability.* (1) You must make all records required under this subpart available promptly to an authorized FDA representative, upon request, for inspection and copying. Upon FDA request, you must provide within a reasonable time an English translation of records maintained in a language other than English.

(2) Offsite storage of records, including records maintained by other entities in accordance with § 1.504, § 1.505, or § 1.506, is permitted if such records can be retrieved and provided onsite within 24 hours of request for official review. Electronic records are considered to be onsite if they are accessible from an onsite location.

(3) If requested in writing by FDA, you must send records to the Agency electronically, or through another means that delivers the records promptly, rather than making the records available for review at your place of business.

(c) *Record retention.* (1) Except as specified in paragraph (c)(2) of this section, you must retain records referenced in this subpart until at least 2 years after you created or obtained the records.

(2) You must retain records that relate to your processes and procedures, including the results of evaluations and determinations you conduct, for at least 2 years after their use is discontinued (*e.g.*, because you no longer import a particular food, you no longer use a particular foreign supplier, you have reevaluated the risks associated with a food and the foreign supplier, or you have changed your supplier verification activities for a particular food and foreign supplier).

(d) *Electronic records.* Records that are established or maintained to satisfy the requirements of this subpart and that meet the definition of electronic records in § 11.3(b)(6) of this chapter are exempt from the requirements of part 11 of this chapter. Records that satisfy the requirements of this subpart, but that also are required under other applicable statutory provisions or regulations, remain subject to part 11.

(e) *Use of existing records.* (1) You do not need to duplicate existing records you have (*e.g.*, records that you maintain to comply with other Federal,

State, or local regulations) if they contain all of the information required by this subpart. You may supplement any such existing records as necessary to include all of the information required by this subpart.

(2) You do not need to maintain the information required by this subpart in one set of records. If existing records you have contain some of the required information, you may maintain any new information required by this subpart either separately or combined with the existing records.

(f) *Public disclosure.* Records obtained by FDA in accordance with this subpart are subject to the disclosure requirements under part 20 of this chapter.

§ 1.511 What FSVP must I have if I am importing a food subject to certain requirements in the dietary supplement current good manufacturing practice regulation?

(a) *Importers subject to certain requirements in the dietary supplement current good manufacturing practice regulation.* If you are required to establish specifications under § 111.70(b) or (d) of this chapter with respect to a food that is a dietary supplement or dietary supplement component you import for further manufacturing, processing, or packaging as a dietary supplement, and you are in compliance with the requirements in §§ 111.73 and 111.75 of this chapter applicable to determining whether the specifications you established are met for such food, then for that food you must comply with the requirements in §§ 1.503 and 1.509, but you are not required to comply with the requirements in § 1.502, §§ 1.504 through 1.508, or § 1.510. This requirement does not limit your obligations with respect to part 111 of this chapter or any other laws enforced by FDA.

(b) *Importers whose customer is subject to certain requirements in the dietary supplement current good manufacturing practice regulation.* If your customer is required to establish specifications under § 111.70(b) or (d) of this chapter with respect to a food that is a dietary supplement or dietary supplement component you import for further manufacturing, processing, or packaging as a dietary supplement, your customer is in compliance with the requirements of §§ 111.73 and 111.75 of this chapter applicable to determining whether the specifications it established are met for such food, and you annually obtain from your customer written assurance that it is in compliance with those requirements, then for that food you must comply with the requirements in §§ 1.503, 1.509, and 1.510, but you are not required to comply with the requirements in § 1.502 or §§ 1.504 through 1.508.

(c) *Other importers of dietary supplements*—(1) *General.* If the food you import is a dietary supplement and neither paragraph (a) or (b) of this section is applicable, you must comply with paragraph (c) of this section and the requirements in §§ 1.503, 1.505(a)(1)(ii) through (iv), (a)(2), and (b) through (d), and 1.508 through 1.510, but you are not required to comply with the requirements in §§ 1.504, 1.505(a)(1)(i), 1.506, and 1.507. This requirement does not limit your obligations with respect to part 111 of this chapter or any other laws enforced by FDA.

(2) *Use of approved foreign suppliers.* (i) You must establish and follow written procedures to ensure that you import foods only from foreign suppliers that you have approved based on the evaluation conducted under § 1.505 (or, when necessary and appropriate, on a temporary basis from unapproved foreign suppliers whose foods you subject to adequate verification activities before importing the food). You must document your use of these procedures.

(ii) You may rely on an entity other than the foreign supplier to establish the procedures and perform and document the activities required under paragraph (c)(2)(i) of this section provided that you review and assess that entity's documentation of the procedures and activities, and you document your review and assessment.

(3) *Foreign supplier verification procedures.* You must establish and follow adequate written procedures for ensuring that appropriate foreign supplier verification activities are conducted with respect to the foods you import.

(4) *Determination of appropriate foreign supplier verification activities*—(i) *General.* Except as provided in paragraph

(c)(4)(iii) of this section, before importing a dietary supplement from a foreign supplier, you must determine and document which verification activity or activities listed in paragraphs (c)(4)(ii)(A) through (D) of this section, as well as the frequency with which the activity or activities must be conducted, are needed to provide adequate assurances that the foreign supplier is producing the dietary supplement in accordance with processes and procedures that provide the same level of public health protection as those required under part 111 of this chapter. This determination must be based on the evaluation conducted under § 1.505.

(ii) *Appropriate verification activities.* The following are appropriate supplier verification activities:

(A) Onsite audits as specified in paragraph (c)(5)(i)(A) of this section;

(B) Sampling and testing of a food as specified in paragraph (c)(5)(i)(B) of this section;

(C) Review of the foreign supplier's relevant food safety records as specified in paragraph (c)(5)(i)(C) of this section; and

(D) Other appropriate supplier verification activities as specified in paragraph (c)(5)(i)(D) of this section.

(iii) *Reliance upon determination by other entity.* You may rely on a determination of appropriate foreign supplier verification activities in accordance with paragraph (c)(4)(i) of this section made by an entity other than the foreign supplier if you review and assess whether the entity's determination regarding appropriate activities (including the frequency with which such activities must be conducted) is appropriate based on the evaluation conducted in accordance with § 1.505. You must document your review and assessment, including documenting that the determination of appropriate verification activities was made by a qualified individual.

(5) *Performance of foreign supplier verification activities.* (i) Except as provided in paragraph (c)(5)(ii) of this section, for each dietary supplement you import under paragraph (c) of this section, you must conduct (and document) or obtain documentation of one or more of the verification activities listed in paragraphs (c)(5)(i)(A) through (D) of this section before importing the dietary supplement and periodically thereafter.

(A) *Onsite auditing.* You conduct (and document) or obtain documentation of a periodic onsite audit of your foreign supplier.

(*1*) An onsite audit of a foreign supplier must be performed by a qualified auditor.

(*2*) The onsite audit must consider the applicable requirements of part 111 of this chapter and include a review of the foreign supplier's written food safety plan, if any, and its implementation (or, when applicable, an onsite audit may consider relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or determined to be equivalent to that of the United States).

(*3*) If the onsite audit is conducted solely to meet the requirements of paragraph (c)(5) of this section by an audit agent of a certification body that is accredited in accordance with subpart M of this part, the audit is not subject to the requirements in that subpart.

(*4*) You must retain documentation of each onsite audit, including the audit procedures, the dates the audit was conducted, the conclusions of the audit, any corrective actions taken in response to significant deficiencies identified during the audit, and documentation that the audit was conducted by a qualified auditor.

(*5*) The following inspection results may be substituted for an onsite audit, provided that the inspection was conducted within 1 year of the date by which the onsite audit would have been required to be conducted:

(*i*) The written results of appropriate inspection of the foreign supplier for compliance with the applicable requirements in part 111 of this chapter conducted by FDA, representatives of other Federal Agencies (such as the USDA), or representatives of State, local, tribal, or territorial agencies; or

(*ii*) The written results of an inspection by the food safety authority of a country whose food safety system FDA has officially recognized as comparable or determined to be equivalent to that of the United States, provided that the

food that is the subject of the onsite audit is within the scope of the official recognition or equivalence determination, and the foreign supplier is in, and under the regulatory oversight of, such country.

(B) *Sampling and testing of the food.* You must retain documentation of each sampling and testing of a dietary supplement, including identification of the food tested (including lot number, as appropriate), the number of samples tested, the test(s) conducted (including the analytical method(s) used), the date(s) on which the test(s) were conducted and the date of the report of the testing, the results of the testing, any corrective actions taken in response to detection of hazards, information identifying the laboratory conducting the testing, and documentation that the testing was conducted by a qualified individual.

(C) *Review of the foreign supplier's food safety records.* You must retain documentation of each record review, including the date(s) of review, the general nature of the records reviewed, the conclusions of the review, any corrective actions taken in response to significant deficiencies identified during the review, and documentation that the review was conducted by a qualified individual.

(D) *Other appropriate activity.* (*1*) You may conduct (and document) or obtain documentation of other supplier verification activities that are appropriate based on foreign supplier performance and the risk associated with the food.

(*2*) You must retain documentation of each activity conducted in accordance with paragraph (c)(5)(i)(D)(*1*) of this section, including a description of the activity, the date on which it was conducted, the findings or results of the activity, any corrective actions taken in response to significant deficiencies identified, and documentation that the activity was conducted by a qualified individual.

(ii) *Reliance upon performance of activities by other entities.* (A) Except as specified in paragraph (c)(5)(ii)(B) of this section, you may rely on supplier verification activities conducted in accordance with paragraph (c)(5)(i) by another entity provided that you review and assess the results of these activities in accordance with paragraph (c)(5)(iii) of this section.

(B) You may not rely on the foreign supplier or employees of the foreign supplier to perform supplier verification activities, except with respect to sampling and testing of food in accordance with paragraph (c)(5)(i)(B) of this section.

(iii) *Review of results of verification activities.* You must promptly review and assess the results of the verification activities that you conduct or obtain documentation of under paragraph (c)(5)(i) of this section, or that are conducted by other entities in accordance with paragraph (c)(5)(ii) of this section. You must document your review and assessment of the results of verification activities. If the results show that the foreign supplier is not producing the dietary supplement in accordance with processes and procedures that provide the same level of public health protection as those required under part 111 of this chapter, you must take appropriate action in accordance with § 1.508(a). You are not required to retain documentation of supplier verification activities conducted by other entities, provided that you can obtain the documentation and make it available to FDA in accordance with § 1.510(b).

(iv) *Independence of qualified individuals conducting verification activities.* There must not be any financial conflicts of interest that influence the results of the verification activities set forth in paragraph (c)(5)(i) of this section, and payment must not be related to the results of the activity.

[80 FR 74340, Nov. 27, 2015, as amended at 81 FR 25327, Apr. 28, 2016]

§ 1.512 What FSVP may I have if I am a very small importer or I am importing certain food from certain small foreign suppliers?

(a) *Eligibility.* This section applies only if:

(1) You are a very small importer; or

(2) You are importing certain food from certain small foreign suppliers as follows:

(i) The foreign supplier is a qualified facility as defined by § 117.3 or § 507.3 of this chapter;

(ii) You are importing produce from a foreign supplier that is a farm that grows produce and is not a covered farm under part 112 of this chapter in accordance with § 112.4(a) of this chapter, or in accordance with §§ 112.4(b) and 112.5 of this chapter; or

(iii) You are importing shell eggs from a foreign supplier that is not subject to the requirements of part 118 of this chapter because it has fewer than 3,000 laying hens.

(b) *Applicable requirements*—(1) *Documentation of eligibility*—(i) *Very small importer status.* (A) If you are a very small importer and you choose to comply with the requirements in this section, you must document that you meet the definition of very small importer in § 1.500 with respect to human food and/or animal food before initially importing food as a very small importer and thereafter on an annual basis by December 31 of each calendar year.

(B) For the purpose of determining whether you satisfy the definition of very small importer with respect to human food and/or animal food for a given calendar year, the relevant 3-year period of sales (and U.S. market value of human or animal food, as appropriate) is the period ending 1 year before the calendar year for which you intend to import food as a very small importer. The baseline year for calculating the adjustment for inflation is 2011. If you conduct any food sales in currency other than U.S. dollars, you must use the relevant currency exchange rate in effect on December 31 of the year in which sales occurred to calculate the value of these sales.

(ii) *Small foreign supplier status.* If you are a importing food from a small foreign supplier as specified in paragraph (a)(2) of this section and you choose to comply with the requirements in this section, you must obtain written assurance that your foreign supplier meets the criteria in paragraph (a)(2)(i), (ii), or (iii) of this section before first approving the supplier for an applicable calendar year and thereafter on an annual basis by December 31 of each calendar year, for the following calendar year.

(2) *Additional requirements.* If this section applies and you choose to comply with the requirements in paragraph (b) of this section, you also are required to comply with the requirements in §§ 1.502, 1.503, and 1.509, but you are not required to comply with the requirements in §§ 1.504 through 1.508 or § 1.510.

(3) *Foreign supplier verification activities.* (i) If you are a very small importer, for each food you import, you must obtain written assurance, before importing the food and at least every 2 years thereafter, that your foreign supplier is producing the food in compliance with processes and procedures that provide at least the same level of public health protection as those required under section 418 or 419 of the Federal Food, Drug, and Cosmetic Act, if either is applicable, and the implementing regulations, and is producing the food in compliance with sections 402 and 403(w) (if applicable) of the Federal Food, Drug, and Cosmetic Act.

(ii) If your foreign supplier is a qualified facility as defined by § 117.3 or § 507.3 of this chapter and you choose to comply with the requirements in this section, you must obtain written assurance, before importing the food and at least every 2 years thereafter, that the foreign supplier is producing the food in compliance with applicable FDA food safety regulations (or, when applicable, relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or determined to be equivalent to that of the United States). The written assurance must include either:

(A) A brief description of the preventive controls that the supplier is implementing to control the applicable hazard in the food; or

(B) A statement that the supplier is in compliance with State, local, county, tribal, or other applicable non-Federal food safety law, including relevant laws and regulations of foreign countries.

(iii) If your foreign supplier is a farm that grows produce and is not a covered farm under part 112 of this chapter in accordance with § 112.4(a) of this chapter, or in accordance with §§ 112.4(b) and 112.5 of this chapter, and you choose to comply with the requirements in this section, you must obtain written assurance, before importing the produce and at least every 2 years thereafter, that the farm acknowledges

that its food is subject to section 402 of the Federal Food, Drug, and Cosmetic Act (or, when applicable, that its food is subject to relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or determined to be equivalent to that of the United States).

(iv) If your foreign supplier is a shell egg producer that is not subject to the requirements of part 118 of this chapter because it has fewer than 3,000 laying hens and you choose to comply with the requirements in this section, you must obtain written assurance, before importing the shell eggs and at least every 2 years thereafter, that the shell egg producer acknowledges that its food is subject to section 402 of the Federal Food, Drug, and Cosmetic Act (or, when applicable, that its food is subject to relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or determined to be equivalent to that of the United States).

(4) *Corrective actions.* You must promptly take appropriate corrective actions if you determine that a foreign supplier of food you import does not produce the food consistent with the assurance provided in accordance with §1.512(b)(3)(i) through (iv). The appropriate corrective actions will depend on the circumstances but could include discontinuing use of the foreign supplier until the cause or causes of noncompliance, adulteration, or misbranding have been adequately addressed. You must document any corrective actions you take in accordance with this paragraph (b)(4). This paragraph (b)(4) does not limit your obligations with respect to other laws enforced by FDA, such as those relating to product recalls.

(5) *Records*—(i) *General requirements for records.* (A) You must keep records as original records, true copies (such as photocopies, pictures, scanned copies, microfilm, microfiche, or other accurate reproductions of the original records), or electronic records.

(B) You must sign and date records concerning your FSVP upon initial completion and upon any modification of the FSVP.

(C) All records must be legible and stored to prevent deterioration or loss.

(ii) *Availability.* (A) You must make all records required under this subpart available promptly to an authorized FDA representative, upon request, for inspection and copying. Upon FDA request, you must provide within a reasonable time an English translation of records maintained in a language other than English.

(B) Offsite storage of records, including records retained by other entities in accordance with paragraph (c) of this section, is permitted if such records can be retrieved and provided onsite within 24 hours of request for official review. Electronic records are considered to be onsite if they are accessible from an onsite location.

(C) If requested in writing by FDA, you must send records to the Agency electronically or through another means that delivers the records promptly, rather than making the records available for review at your place of business.

(iii) *Record retention.* (A) Except as specified in paragraph (b)(5)(iii)(B) or (C) of this section, you must retain records required under this subpart for a period of at least 2 years after you created or obtained the records.

(B) If you are subject to paragraph (c) of this section, you must retain records that relate to your processes and procedures, including the results of evaluations of foreign suppliers and procedures to ensure the use of approved suppliers, for at least 2 years after their use is discontinued (*e.g.*, because you have reevaluated a foreign supplier's compliance history or changed your procedures to ensure the use of approved suppliers).

(C) You must retain for at least 3 years records that you rely on during the 3-year period preceding the applicable calendar year to support your status as a very small importer.

(iv) *Electronic records.* Records that are established or maintained to satisfy the requirements of this subpart and that meet the definition of electronic records in §11.3(b)(6) of this chapter are exempt from the requirements of part 11 of this chapter. Records that satisfy the requirements of this part, but that also are required

under other applicable statutory provisions or regulations, remain subject to part 11.

(v) *Use of existing records.* (A) You do not need to duplicate existing records you have (*e.g.*, records that you maintain to comply with other Federal, State, or local regulations) if they contain all of the information required by this subpart. You may supplement any such existing records as necessary to include all of the information required by this subpart.

(B) You do not need to maintain the information required by this subpart in one set of records. If existing records you have contain some of the required information, you may maintain any new information required by this subpart either separately or combined with the existing records.

(vi) *Public disclosure.* Records obtained by FDA in accordance with this subpart are subject to the disclosure requirements under part 20 of this chapter.

(c) *Requirements for importers of food from certain small foreign suppliers.* The following additional requirements apply if you are importing food from certain small foreign suppliers as specified in paragraph (a)(2) of this section and you are not a very small importer:

(1) *Evaluation of foreign supplier compliance history*—(i) *Initial evaluation.* Except as specified in paragraph (c)(1)(iii) of this section, in approving your foreign suppliers, you must evaluate the applicable FDA food safety regulations and information relevant to the foreign supplier's compliance with those regulations, including whether the foreign supplier is the subject of an FDA warning letter, import alert, or other FDA compliance action related to food safety, and document the evaluation. You may also consider other factors relevant to a foreign supplier's performance, including those specified in § 1.505(a)(1)(iii)(A) and (C).

(ii) *Reevaluation of foreign supplier compliance history.* (A) Except as specified in paragraph (c)(1)(iii) of this section, you must promptly reevaluate the concerns associated with the foreign supplier's compliance history when you become aware of new information about the matters in paragraph (c)(1)(i) of this section, and the reevaluation must be documented. If you determine that the concerns associated with importing a food from a foreign supplier have changed, you must promptly determine (and document) whether it is appropriate to continue to import the food from the foreign supplier.

(B) If at the end of any 3-year period you have not reevaluated the concerns associated with the foreign supplier's compliance history in accordance with paragraph (c)(1)(ii)(A) of this section, you must reevaluate those concerns and take other appropriate actions, if necessary, in accordance with paragraph (c)(1)(ii)(A). You must document your reevaluation and any subsequent actions you take in accordance with paragraph (c)(1)(ii)(A).

(iii) *Review of another entity's evaluation or reevaluation of foreign supplier compliance history.* If an entity other than the foreign supplier has, using a qualified individual, performed the evaluation described in paragraph (c)(1)(i) of this section or the reevaluation described in paragraph (c)(1)(ii), you may meet the requirements of the applicable paragraph by reviewing and assessing the evaluation or reevaluation conducted by that entity. You must document your review and assessment, including documenting that the evaluation or reevaluation was conducted by a qualified individual.

(2) *Approval of foreign supplier.* You must approve your foreign suppliers on the basis of the evaluation you conducted under paragraph (c)(1)(i) of this section or that you review and assess under paragraph (c)(1)(iii) of this section, and document your approval.

(3) *Use of approved foreign suppliers.* (i) You must establish and follow written procedures to ensure that you import foods only from foreign suppliers you have approved based on the evaluation conducted under paragraph (c)(1)(i) of this section (or, when necessary and appropriate, on a temporary basis from unapproved foreign suppliers whose foods you subject to adequate verification activities before importing the food). You must document your use of these procedures.

(ii) You may rely on an entity other than the foreign supplier to establish

the procedures and perform and document the activities required under paragraph (c)(3)(i) of this section provided that you review and assess that entity's documentation of the procedures and activities, and you document your review and assessment.

[80 FR 74340, Nov. 27, 2015, as amended at 81 FR 25327, Apr. 28, 2016]

§ 1.513 What FSVP may I have if I am importing certain food from a country with an officially recognized or equivalent food safety system?

(a) *General.* (1) If you meet the conditions and requirements of paragraph (b) of this section for a food of the type specified in paragraph (a)(2) of this section that you are importing, then you are not required to comply with the requirements in §§ 1.504 through 1.508. You would still be required to comply with the requirements in §§ 1.503, 1.509, and 1.510.

(2) This section applies to food that is not intended for further manufacturing/processing, including packaged food products and raw agricultural commodities that will not be commercially processed further before consumption.

(b) *Conditions and requirements.* (1) Before importing a food from the foreign supplier and annually thereafter, you must document that the foreign supplier is in, and under the regulatory oversight of, a country whose food safety system FDA has officially recognized as comparable or determined to be equivalent to that of the United States, and that the food is within the scope of that official recognition or equivalency determination.

(2) Before importing a food from the foreign supplier, you must determine and document whether the foreign supplier of the food is in good compliance standing with the food safety authority of the country in which the foreign supplier is located. You must continue to monitor whether the foreign supplier is in good compliance standing and promptly review any information obtained. If the information indicates that food safety hazards associated with the food are not being significantly minimized or prevented, you must take prompt corrective action. The appropriate corrective action will depend on the circumstances but could include discontinuing use of the foreign supplier. You must document any corrective actions that you undertake in accordance with this paragraph (b)(2).

§ 1.514 What are some consequences of failing to comply with the requirements of this subpart?

(a) *Refusal of admission.* An article of food is subject to refusal of admission under section 801(a)(3) of the Federal Food, Drug, and Cosmetic Act if it appears that the importer of that food fails to comply with this subpart with respect to that food. If there is no U.S. owner or consignee of an article of food at the time the food is offered for entry into the United States, the article of food may not be imported into the United States unless the foreign owner or consignee has appropriately designated a U.S. agent or representative as the importer in accordance with § 1.500.

(b) *Prohibited act.* The importation or offering for importation into the United States of an article of food without the importer having an FSVP that meets the requirements of section 805 of the Federal Food, Drug, and Cosmetic Act, including the requirements of this subpart, is prohibited under section 301(zz) of the Federal Food, Drug, and Cosmetic Act.

Subpart M—Accreditation of Third-Party Certification Bodies To Conduct Food Safety Audits and To Issue Certifications

SOURCE: 80 FR 74650, Nov. 27, 2015, unless otherwise noted.

§ 1.600 What definitions apply to this subpart?

(a) The *FD&C Act* means the Federal Food, Drug, and Cosmetic Act.

(b) Except as otherwise defined in paragraph (c) of this section, the definitions of terms in section 201 of the FD&C Act apply when the terms are used in this subpart.

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

Accreditation means a determination by a recognized accreditation body (or, in the case of direct accreditation, by

FDA) that a third-party certification body meets the applicable requirements of this subpart.

Accreditation body means an authority that performs accreditation of third-party certification bodies.

Accredited third-party certification body means a third-party certification body that a recognized accreditation body (or, in the case of direct accreditation, FDA) has determined meets the applicable requirements of this subpart and is accredited to conduct food safety audits and to issue food or facility certifications to eligible entities. An accredited third-party certification body has the same meaning as accredited third-party auditor as defined in section 808(a)(4) of the FD&C Act.

Assessment means:

(i) With respect to an accreditation body, an evaluation by FDA of the competency and capacity of the accreditation body under the applicable requirements of this subpart for the defined scope of recognition. An assessment of the competency and capacity of the accreditation body involves evaluating the competency and capacity of the operations of the accreditation body that are relevant to decisions on recognition and, if recognized, an evaluation of its performance and the validity of its accreditation decisions under the applicable requirements of this subpart.

(ii) With respect to a third-party certification body, an evaluation by a recognized accreditation body (or, in the case of direct accreditation, FDA) of the competency and capacity of a third-party certification body under the applicable requirements of this subpart for the defined scope of accreditation. An assessment of the competency and capacity of the third-party certification body involves evaluating the competency and capacity of the operations of the third-party certification body that are relevant to decisions on accreditation and, if accredited, an evaluation of its performance and the validity of its audit results and certification decisions under the applicable requirements of this subpart.

Audit means the systematic and functionally independent examination of an eligible entity under this subpart by an accredited third-party certification body or by FDA. An audit conducted under this subpart is not considered an inspection under section 704 of the FD&C Act.

Audit agent means an individual who is an employee or other agent of an accredited third-party certification body who, although not individually accredited, is qualified to conduct food safety audits on behalf of an accredited third-party certification body. An audit agent includes a contractor of the accredited third-party certification body but excludes subcontractors or other agents under outsourcing arrangements for conducting food safety audits without direct control by the accredited third-party certification body.

Consultative audit means an audit of an eligible entity:

(i) To determine whether such entity is in compliance with the applicable food safety requirements of the FD&C Act, FDA regulations, and industry standards and practices;

(ii) The results of which are for internal purposes only; and

(iii) That is conducted in preparation for a regulatory audit; only the results of a regulatory audit may form the basis for issuance of a food or facility certification under this subpart.

Direct accreditation means accreditation of a third-party certification body by FDA.

Eligible entity means a foreign entity in the import supply chain of food for consumption in the United States that chooses to be subject to a food safety audit under this subpart conducted by an accredited third-party certification body. Eligible entities include foreign facilities required to be registered under subpart H of this part.

Facility means any structure, or structures of an eligible entity under one ownership at one general physical location, or, in the case of a mobile facility, traveling to multiple locations, that manufactures/processes, packs, holds, grows, harvests, or raises animals for 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. Non-bottled water drinking water collection and distribution establishments and their structures are not facilities. Facilities for the purposes of this subpart are not limited to facilities required to be registered under subpart H of this part.

Facility certification means an attestation, issued for purposes of section 801(q) or 806 of the FD&C Act by an accredited third-party certification body, after conducting a regulatory audit and any other activities necessary to establish whether a facility complies with the applicable food safety requirements of the FD&C Act and FDA regulations.

Food has the meaning given in section 201(f) of the FD&C Act, except that food does not include pesticides (as defined in 7 U.S.C. 136(u)).

Food certification means an attestation, issued for purposes of section 801(q) of the FD&C Act by an accredited third-party certification body, after conducting a regulatory audit and any other activities necessary to establish whether a food of an eligible entity complies with the applicable food safety requirements of the FD&C Act and FDA regulations.

Food safety audit means a regulatory audit or a consultative audit that is conducted to determine compliance with the applicable food safety requirements of the FD&C Act, FDA regulations, and for consultative audits, also includes conformance with industry standards and practices. An eligible entity must declare that an audit is to be conducted as a regulatory audit or consultative audit at the time of audit planning and the audit will be conducted on an unannounced basis under this subpart.

Foreign cooperative means an autonomous association of persons, identified as members, who are united through a jointly owned enterprise to aggregate food from member growers or processors that is intended for export to the United States.

Recognized accreditation body means an accreditation body that FDA has determined meets the applicable requirements of this subpart and is authorized to accredit third-party certification bodies under this subpart.

Regulatory audit means an audit of an eligible entity:

(i) To determine whether such entity is in compliance with the applicable food safety requirements of the FD&C Act and FDA regulations; and

(ii) The results of which are used in determining eligibility for certification under section 801(q) or under section 806 of the FD&C Act.

Relinquishment means:

(i) With respect to an accreditation body, a decision to cede voluntarily its authority to accredit third-party certification bodies as a recognized accreditation body prior to expiration of its recognition under this subpart; and

(ii) With respect to a third-party certification body, a decision to cede voluntarily its authority to conduct food safety audits and to issue food and facility certifications to eligible entities as an accredited third-party certification body prior to expiration of its accreditation under this subpart.

Self-assessment means an evaluation conducted by a recognized accreditation body or by an accredited third-party certification body of its competency and capacity under the applicable requirements of this subpart for the defined scope of recognition or accreditation. For recognized accreditation bodies this involves evaluating the competency and capacity of the entire operations of the accreditation body and the validity of its accreditation decisions under the applicable requirements of this subpart. For accredited third-party certification bodies this involves evaluating the competency and capacity of the entire operations of the third-party certification body and the validity of its audit results under the applicable requirements of this subpart.

Third-party certification body has the same meaning as third-party auditor as that term is defined in section 808(a)(3) of the FD&C Act and means a foreign government, agency of a foreign government, foreign cooperative, or any other third party that is eligible to be considered for accreditation to conduct food safety audits and to certify that eligible entities meet the applicable food safety requirements of the FD&C

Act and FDA regulations. A third-party certification body may be a single individual or an organization. Once accredited, a third-party certification body may use audit agents to conduct food safety audits.

§ 1.601 Who is subject to this subpart?

(a) *Accreditation bodies.* Any accreditation body seeking recognition from FDA to accredit third-party certification bodies to conduct food safety audits and to issue food and facility certifications under this subpart.

(b) *Third-party certification bodies.* Any third-party certification body seeking accreditation from a recognized accreditation body or direct accreditation by FDA for:

(1) Conducting food safety audits; and

(2) Issuing certifications that may be used in satisfying a condition of admissibility of an article of food under section 801(q) of the FD&C Act; or issuing a facility certification for meeting the eligibility requirements for the Voluntary Qualified Importer Program under section 806 of the FD&C Act.

(c) *Eligible entities.* Any eligible entity seeking a food safety audit or a food or facility certification from an accredited third-party certification body under this subpart.

(d) *Limited exemptions from section 801(q) of the FD&C Act*—(1) *Alcoholic beverages.* (i) Any certification required under section 801(q) of the FD&C Act does not apply with respect to alcoholic beverages from an eligible entity that is a facility that meets the following two conditions:

(A) Under the Federal Alcohol Administration Act (27 U.S.C. 201 *et seq.*) or chapter 51 of subtitle E of the Internal Revenue Code of 1986 (26 U.S.C. 5001 *et seq.*), the facility is a foreign facility of a type that, if it were a domestic facility, would require obtaining a permit from, registering with, or obtaining approval of a notice or application from the Secretary of the Treasury as a condition of doing business in the United States; and

(B) Under section 415 of the FD&C Act, the facility is required to register as a facility because it is engaged in manufacturing/processing one or more alcoholic beverages.

(ii) Any certification required under section 801(q) of the FD&C Act does not apply with respect to food that is not an alcoholic beverage that is received and distributed by a facility described in paragraph (d)(1)(i) of this section, provided such food:

(A) Is received and distributed in prepackaged form that prevents any direct human contact with such food; and

(B) Constitutes not more than 5 percent of the overall sales of the facility, as determined by the Secretary of the Treasury.

(iii) Any certification required under section 801(q) of the FD&C Act does not apply with respect to raw materials or other ingredients that are imported for use in alcoholic beverages provided that:

(A) The imported raw materials or other ingredients are used in the manufacturing/processing, packing, or holding of alcoholic beverages;

(B) Such manufacturing/processing, packing, or holding is performed by the importer;

(C) The importer is required to register under section 415 of the Federal Food, Drug, and Cosmetic Act; and

(D) The importer is exempt from the regulations in part 117 of this chapter in accordance with § 117.5(i).

(2) *Certain meat, poultry, and egg products.* Any certification required under section 801(q) of the FD&C Act does not apply with respect to:

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

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

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

RECOGNITION OF ACCREDITATION BODIES UNDER THIS SUBPART

§ 1.610 Who is eligible to seek recognition?

An accreditation body is eligible to seek recognition by FDA if it can demonstrate that it meets the requirements of §§ 1.611 through 1.615. The accreditation body may use documentation of conformance with International Organization for Standardization/International Electrotechnical Commission (ISO/IEC) 17011:2004, supplemented as necessary, in meeting the applicable requirements of this subpart.

§ 1.611 What legal authority must an accreditation body have to qualify for recognition?

(a) An accreditation body seeking recognition must demonstrate that it has the authority (as a governmental entity or as a legal entity with contractual rights) to perform assessments of a third-party certification body as are necessary to determine its capability to conduct audits and certify food facilities and food, including authority to:

(1) Review any relevant records;

(2) Conduct onsite assessments of the performance of third-party certification bodies, such as by witnessing the performance of a representative sample of its agents (or, in the case of a third-party certification body that is an individual, such individual) conducting a representative sample of audits;

(3) Perform any reassessments or surveillance necessary to monitor compliance of accredited third-party certification bodies; and

(4) Suspend, withdraw, or reduce the scope of accreditation for failure to comply with the requirements of accreditation.

(b) An accreditation body seeking recognition must demonstrate that it is capable of exerting the authority (as a governmental entity or as a legal entity with contractual rights) necessary to meet the applicable requirements of this subpart, if recognized.

§ 1.612 What competency and capacity must an accreditation body have to qualify for recognition?

An accreditation body seeking recognition must demonstrate that it has:

(a) The resources required to adequately implement its accreditation program, including:

(1) Adequate numbers of employees and other agents with relevant knowledge, skills, and experience to effectively evaluate the qualifications of third-party certification bodies seeking accreditation and to effectively monitor the performance of accredited third-party certification bodies; and

(2) Adequate financial resources for its operations; and

(b) The capability to meet the applicable assessment and monitoring requirements, the reporting and notification requirements, and the procedures of this subpart, if recognized.

§ 1.613 What protections against conflicts of interest must an accreditation body have to qualify for recognition?

An accreditation body must demonstrate that it has:

(a) Implemented written measures to protect against conflicts of interest between the accreditation body (and its officers, employees, and other agents involved in accreditation activities) and any third-party certification body (and its officers, employees, and other agents involved in auditing and certification activities) seeking accreditation from, or accredited by, such accreditation body; and

(b) The capability to meet the applicable conflict of interest requirements of this subpart, if recognized.

§ 1.614 What quality assurance procedures must an accreditation body have to qualify for recognition?

An accreditation body seeking recognition must demonstrate that it has:

(a) Implemented a written program for monitoring and evaluating the performance of its officers, employees, and other agents and its accreditation program, including procedures to:

(1) Identify areas in its accreditation program or performance where deficiencies exist; and

(2) Quickly execute corrective actions that effectively address deficiencies when identified; and

(b) The capability to meet the applicable quality assurance requirements of this subpart, if recognized.

§ 1.615 What records procedures must an accreditation body have to qualify for recognition?

An accreditation body seeking recognition must demonstrate that it has:

(a) Implemented written procedures to establish, control, and retain records (including documents and data) for the period of time necessary to meet its contractual and legal obligations pertaining to this subpart and to provide an adequate basis for evaluating its program and performance; and

(b) The capability to meet the applicable reporting and notification requirements of this subpart, if recognized.

REQUIREMENTS FOR ACCREDITATION BODIES THAT HAVE BEEN RECOGNIZED UNDER THIS SUBPART

§ 1.620 How must a recognized accreditation body evaluate third-party certification bodies seeking accreditation?

(a) Prior to accrediting a third-party certification body under this subpart, a recognized accreditation body must perform, at a minimum, the following:

(1) In the case of a foreign government or an agency of a foreign government, such reviews and audits of the government's or agency's food safety programs, systems, and standards as are necessary to determine that it meets the eligibility requirements of § 1.640(b).

(2) In the case of a foreign cooperative or any other third-party seeking accreditation as a third-party certification body, such reviews and audits of the training and qualifications of agents conducting audits for such cooperative or other third party (or in the case of a third-party certification body that is an individual, such individual) and such reviews of internal systems and any other investigation of the cooperative or other third party necessary to determine that it meets the eligibility requirements of § 1.640(c).

(3) In conducting a review and audit under paragraph (a)(1) or (2) of this section, an observation of a representative sample of onsite audits examining compliance with the applicable food safety requirements of the FD&C Act and FDA regulations as conducted by the third-party certification body or its agents (or, in the case of a third-party certification body that is an individual, such individual).

(b) A recognized accreditation body must require a third-party certification body, as a condition of accreditation under this subpart, to comply with the reports and notification requirements of §§ 1.652 and 1.656 and to agree to submit to FDA, electronically and in English, any food or facility certifications it issues for purposes of sections 801(q) or 806 of the FD&C Act.

(c) A recognized accreditation body must maintain records on any denial of accreditation (in whole or in part) and on any withdrawal, suspension, or reduction in scope of accreditation of a third-party certification body under this subpart. The records must include the name and contact information for the third-party certification body; the date of the action; the scope of accreditation denied, withdrawn, suspended, or reduced; and the basis for such action.

(d) A recognized accreditation body must notify any third-party certification body of an adverse decision associated with its accreditation under this subpart, including denial of accreditation or the withdrawal, suspension, or reduction in the scope of its accreditation. The recognized accreditation body must establish and implement written procedures for receiving and addressing appeals from any third-party certification body challenging such an adverse decision and for investigating and deciding on appeals in a fair and meaningful manner. The appeals procedures must provide similar protections to those offered by FDA under §§ 1.692 and 1.693, and include requirements to:

(1) Make the appeals procedures publicly available;

(2) Use competent persons, who may or may not be external to the recognized accreditation body, who are free from bias or prejudice and have not

participated in the accreditation decision or be subordinate to a person who has participated in the accreditation decision to investigate and decide appeals;

(3) Advise third-party certification bodies of the final decisions on their appeals; and

(4) Maintain records under § 1.625 of appeals, final decisions on appeals, and the bases for such decisions.

§ 1.621 How must a recognized accreditation body monitor the performance of third-party certification bodies it accredited?

(a) A recognized accreditation body must annually conduct a comprehensive assessment of the performance of each third-party certification body it accredited under this subpart by reviewing the accredited third-party certification body's self-assessments (including information on compliance with the conflict of interest requirements of §§ 1.643 and 1.657); its regulatory audit reports and notifications submitted to FDA under § 1.656; and any other information reasonably available to the recognized accreditation body regarding the compliance history of eligible entities the accredited third-party certification body certified under this subpart; or that is otherwise relevant to a determination whether the accredited third-party certification body is in compliance with this subpart.

(b) No later than 1 year after the initial date of accreditation of the third-party certification body and every 2 years thereafter for duration of its accreditation under this subpart, a recognized accreditation body must conduct onsite observations of a representative sample of regulatory audits performed by the third-party certification body (or its audit agents) (or, in the case of a third-party certification body that is an individual, such individual) accredited under this subpart and must visit the accredited third-party certification body's headquarters (or other location that manages audit agents conducting food safety audits under this subpart, if different than its headquarters). The recognized accreditation body will consider the results of such observations and visits in the annual assessment of the accredited third-party certification body required by paragraph (a) of this section.

§ 1.622 How must a recognized accreditation body monitor its own performance?

(a) A recognized accreditation body must annually, and as required under § 1.664(g), conduct a self-assessment that includes evaluation of compliance with this subpart, including:

(1) The performance of its officers, employees, or other agents involved in accreditation activities and the degree of consistency in conducting accreditation activities;

(2) The compliance of the recognized accreditation body and its officers, employees, and other agents involved in accreditation activities, with the conflict of interest requirements of § 1.624; and

(3) If requested by FDA, any other aspects of its performance relevant to a determination whether the recognized accreditation body is in compliance with this subpart.

(b) As a means to evaluate the recognized accreditation body's performance, the self-assessment must include onsite observation of regulatory audits of a representative sample of third-party certification bodies it accredited under this subpart. In meeting this requirement, the recognized accreditation body may use the results of onsite observations performed under § 1.621(b).

(c) Based on the evaluations conducted under paragraphs (a) and (b) of this section, the recognized accreditation body must:

(1) Identify any area(s) where deficiencies exist;

(2) Quickly implement corrective action(s) that effectively address those deficiencies; and

(3) Establish and maintain records of any such corrective action(s) under § 1.625.

(d) The recognized accreditation body must prepare, and as required by § 1.623(b) submit, a written report of the results of its self-assessment that includes the following elements. Documentation of conformance to ISO/IEC 17011:2004 may be used, supplemented as necessary, in meeting the requirements of this paragraph.

(1) A description of any corrective actions taken under paragraph (c) of this section;

(2) A statement disclosing the extent to which the recognized accreditation body, and its officers, employees, and other agents involved in accreditation activities, complied with the conflict of interest requirements in § 1.624; and

(3) A statement attesting to the extent to which the recognized accreditation body complied with applicable requirements of this subpart.

§ 1.623 What reports and notifications must a recognized accreditation body submit to FDA?

(a) *Reporting results of assessments of accredited third-party certification body performance.* A recognized accreditation body must submit to FDA electronically, in English, a report of the results of any assessment conducted under § 1.621, no later than 45 days after completing such assessment. The report must include an up-to-date list of any audit agents used by the accredited third-party certification body to conduct food safety audits under this subpart.

(b) *Reporting results of recognized accreditation body self-assessments.* A recognized accreditation body must submit to FDA electronically, in English:

(1) A report of the results of an annual self-assessment required under § 1.622, no later than 45 days after completing such self-assessment; and

(2) For a recognized accreditation body subject to § 1.664(g)(1), a report of such self-assessment to FDA within 60 days of the third-party certification body's withdrawal. A recognized accreditation body may use a report prepared for conformance to ISO/IEC 17011:2004, supplemented as necessary, in meeting the requirements this section.

(c) *Immediate notification to FDA.* A recognized accreditation body must notify FDA electronically, in English, immediately upon:

(1) Granting (including expanding the scope of) accreditation to a third-party certification body under this subpart, and include:

(i) The name, address, telephone number, and email address of the accredited third-party certification body;

(ii) The name of one or more officers of the accredited third-party certification body;

(iii) A list of the accredited third-party certification body's audit agents; and

(iv) The scope of accreditation, the date on which it was granted, and its expiration date.

(2) Withdrawing, suspending, or reducing the scope of an accreditation under this subpart, and include:

(i) The basis for such action; and

(ii) Any additional changes to accreditation information previously submitted to FDA under paragraph (c)(1) of this section.

(3) Determining that a third-party certification body it accredited failed to comply with § 1.653 in issuing a food or facility certification under this subpart, and include:

(i) The basis for such determination; and

(ii) Any changes to accreditation information previously submitted to FDA under paragraph (c)(1) of this section.

(d) *Other notification to FDA.* A recognized accreditation body must notify FDA electronically, in English, within 30 days after:

(1) Denying accreditation (in whole or in part) under this subpart and include:

(i) The name, address, telephone number, and email address of the third-party certification body;

(ii) The name of one or more officers of the third-party certification body;

(iii) The scope of accreditation requested; and

(iv) The scope and basis for such denial.

(2) Making any significant change that would affect the manner in which it complies with the applicable requirements of this subpart and include:

(i) A description of the change; and

(ii) An explanation for the purpose of the change.

§ 1.624 How must a recognized accreditation body protect against conflicts of interest?

(a) A recognized accreditation body must implement a written program to protect against conflicts of interest between the recognized accreditation

body (and its officers, employees, and other agents involved in accreditation activities) and any third-party certification body (and its officers, employees, and other agents involved in auditing and certification activities) seeking accreditation from, or accredited by, such recognized accreditation body, including the following:

(1) Ensuring that the recognized accreditation body (and its officers, employees, or other agents involved in accreditation activities) does not own or have a financial interest in, manage, or otherwise control the third-party certification body (or any affiliate, parent, or subsidiary); and

(2) Prohibiting officers, employees, or other agents involved in accreditation activities of the recognized accreditation body from accepting any money, gift, gratuity, or item of value from the third-party certification body.

(3) The items specified in paragraph (a)(2) of this section do not include:

(i) Money representing payment of fees for accreditation services and reimbursement of direct costs associated with an onsite assessment of the third-party certification body; or

(ii) Lunch of de minimis value provided during the course of an assessment and on the premises where the assessment is conducted, if necessary to facilitate the efficient conduct of the assessment.

(b) A recognized accreditation body may accept the payment of fees for accreditation services and the reimbursement of direct costs associated with assessment of a certification body only after the date on which the report of such assessment was completed or the date of which the accreditation was issued, whichever comes later. Such payment is not considered a conflict of interest for purposes of paragraph (a) of this section.

(c) The financial interests of the spouses and children younger than 18 years of age of a recognized accreditation body's officers, employees, and other agents involved in accreditation activities will be considered the financial interests of such officers, employees, and other agents involved in accreditation activities.

(d) A recognized accreditation body must maintain on its Web site an up-to-date list of the third-party certification bodies it accredited under this subpart and must identify the duration and scope of each accreditation and the date(s) on which the accredited third-party certification body paid any fee or reimbursement associated with such accreditation. If the accreditation of a certification body is suspended, withdrawn, or reduced in scope, this list must also include the date of suspension, withdrawal, or reduction in scope and maintain that information for the duration of accreditation or until the suspension is lifted, the certification body is reaccredited, or the scope of accreditation is reinstated, whichever comes first.

§ 1.625 What records requirements must an accreditation body that has been recognized meet?

(a) An accreditation body that has been recognized must maintain electronically for 5 years records created while it is recognized (including documents and data) demonstrating its compliance with this subpart, including records relating to:

(1) Applications for accreditation and renewal of accreditation under § 1.660;

(2) Decisions to grant, deny, suspend, withdraw, or expand or reduce the scope of an accreditation;

(3) Challenges to adverse accreditation decisions under § 1.620(c);

(4) Its monitoring of accredited third-party certification bodies under § 1.621;

(5) Self-assessments and corrective actions under § 1.622;

(6) Regulatory audit reports, including any supporting information, that an accredited third-party certification body may have submitted;

(7) Any reports or notifications to FDA under § 1.623, including any supporting information; and

(8) Records of fee payments and reimbursement of direct costs.

(b) An accreditation body that has been recognized must make records required by paragraph (a) of this section available for inspection and copying promptly upon written request of an authorized FDA officer or employee at the place of business of the accreditation body or at a reasonably accessible location. If the records required by

paragraph (a) of this section are requested by FDA electronically, the records must be submitted to FDA electronically not later than 10 business days after the date of the request. Additionally, if the requested records are maintained in a language other than English, the accreditation body must electronically submit an English translation within a reasonable time.

(c) An accreditation body that has been recognized must not prevent or interfere with FDA's access to its accredited third-party certification bodies and the accredited third-party certification body records required by § 1.658.

PROCEDURES FOR RECOGNITION OF ACCREDITATION BODIES UNDER THIS SUBPART

§ 1.630 How do I apply to FDA for recognition or renewal of recognition?

(a) *Applicant for recognition.* An accreditation body seeking recognition must submit an application demonstrating that it meets the eligibility requirements in § 1.610.

(b) *Applicant for renewal of recognition.* An accreditation body seeking renewal of its accreditation must submit a renewal application demonstrating that it continues to meet the requirements of this subpart.

(c) *Submission.* Recognition and renewal applications and any documents provided as part of the application process must be submitted electronically, in English. An applicant must provide any translation and interpretation services needed by FDA during the processing of the application, including during onsite assessments of the applicant by FDA.

(d) *Signature.* Recognition and renewal applications must be signed in the manner designated by FDA, by an individual authorized to act on behalf of the applicant for purposes of seeking recognition or renewal of recognition.

§ 1.631 How will FDA review my application for recognition or renewal of recognition and what happens once FDA decides on my application?

(a) *Review of recognition or renewal application.* FDA will examine an accreditation body's recognition or renewal application for completeness and notify the applicant of any deficiencies. FDA will review an accreditation body's recognition or renewal application on a first in, first out basis according to the date on which the completed application was submitted; however, FDA may prioritize the review of specific applications to meet the needs of the program.

(b) *Evaluation of recognition or renewal.* FDA will evaluate any completed recognition or renewal application to determine whether the applicant meets the applicable requirements of this subpart. Such evaluation may include an onsite assessment of the accreditation body. FDA will notify the applicant, in writing, regarding whether the application has been approved or denied. FDA may make such notification electronically. If FDA does not reach a final decision on a renewal application before an accreditation body's recognition terminates by expiration, FDA may extend such recognition for a specified period of time or until the Agency reaches a final decision on the renewal application.

(c) *Issuance of recognition.* FDA will notify an applicant that its recognition or renewal application has been approved through issuance of recognition that will list any limitations associated with the recognition.

(d) *Issuance of denial of recognition or renewal application.* FDA will notify an applicant that its recognition or renewal application has been denied through issuance of a denial of recognition or denial of a renewal application that will state the basis for such denial and provide the procedures for requesting reconsideration of the application under § 1.691.

(e) *Notice of records custodian after denial of an application for renewal of recognition.* An applicant whose renewal application was denied must notify FDA electronically, in English, within 10 business days of the date of issuance of a denial of a renewal application, of the name and contact information of the custodian who will maintain the records required by § 1.625(a) and make them available to FDA as required by § 1.625(b). The contact information for

the custodian must include, at a minimum, an email address and the physical address where the records required by § 1.625(a) will be located.

(f) *Effect of denial of an application for renewal of recognition of an accreditation body on accredited third-party certification bodies.* (1) FDA will issue a notice of the denial of a recognition renewal to any third-party certification bodies accredited by the accreditation body whose renewal application was denied. The third-party certification body's accreditation will remain in effect so long as the third-party certification body:

(i) No later than 60 days after FDA's issuance of the notice of the denial of recognition renewal, conducts a self-assessment under § 1.655 and reports the results of the self-assessment to FDA under § 1.656(b); and

(ii) No later than 1 year after issuance of the notice of denial of recognition renewal or the original date of the expiration of the accreditation, whichever comes first, becomes accredited by another recognized accreditation body or by FDA through direct accreditation.

(2) FDA may withdraw the accreditation of a third-party certification body whenever FDA determines there is good cause for withdrawal of accreditation under § 1.664(c).

(g) *Effect of denial of an application for renewal of recognition of an accreditation body on food or facility certifications issued to eligible entities.* A food or facility certification issued by a third-party certification body accredited by a recognized accreditation body prior to issuance of a denial of the renewal application will remain in effect until the certification expires. If FDA has reason to believe that a certification issued for purposes of section 801(q) or 806 of the FD&C Act is not valid or reliable, FDA may refuse to consider the certification in determining the admissibility of the article of food for which the certification was offered or in determining the importer's eligibility for participation in the voluntary qualified importer program (VQIP).

(h) *Public notice of denial of an application for renewal of recognition of an accreditation body.* FDA will provide notice on the Web site described in § 1.690 of the date of issuance of a denial of a renewal application and will describe the basis for the denial.

§ 1.632 What is the duration of recognition?

FDA may grant recognition of an accreditation body for a period not to exceed 5 years from the date of recognition.

§ 1.633 How will FDA monitor recognized accreditation bodies?

(a) FDA will evaluate the performance of each recognized accreditation body to determine its compliance with the applicable requirements of this subpart. Such assessment must occur by at least 4 years after the date of recognition for a 5-year recognition period, or by no later than the mid-term point for a recognition period of less than 5 years. FDA may conduct additional assessments of a recognized accreditation body at any time.

(b) An FDA assessment of a recognized accreditation body may include onsite assessments of a representative sample of third-party certification bodies the recognized accreditation body accredited and onsite audits of a representative sample of eligible entities certified by such third-party certification bodies under this subpart. These may be conducted at any time and, as FDA determines necessary or appropriate, may occur without the recognized accreditation body or, in the case of an audit of an eligible entity, the accredited third-party certification body present.

§ 1.634 When will FDA revoke recognition?

(a) *Grounds for revocation of recognition.* FDA will revoke the recognition of an accreditation body found not to be in compliance with the requirements of this subpart, including for any one or more of the following:

(1) Refusal by the accreditation body to allow FDA to access records required by § 1.625, or to conduct an assessment or investigation of the accreditation body or of a third-party certification body it accredited to ensure the accreditation body's continued compliance with the requirements of this subpart.

(2) Failure to take timely and necessary corrective action when:

(i) The accreditation of a third-party certification body it accredited is withdrawn by FDA under §1.664(a);

(ii) A significant deficiency is identified through self-assessment under §1.622, monitoring under §1.621, or self-assessment by one or more of its accredited third-party certification bodies under §1.655; or

(iii) Directed to do so by FDA to ensure compliance with this subpart.

(3) A determination by FDA that the accreditation body has committed fraud or has submitted material false statements to the Agency.

(4) A determination by FDA that there is otherwise good cause for revocation, including:

(i) Demonstrated bias or lack of objectivity when conducting activities under this subpart; or

(ii) Failure to adequately support one or more decisions to grant accreditation under this subpart.

(iii) Failure to pay the annual user fee within 90 days of the payment due date, as specified in §1.725(b)(3).

(b) *Records request associated with revocation.* To assist in determining whether revocation is warranted under paragraph (a) of this section, FDA may request records of the accreditation body required by §1.625 or the records, required by §1.658, of one or more of the third-party certification bodies it accredited under this subpart.

(c) *Issuance of revocation of recognition.* (1) FDA will notify an accreditation body that its recognition has been revoked through issuance of a revocation that will state the grounds for revocation, the procedures for requesting a regulatory hearing under §1.693 on the revocation, and the procedures for requesting reinstatement of recognition under §1.636.

(2) Within 10 business days of the date of issuance of the revocation, the accreditation body must notify FDA electronically, in English, of the name of the custodian who will maintain the records and make them available to FDA as required by §1.625. The contact information for the custodian must provide, at a minimum, an email address and the physical address where the records will be located.

(d) *Effect of revocation of recognition of an accreditation body on accredited third-party certification bodies.* (1) FDA will issue a notice of the revocation of recognition to any accredited third-party certification body accredited by the accreditation body whose recognition was revoked. The third-party certification body's accreditation will remain in effect if the third-party certification body:

(i) No later than 60 days after FDA's issuance of the notice of revocation, conducts a self-assessment under §1.655 and reports the results of the self-assessment to FDA under §1.656(b); and

(ii) No later than 1 year after issuance of the notice of the revocation, or the original date of expiration of the accreditation, whichever comes first, becomes accredited by another recognized accreditation body or by FDA through direct accreditation.

(2) FDA may withdraw the accreditation of a third-party certification body whenever FDA determines there is good cause for withdrawal of accreditation under §1.664(c).

(e) *Effect of revocation of recognition of an accreditation body on food or facility certifications issued to eligible entities.* A food or facility certification issued by a third-party certification body accredited by a recognized accreditation body prior to issuance of the revocation of recognition will remain in effect until the certificate terminates by expiration. If FDA has reason to believe that a certification issued for purposes of section 801(q) or 806 of the FD&C Act is not valid or reliable, FDA may refuse to consider the certification in determining the admissibility of the article of food for which the certification was offered or in determining the importer's eligibility for participation in VQIP.

(f) *Public notice of revocation of recognition.* FDA will provide notice on the Web site described in §1.690 of the issuance of the revocation of recognition of an accreditation body and will describe the basis for revocation.

[80 FR 74650, Nov. 27, 2015, as amended at 81 FR 90193, Dec. 14, 2016]

§ 1.635 What if I want to voluntarily relinquish recognition or do not want to renew recognition?

(a) *Notice to FDA of intent to relinquish or not to renew recognition.* A recognized accreditation body must notify FDA electronically, in English, at least 60 days before voluntarily relinquishing recognition or before allowing recognition to expire without seeking renewal. The recognized accreditation body must provide the name and contact information of the custodian who will maintain the records required under § 1.625(a) after the date of relinquishment or the date recognition expires, as applicable, and make them available to FDA as required by § 1.625(b). The contact information for the custodian must include, at a minimum, an email address and the physical address where the records required by § 1.625(a) will be located.

(b) *Notice to accredited third-party certification bodies of intent to relinquish or not to renew recognition.* No later than 15 business days after notifying FDA under paragraph (a) of this section, the recognized accreditation body must notify any currently accredited third-party certification body that it intends to relinquish recognition or to allow its recognition to expire, specifying the date on which relinquishment or expiration will occur. The recognized accreditation body must establish and maintain records of such notification under § 1.625.

(c)(1) *Effect of voluntary relinquishment or expiration of recognition on third-party certification bodies.* The accreditation of a third-party certification body issued prior to the relinquishment or expiration of its accreditation body's recognition will remain in effect, so long as the third-party certification body:

(i) No later than 60 days after the date of relinquishment or the date of expiration of the recognition, conducts a self-assessment under § 1.655 and reports the results of the self-assessment to FDA under § 1.656(b); and

(ii) No later than 1 year after the date of relinquishment or the date of expiration of recognition, or the original date of the expiration of the accreditation, whichever comes first, becomes accredited by another recognized accreditation body or by FDA through direct accreditation.

(2) FDA may withdraw the accreditation of a third-party certification body whenever FDA determines there is good cause for withdrawal of accreditation under § 1.664(c).

(d) *Effect of voluntary relinquishment or expiration of recognition of an accreditation body on food or facility certifications issued to eligible entities.* A food or facility certification issued by a third-party certification body accredited by a recognized accreditation body prior to relinquishment or expiration of its recognition will remain in effect until the certification expires. If FDA has reason to believe that a certification issued for purposes of section 801(q) or 806 of the FD&C Act is not valid or reliable, FDA may refuse to consider the certification in determining the admissibility of the article of food for which the certification was offered or in determining the importer's eligibility for participation in VQIP.

(e) *Public notice of voluntary relinquishment or expiration of recognition.* FDA will provide notice on the Web site described in § 1.690 of the voluntary relinquishment or expiration of recognition of an accreditation body under this subpart.

§ 1.636 How do I request reinstatement of recognition?

(a) *Application following revocation.* An accreditation body that has had its recognition revoked may seek reinstatement by submitting a new application for recognition under § 1.630. The accreditation body must submit evidence that the grounds for revocation have been resolved, including evidence addressing the cause or conditions that were the basis for revocation and identifying measures that have been implemented to help ensure that such cause(s) or condition(s) are unlikely to recur.

(b) *Application following relinquishment.* An accreditation body that previously relinquished its recognition under § 1.635 may seek recognition by submitting a new application for recognition under § 1.630.

ACCREDITATION OF THIRD-PARTY CERTIFICATION BODIES UNDER THIS SUBPART

§ 1.640 Who is eligible to seek accreditation?

(a) A foreign government, agency of a foreign government, foreign cooperative, or any other third party may seek accreditation from a recognized accreditation body (or, where direct accreditation is appropriate, FDA) to conduct food safety audits and to issue food and facility certifications to eligible entities under this subpart. An accredited third-party certification body may use documentation of conformance with ISO/IEC 17021: 2011 or ISO/IEC 17065: 2012, supplemented as necessary, in meeting the applicable requirements of this subpart.

(b) A foreign government or an agency of a foreign government is eligible for accreditation if it can demonstrate that its food safety programs, systems, and standards meet the requirements of §§ 1.641 through 1.645.

(c) A foreign cooperative or other third party is eligible for accreditation if it can demonstrate that the training and qualifications of its agents used to conduct audits (or, in the case of a third-party certification body that is an individual, such individual) and its internal systems and standards meet the requirements of §§ 1.641 through 1.645.

§ 1.641 What legal authority must a third-party certification body have to qualify for accreditation?

(a) A third-party certification body seeking accreditation from a recognized accreditation body or from FDA must demonstrate that it has the authority (as a governmental entity or as a legal entity with contractual rights) to perform such examinations of facilities, their process(es), and food(s) as are necessary to determine compliance with the applicable food safety requirements of the FD&C Act and FDA regulations, and conformance with applicable industry standards and practices and to issue certifications where appropriate based on a review of the findings of such examinations. This includes authority to:

(1) Review any relevant records;

(2) Conduct onsite audits of an eligible entity; and

(3) Suspend or withdraw certification for failure to comply with applicable requirements.

(b) A third-party certification body seeking accreditation must demonstrate that it is capable of exerting the authority (as a governmental entity or as legal entity with contractual rights) necessary to meet the applicable requirements of accreditation under this subpart if accredited.

§ 1.642 What competency and capacity must a third-party certification body have to qualify for accreditation?

A third-party certification body seeking accreditation must demonstrate that it has:

(a) The resources necessary to fully implement its certification program, including:

(1) Adequate numbers of employees and other agents with relevant knowledge, skills, and experience to effectively examine for compliance with applicable FDA food safety requirements of the FD&C Act and FDA regulations, conformance with applicable industry standards and practices, and issuance of valid and reliable certifications; and

(2) Adequate financial resources for its operations; and

(b) The competency and capacity to meet the applicable requirements of this subpart, if accredited.

§ 1.643 What protections against conflicts of interest must a third-party certification body have to qualify for accreditation?

A third-party certification body must demonstrate that it has:

(a) Implemented written measures to protect against conflicts of interest between the third-party certification body (and its officers, employees, and other agents involved in auditing and certification activities) and clients seeking examinations or certification from, or audited or certified by, such third-party certification body; and

(b) The capability to meet the conflict of interest requirements in § 1.657, if accredited.

§ 1.644 What quality assurance procedures must a third-party certification body have to qualify for accreditation?

A third-party certification body seeking accreditation must demonstrate that it has:

(a) Implemented a written program for monitoring and evaluating the performance of its officers, employees, and other agents involved in auditing and certification activities, including procedures to:

(1) Identify deficiencies in its auditing and certification program or performance; and

(2) Quickly execute corrective actions that effectively address any identified deficiencies; and

(b) The capability to meet the quality assurance requirements of § 1.655, if accredited.

§ 1.645 What records procedures must a third-party certification body have to qualify for accreditation?

A third-party certification body seeking accreditation must demonstrate that it:

(a) Implemented written procedures to establish, control, and retain records (including documents and data) for a period of time necessary to meet its contractual and legal obligations and to provide an adequate basis for evaluating its program and performance; and

(b) Is capable of meeting the reporting, notification, and records requirements of this subpart, if accredited.

REQUIREMENTS FOR THIRD-PARTY CERTIFICATION BODIES THAT HAVE BEEN ACCREDITED UNDER THIS SUBPART

§ 1.650 How must an accredited third-party certification body ensure its audit agents are competent and objective?

(a) An accredited third-party certification body that uses audit agents to conduct food safety audits must ensure that each such audit agent meets the following requirements with respect to the scope of its accreditation under this subpart. If the accredited third-party certification body is an individual, that individual is also subject to the following requirements, as applicable:

(1) Has relevant knowledge and experience that provides an adequate basis for the audit agent to evaluate compliance with applicable food safety requirements of the FD&C Act and FDA regulations and, for consultative audits, also includes conformance with applicable industry standards and practices;

(2) Has been determined by the accredited third-party certification body, through observations of a representative sample of audits, to be competent to conduct food safety audits under this subpart relevant to the audits they will be assigned to perform;

(3) Has completed annual food safety training that is relevant to activities conducted under this subpart;

(4) Is in compliance with the conflict of interest requirements of § 1.657 and has no other conflicts of interest with the eligible entity to be audited that might impair the audit agent's objectivity; and

(5) Agrees to notify its accredited third-party certification body immediately upon discovering, during a food safety audit, any condition that could cause or contribute to a serious risk to the public health.

(b) In assigning an audit agent to conduct a food safety audit at a particular eligible entity, an accredited third-party certification body must determine that the audit agent is qualified to conduct such audit under the criteria established in paragraph (a) of this section and based on the scope and purpose of the audit and the type of facility, its process(es), and food.

(c) An accredited third-party certification body cannot use an audit agent to conduct a regulatory audit at an eligible entity if such audit agent conducted a consultative audit or regulatory audit for the same eligible entity in the preceding 13 months, except that such limitation may be waived if the accredited third-party certification body demonstrates to FDA, under § 1.663, there is insufficient access to audit agents in the country or region where the eligible entity is located. If the accredited third-party certification body is an individual, that individual is also subject to such limitations.

§ 1.651 How must an accredited third-party certification body conduct a food safety audit of an eligible entity?

(a) *Audit planning.* Before beginning to conduct a food safety audit under this subpart, an accredited third-party certification body must:

(1) Require the eligible entity seeking a food safety audit to:

(i) Identify the scope and purpose of the food safety audit, including the facility, process(es), or food to be audited; whether the food safety audit is to be conducted as a consultative or regulatory audit subject to the requirements of this subpart, and if a regulatory audit, the type(s) of certification(s) sought; and

(ii) Provide a 30-day operating schedule for such facility that includes information relevant to the scope and purpose of the audit; and

(2) Determine whether the requested audit is within its scope of accreditation.

(b) *Authority to audit.* In arranging a food safety audit with an eligible entity under this subpart, an accredited third-party certification body must ensure it has authority, whether contractual or otherwise, to:

(1) Conduct an unannounced audit to determine whether the facility, process(es), and food of the eligible entity (within the scope of the audit) comply with the applicable food safety requirements of the FD&C Act and FDA regulations and, for consultative audits, also includes conformance with applicable industry standards and practices;

(2) Access any records and any area of the facility, process(es), and food of the eligible entity relevant to the scope and purpose of such audit;

(3) When, for a regulatory audit, sampling and analysis is conducted, the accredited third-party certification body must use a laboratory that is accredited in accordance with:

(i) ISO/IEC 17025:2005; or

(ii) Another laboratory accreditation standard that provides at least a similar level of assurance in the validity and reliability of sampling methodologies, analytical methodologies, and analytical results.

(4) Notify FDA immediately if, at any time during a food safety audit, the accredited third-party certification body (or its audit agent, where applicable) discovers a condition that could cause or contribute to a serious risk to the public health and provide information required by § 1.656(c);

(5) Prepare reports of audits conducted under this subpart as follows:

(i) For consultative audits, prepare reports that contain the elements specified in § 1.652(a) and maintain such records, subject to FDA access in accordance with section 414 of the FD&C Act; and

(ii) For regulatory audits, prepare reports that contain the elements specified in § 1.652(b) and submit them to FDA and to its recognized accreditation body (where applicable) under § 1.656(a); and

(6) Allow FDA and the recognized accreditation body that accredited such third-party certification body, if any, to observe any food safety audit conducted under this subpart for purposes of evaluating the accredited third-party certification body's performance under §§ 1.621 and 1.662 or, where appropriate, the recognized accreditation body's performance under §§ 1.622 and 1.633.

(c) *Audit protocols.* An accredited third-party certification body (or its audit agent, where applicable) must conduct a food safety audit in a manner consistent with the identified scope and purpose of the audit and within the scope of its accreditation.

(1) With the exception of records review, which may be scheduled, the audit must be conducted without announcement during the 30-day timeframe identified under paragraph (a)(1)(ii) of this section and must be focused on determining whether the facility, its process(es), and food are in compliance with applicable food safety requirements of the FD&C Act and FDA regulations, and, for consultative audits, also includes conformance with applicable industry standards and practices that are within the scope of the audit.

(2) The audit must include records review prior to the onsite examination; an onsite examination of the facility, its process(es), and the food that results from such process(es); and where appropriate or when required by FDA,

environmental or product sampling and analysis. When, for a regulatory audit, sampling and analysis is conducted, the accredited third-party certification body must use a laboratory that is accredited in accordance with paragraph (b)(3) of this section. The audit may include any other activities necessary to determine compliance with applicable food safety requirements of the FD&C Act and FDA regulations, and, for consultative audits, also includes conformance with applicable industry standards and practices.

(3) The audit must be sufficiently rigorous to allow the accredited third-party certification body to determine whether the eligible entity is in compliance with the applicable food safety requirements of the FD&C Act and FDA regulations, and for consultative audits, also includes conformance with applicable industry standards and practices, at the time of the audit; and for a regulatory audit, whether the eligible entity, given its food safety system and practices would be likely to remain in compliance with the applicable food safety requirements of the FD&C Act and FDA regulations for the duration of any certification issued under this subpart. An accredited third-party certification body (or its audit agent, where applicable) that identifies a deficiency requiring corrective action may verify the effectiveness of a corrective action once implemented by the eligible entity but must not recommend or provide input to the eligible entity in identifying, selecting, or implementing the corrective action.

(4) Audit observations and other data and information from the examination, including information on corrective actions, must be documented and must be used to support the findings contained in the audit report required by § 1.652 and maintained as a record under § 1.658.

§ 1.652 What must an accredited third-party certification body include in food safety audit reports?

(a) *Consultative audits.* An accredited third-party certification body must prepare a report of a consultative audit not later than 45 days after completing such audit and must provide a copy of such report to the eligible entity and must maintain such report under § 1.658, subject to FDA access in accordance with the requirements of section 414 of the FD&C Act. A consultative audit report must include:

(1) The identity of the site or location where the consultative audit was conducted, including:

(i) The name, address and the FDA Establishment Identifier of the facility subject to the consultative audit and a unique facility identifier, if designated by FDA; and

(ii) Where applicable, the FDA registration number assigned to the facility under subpart H of this part;

(2) The identity of the eligible entity, if different from the facility, including the name, address, the FDA Establishment Identifier and unique facility identifier, if designated by FDA, and, where applicable, registration number under subpart H of this part;

(3) The name(s) and telephone number(s) of the person(s) responsible for compliance with the applicable food safety requirements of the FD&C Act and FDA regulations

(4) The dates and scope of the consultative audit;

(5) The process(es) and food(s) observed during such consultative audit; and

(6) Any deficiencies observed that relate to or may influence a determination of compliance with the applicable food safety requirements of the FD&C Act and FDA regulations that require corrective action, the corrective action plan, and the date on which such corrective actions were completed. Such consultative audit report must be maintained as a record under § 1.658 and must be made available to FDA in accordance with section 414 of the FD&C Act.

(b) *Regulatory audits.* An accredited third-party certification body must, no later than 45 days after completing a regulatory audit, prepare and submit electronically, in English, to FDA and to its recognized accreditation body (or, in the case of direct accreditation, only to FDA) and must provide to the eligible entity a report of such regulatory audit that includes the following information:

(1) The identity of the site or location where the regulatory audit was conducted, including:

(i) The name, address, and FDA Establishment Identifier of the facility subject to the regulatory audit and a unique facility identifier, if designated by FDA; and

(ii) Where applicable, the FDA registration number assigned to the facility under subpart H of this part;

(2) The identity of the eligible entity, if different from the facility, including the name, address, FDA Establishment Identifier, and unique facility identifier, if designated by FDA, and, where applicable, registration number under subpart H of this part;

(3) The dates and scope of the regulatory audit;

(4) The process(es) and food(s) observed during such regulatory audit;

(5) The name(s) and telephone number(s) of the person(s) responsible for the facility's compliance with the applicable food safety requirements of the FD&C Act and FDA regulations;

(6) Any deficiencies observed during the regulatory audit that present a reasonable probability that the use of or exposure to a violative product:

(i) Will cause serious adverse health consequences or death to humans and animals; or

(ii) May cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences or death to humans or animals is remote;

(7) The corrective action plan for addressing each deficiency identified under paragraph (b)(6) of this section, unless corrective action was implemented immediately and verified onsite by the accredited third-party certification body (or its audit agent, where applicable);

(8) Whether any sampling and laboratory analysis (*e.g.*, under a microbiological sampling plan) is performed in or used by the facility; and

(9) Whether the eligible entity has made significant changes to the facility, its process(es), or food products during the 2 years preceding the regulatory audit.

(c) *Submission of regulatory audit report.* An accredited third-party certification body must submit a completed regulatory audit report as required by paragraph (b) of this section, regardless of whether the certification body issued a food or facility certification to the eligible entity.

(d) *Notice and appeals of adverse regulatory audit results.* An accredited third-party certification body must notify an eligible entity of a denial of certification and must establish and implement written procedures for receiving and addressing appeals from eligible entities challenging such adverse regulatory audit results and for investigating and deciding on appeals in a fair and meaningful manner. The appeals procedures must provide similar protections to those offered by FDA under §§1.692 and 1.693, including requirements to:

(1) Make the appeals procedures publicly available;

(2) Use competent persons, who may or may not be external to the accredited third-party certification body, who are free from bias or prejudice and have not participated in the certification decision or be subordinate to a person who has participated in the certification decision, to investigate and decide appeals;

(3) Advise the eligible entity of the final decision on its appeal; and

(4) Maintain records under §1.658 of the appeal, the final decision, and the basis for such decision.

§ 1.653 What must an accredited third-party certification body do when issuing food or facility certifications?

(a) *Basis for issuance of a food or facility certification.* (1) Prior to issuing a food or facility certification to an eligible entity, an accredited third-party certification body (or, where applicable, an audit agent on its behalf) must complete a regulatory audit that meets the requirements of §1.651 and any other activities that may be necessary to determine compliance with the applicable food safety requirements of the FD&C Act and FDA regulations.

(2) If, as a result of an observation during a regulatory audit, an eligible entity must implement a corrective action plan to address a deficiency, an accredited third-party certification body

may not issue a food or facility certification to such entity until after the accredited third-party certification body verifies that eligible entity has implemented the corrective action plan through methods that reliably verify the corrective action was taken and as a result the identified deficiency is unlikely to recur, except onsite verification is required for corrective actions required to address deficiencies that are the subject of a notification under § 1.656(c).

(3) An accredited third-party certification body must consider each observation and the data and other information from a regulatory audit and other activities conducted under § 1.651 to determine whether the entity was in compliance with the applicable food safety requirements of the FD&C Act and FDA regulations at the time of the audit and whether the eligible entity, given its food safety system and practices, would be likely to remain in compliance for the duration of any certification issued under this subpart.

(4) A single regulatory audit may result in issuance of one or more food or facility certifications under this subpart, provided that the requirements of issuance are met as to each such certification.

(5) Where an accredited third-party certification body uses an audit agent to conduct a regulatory audit of an eligible entity under this subpart, the accredited third-party certification body (and not the audit agent) must make the determination whether to issue a food or facility certification based on the results of such regulatory audit.

(b) *Issuance of a food or facility certification and submission to FDA.* (1) Any food or facility certification issued under this subpart must be submitted to FDA electronically and in English. The accredited third-party certification body may issue a food or facility certification under this subpart for a term of up to 12 months.

(2) A food or facility certification must contain, at a minimum, the following elements:

(i) The name and address of the accredited third-party certification body and the scope and date of its accreditation under this subpart;

(ii) The name, address, FDA Establishment Identifier, and unique facility identifier, if designated by FDA, of the eligible entity to which the food or facility certification was issued;

(iii) The name, address, FDA Establishment Identifier, and unique facility identifier, if designated by FDA, of the facility where the regulatory audit was conducted, if different than the eligible entity;

(iv) The scope and date(s) of the regulatory audit and the certification number;

(v) The name of the audit agent(s) (where applicable) conducting the regulatory audit; and

(vi) The scope of the food or facility certification, date of issuance, and date of expiration.

(3) FDA may refuse to accept any certification for purposes of section 801(q) or 806 of the FD&C Act, if FDA determines, that such food or facility certification is not valid or reliable because, for example:

(i) The certification is offered in support of the admissibility of a food that was not within the scope of the certification;

(ii) The certification was issued by an accredited third-party certification body acting outside the scope of its accreditation under this subpart; or

(iii) The certification was issued without reliable demonstration that the requirements of paragraph (a) of this section were met.

§ 1.654 When must an accredited third-party certification body monitor an eligible entity that it has issued a food or facility certification?

If an accredited third-party certification body has reason to believe that an eligible entity to which it issued a food or facility certification may no longer be in compliance with the applicable food safety requirements of the FD&C Act and FDA regulations, the accredited third-party certification body must conduct any monitoring (including an onsite audit) of such eligible entity necessary to determine whether the entity is in compliance with such requirements. The accredited third-party certification body must immediately notify FDA, under § 1.656(d), if

it withdraws or suspends a food or facility certification because it determines that the entity is no longer in compliance with the applicable food safety requirements of the FD&C Act and FDA regulations. The accredited third-party certification body must maintain records of such monitoring under § 1.658.

§ 1.655 How must an accredited third-party certification body monitor its own performance?

(a) An accredited third-party certification body must annually, upon FDA request made for cause, or as required under § 1.631(f)(1)(i), § 1.634(d)(1)(i), or § 1.635(c)(1)(i), conduct a self-assessment that includes evaluation of compliance with this subpart, including:

(1) The performance of its officers, employees, or other agents involved in auditing and certification activities, including the performance of audit agents in examining facilities, process(es), and food using the applicable food safety requirements of the FD&C Act and FDA regulations;

(2) The degree of consistency among its officers, employees, or other agents involved in auditing and certification activities, including evaluating whether its audit agents interpreted audit protocols in a consistent manner;

(3) The compliance of the accredited third-party certification body and its officers, employees, and other agents involved in auditing and certification activities, with the conflict of interest requirements of § 1.657;

(4) Actions taken in response to the results of any assessments conducted by FDA or, where applicable, the recognized accreditation body under § 1.621; and

(5) As requested by FDA, any other aspects of its performance relevant to a determination of whether the accredited third-party certification body is in compliance with this subpart.

(b) As a means to assess its performance, the accredited third-party certification body may evaluate the compliance of one or more of eligible entities to which a food or facility certification was issued under this subpart.

(c) Based on the assessments and evaluations conducted under paragraphs (a) and (b) of this section, the accredited third-party certification body must:

(1) Identify any deficiencies in complying with the requirements of this subpart;

(2) Quickly implement corrective action(s) that effectively address the identified deficiencies; and

(3) Under § 1.658, establish and maintain records of such corrective action(s).

(d) The accredited third-party certification body must prepare a written report of the results of its self-assessment that includes:

(1) A description of any corrective action(s) taken under paragraph (c) of this section;

(2) A statement disclosing the extent to which the accredited third-party certification body, and its officers, employees, and other agents involved in auditing and certification activities, complied with the conflict of interest requirements in § 1.657; and

(3) A statement attesting to the extent to which the accredited third-party certification body complied with the applicable requirements of this subpart.

(e) An accredited third-party certification body may use a report, supplemented as necessary, on its conformance to ISO/IEC 17021: 2011 or ISO/IEC 17065: 2012 in meeting the requirements of this section.

§ 1.656 What reports and notifications must an accredited third-party certification body submit?

(a) *Reporting results of regulatory audits.* An accredited third-party certification body must submit a regulatory audit report, as described in § 1.652(b), electronically, in English, to FDA and to the recognized accreditation body that granted its accreditation (where applicable), no later than 45 days after completing such audit.

(b) *Reporting results of accredited third-party certification body self-assessments.* An accredited third-party certification body must submit the report of its annual self-assessment required by § 1.655 electronically to its recognized accreditation body (or, in the case of direct accreditation, electronically and in English, to FDA), within 45 days of the anniversary date of its accreditation

under this subpart. For an accredited third-party certification body subject to an FDA request for cause, or § 1.631(f)(1)(i), § 1.634(d)(1)(i), or § 1.635(c)(1)(i), the report of its self-assessment must be submitted to FDA electronically, in English, within 60 days of the FDA request, denial of renewal, revocation, or relinquishment of recognition of the accreditation body that granted its accreditation. Such report must include an up-to-date list of any audit agents it uses to conduct audits under this subpart.

(c) *Notification to FDA of a serious risk to public health.* An accredited third-party certification body must immediately notify FDA electronically, in English, if during a regulatory or consultative audit, any of its audit agents or the accredited third-party certification body itself discovers a condition that could cause or contribute to a serious risk to the public health, providing the following information:

(1) The name, physical address, and unique facility identifier, if designated by FDA, of the eligible entity subject to the audit, and, where applicable, the registration number under subpart H of this part;

(2) The name, physical address, and unique facility identifier, if designated by FDA, of the facility where the condition was discovered (if different from that of the eligible entity) and, where applicable, the registration number assigned to the facility under subpart H of this part; and

(3) The condition for which notification is submitted.

(d) *Immediate notification to FDA of withdrawal or suspension of a food or facility certification.* An accredited third-party certification body must notify FDA electronically, in English, immediately upon withdrawing or suspending any food or facility certification of an eligible entity and the basis for such action.

(e) *Notification to its recognized accreditation body or an eligible entity.* (1) After notifying FDA under paragraph (c) of this section, an accredited third-party certification body must immediately notify the eligible entity of such condition and must immediately thereafter notify the recognized accreditation body that granted its accreditation, except for third-party certification bodies directly accredited by FDA. Where feasible and reliable, the accredited third-party certification body may contemporaneously notify its recognized accreditation body and/or the eligible entity when notifying FDA.

(2) An accredited third-party certification body must notify its recognized accreditation body (or, in the case of direct accreditation, FDA) electronically, in English, within 30 days after making any significant change that would affect the manner in which it complies with the requirements of this subpart and must include with such notification the following information:

(i) A description of the change; and

(ii) An explanation for the purpose of the change.

§ 1.657 How must an accredited third-party certification body protect against conflicts of interest?

(a) An accredited third-party certification body must implement a written program to protect against conflicts of interest between the accredited third-party certification body (and its officers, employees, and other agents involved in auditing and certification activities) and an eligible entity seeking a food safety audit or food or facility certification from, or audited or certified by, such accredited third-party certification body, including the following:

(1) Ensuring that the accredited third-party certification body and its officers, employees, or other agents involved in auditing and certification activities do not own, operate, have a financial interest in, manage, or otherwise control an eligible entity to be certified, or any affiliate, parent, or subsidiary of the entity;

(2) Ensuring that the accredited third-party certification body and, its officers, employees, or other agents involved in auditing and certification activities are not owned, managed, or controlled by any person that owns or operates an eligible entity to be certified;

(3) Ensuring that an audit agent of the accredited third-party certification

body does not own, operate, have a financial interest in, manage, or otherwise control an eligible entity or any affiliate, parent, or subsidiary of the entity that is subject to a consultative or regulatory audit by the audit agent; and

(4) Prohibiting an accredited third-party certification body's officer, employee, or other agent involved in auditing and certification activities from accepting any money, gift, gratuity, or other item of value from the eligible entity to be audited or certified under this subpart.

(5) The items specified in paragraph (a)(4) of this section do not include:

(i) Money representing payment of fees for auditing and certification services and reimbursement of direct costs associated with an onsite audit by the third-party certification body; or

(ii) Lunch of de minimis value provided during the course of an audit and on the premises where the audit is conducted, if necessary to facilitate the efficient conduct of the audit.

(b) An accredited third-party certification body may accept the payment of fees for auditing and certification services and the reimbursement of direct costs associated with an audit of an eligible entity only after the date on which the report of such audit was completed or the date a food or facility certification was issued, whichever is later. Such payment is not considered a conflict of interest for purposes of paragraph (a) of this section.

(c) The financial interests of the spouses and children younger than 18 years of age of accredited third-party certification body's officers, employees, and other agents involved in auditing and certification activities will be considered the financial interests of such officers, employees, and other agents involved in auditing and certification activities.

(d) An accredited third-party certification body must maintain on its Web site an up-to-date list of the eligible entities to which it has issued food or facility certifications under this subpart. For each such eligible entity, the Web site also must identify the duration and scope of the food or facility certification and date(s) on which the eligible entity paid the accredited third-party certification body any fee or reimbursement associated with such audit or certification.

§ 1.658 What records requirements must a third-party certification body that has been accredited meet?

(a) A third-party certification body that has been accredited must maintain electronically for 4 years records created during its period of accreditation (including documents and data) that document compliance with this subpart, including:

(1) Any audit report and other documents resulting from a consultative audit conducted under this subpart, including the audit agent's observations, correspondence with the eligible entity, verification of any corrective action(s) taken to address deficiencies identified during the audit;

(2) Any request for a regulatory audit from an eligible entity;

(3) Any audit report and other documents resulting from a regulatory audit conducted under this subpart, including the audit agent's observations, correspondence with the eligible entity, verification of any corrective action(s) taken to address deficiencies identified during the audit, and, when sampling and analysis is conducted, laboratory testing records and results from a laboratory that is accredited in accordance with § 1.651(b)(3), and documentation demonstrating such laboratory is accredited in accordance with § 1.651(b)(3);

(4) Any notification submitted by an audit agent to the accredited third-party certification body in accordance with § 1.650(a)(5);

(5) Any challenge to an adverse regulatory audit decision and the disposition of the challenge;

(6) Any monitoring it conducted of an eligible entity to which food or facility certification was issued;

(7) Its self-assessments and corrective actions taken to address any deficiencies identified during a self-assessment; and

(8) Significant changes to its auditing or certification program that might affect compliance with this subpart.

(b) An accredited third-party certification body must make the records of a consultative audit required by paragraph (a)(1) of this section available to FDA in accordance with section 414 of the FD&C Act.

(c) An accredited third-party certification body must make the records required by paragraphs (a)(2) through (8) of this section available for inspection and copying promptly upon written request of an authorized FDA officer or employee at the place of business of the accredited third-party certification body or at a reasonably accessible location. If such records are requested by FDA electronically, the records must be submitted electronically not later than 10 business days after the date of the request. Additionally, if the records are maintained in a language other than English, an accredited third-party certification body must electronically submit an English translation within a reasonable time.

PROCEDURES FOR ACCREDITATION OF THIRD-PARTY CERTIFICATION BODIES UNDER THIS SUBPART

§ 1.660 Where do I apply for accreditation or renewal of accreditation by a recognized accreditation body and what happens once the recognized accreditation body decides on my application?

(a) *Submission of accreditation or renewal application to a recognized accreditation body.* A third-party certification body seeking accreditation must submit its request for accreditation or renewal of accreditation by a recognized accreditation body identified on the Web site described in § 1.690.

(b) *Notice of records custodian after denial of application for renewal of accreditation.* An applicant whose renewal application was denied by a recognized accreditation body must notify FDA electronically, in English, within 10 business days of the date of issuance of a denial of accreditation or denial of the renewal application, of the name and contact information of the custodian who will maintain the records required by § 1.658(a) and make them available to FDA as required by § 1.658(b) and (c). The contact information for the custodian must include, at a minimum, an email address and the physical address where the records required by § 1.658(a) will be located.

(c) *Effect of denial of an application for renewal of accreditation on food or facility certifications issued to eligible entities.* A food or facility certification issued by an accredited third-party certification body prior to issuance of the denial of its renewal application l will remain in effect until the certification expires. If FDA has reason to believe that a certification issued for purposes of section 801(q) or 806 of the FD&C Act is not valid or reliable, FDA may refuse to consider the certification in determining the admissibility of the article of food for which the certification was offered or in determining the importer's eligibility for participation in VQIP.

(d) *Public notice of denial of an application for renewal of accreditation.* FDA will provide notice on the Web site described in § 1.690 of the date of issuance of a denial of renewal of accreditation of a third-party certification body that had previous been accredited.

§ 1.661 What is the duration of accreditation by a recognized accreditation body?

A recognized accreditation body may grant accreditation to a third-party certification body under this subpart for a period not to exceed 4 years.

§ 1.662 How will FDA monitor accredited third-party certification bodies?

(a) FDA will periodically evaluate the performance of each accredited third-party certification body to determine whether the accredited third-party certification body continues to comply with the applicable requirements of this subpart and whether there are deficiencies in the performance of the accredited third-party certification body that, if not corrected, would warrant withdrawal of its accreditation under § 1.664. FDA will evaluate each directly accredited third-party certification body annually. For a third-party certification body accredited by a recognized accreditation body, FDA will evaluate an accredited third-party certification body not later than 3 years after the date of

accreditation for a 4-year term of accreditation, or by no later than the mid-term point for accreditation granted for less than 4 years. FDA may conduct additional performance assessments of an accredited third-party certification body at any time.

(b) In evaluating the performance of an accredited third-party certification body under paragraph (a) of this section, FDA may review any one or more of the following:

(1) Regulatory audit reports and food and facility certifications;

(2) The accredited third-party certification body's self-assessments under § 1.655;

(3) Reports of assessments by a recognized accreditation body under § 1.621;

(4) Documents and other information relevant to a determination of the accredited third-party certification body's compliance with the applicable requirements of this subpart; and

(5) Information obtained by FDA, including during inspections, audits, onsite observations, or investigations, of one or more eligible entities to which a food or facility certification was issued by such accredited third-party certification body.

(c) FDA may conduct its evaluation of an accredited third-party certification body through a site visit to an accredited third-party certification body's headquarters (or other location that manages audit agents conducting food safety audits under this subpart, if different than its headquarters), through onsite observation of an accredited third party certification body's performance during a food safety audit of an eligible entity, or through document review.

§ 1.663 How do I request an FDA waiver or waiver extension for the 13-month limit for audit agents conducting regulatory audits?

(a) An accredited third-party certification body may submit a request to FDA to waive the requirements of § 1.650(c) preventing an audit agent from conducting a regulatory audit of an eligible entity if the audit agent (or, in the case that the third-party certification body is an individual, the third-party certification body) has conducted a food safety audit of such entity during the previous 13 months. The accredited third-party certification body seeking a waiver or waiver extension must demonstrate there is insufficient access to audit agents and any third-party certification bodies that are comprised of an individual in the country or region where the eligible entity is located.

(b) Requests for a waiver or waiver extension and all documents provided in support of the request must be submitted to FDA electronically, in English. The requestor must provide such translation and interpretation services as are needed by FDA to process the request.

(c) The request must be signed by the requestor or by any individual authorized to act on behalf of the requestor for purposes of seeking such waiver or waiver extension.

(d) FDA will review requests for waivers and waiver extensions on a first in, first out basis according to the date on which the completed submission is received; however, FDA may prioritize the review of specific requests to meet the needs of the program. FDA will evaluate any completed waiver request to determine whether the criteria for waiver have been met.

(e) FDA will notify the requestor whether the request for a waiver or waiver extension is approved or denied.

(f) If FDA approves the request, issuance of the waiver will state the duration of the waiver and list any limitations associated with it. If FDA denies the request, the issuance of a denial of a waiver request will state the basis for denial and will provide the address and procedures for requesting reconsideration of the request under § 1.691.

(g) Unless FDA notifies a requestor that its waiver request has been approved, an accredited third-party certification body must not use the audit agent to conduct a regulatory audit of such eligible entity until the 13-month limit in § 1.650(c) has elapsed.

§ 1.664 When would FDA withdraw accreditation?

(a) *Mandatory withdrawal.* FDA will withdraw accreditation from a third-party certification body:

(1) Except as provided in paragraph (b) of this section, if the food or facility certified under this subpart is linked to an outbreak of foodborne illness or chemical or physical hazard that has a reasonable probability of causing serious adverse health consequences or death in humans or animals;

(2) Following an evaluation and finding by FDA that the third-party certification body no longer complies with the applicable requirements of this subpart; or

(3) Following its refusal to allow FDA to access records under §1.658 or to conduct an audit, assessment, or investigation necessary to ensure continued compliance with this subpart.

(4) If payment of the third-party certification body's annual fee is not received within 90 days of the payment due date, as specified in §1.725(c)(3).

(b) *Exception*. FDA may waive mandatory withdrawal under paragraph (a)(1) of this section, if FDA:

(1) Conducts an investigation of the material facts related to the outbreak of human or animal illness;

(2) Reviews the relevant audit records and the actions taken by the accredited third-party certification body in support of its decision to certify; and

(3) Determines that the accredited third-party certification body satisfied the requirements for issuance of certification under this subpart.

(c) *Discretionary withdrawal*. FDA may withdraw accreditation, in whole or in part, from a third-party certification body when such third-party certification body is accredited by an accreditation body for which recognition is revoked under §1.634, if FDA determines there is good cause for withdrawal, including:

(1) Demonstrated bias or lack of objectivity when conducting activities under this subpart; or

(2) Performance that calls into question the validity or reliability of its food safety audits or certifications.

(d) *Records access*. FDA may request records of the accredited third-party certification body under §1.658 and, where applicable, may request records under §1.625 of an accreditation body that has been recognized under §1.625, when considering withdrawal under paragraph (a)(1), (a)(2), or (c) of this section.

(e) *Notice to the third-party certification body of withdrawal of accreditation*. (1) FDA will notify a third-party certification body of the withdrawal of its accreditation through issuance of a withdrawal that will state the grounds for withdrawal, the procedures for requesting a regulatory hearing under §1.693 on the withdrawal, and the procedures for requesting reaccreditation under §1.666.

(2) Within 10 business days of the date of issuance of the withdrawal, the third-party certification body must notify FDA electronically, in English, of the name of the custodian who will maintain the records required by §1.658, and provide contact information for the custodian, which will at least include an email address, and the street address where the records will be located.

(f) *Effect of withdrawal of accreditation on eligible entities*. A food or facility certification issued by a third-party certification body prior to withdrawal will remain in effect until the certification terminates by expiration. If FDA has reason to believe that a certification issued for purposes of section 801(q) or 806 of the FD&C Act is not valid or reliable, FDA may refuse to consider the certification in determining the admissibility of the article of food for which the certification was offered or in determining the importer's eligibility for participation in VQIP.

(g) *Effect of withdrawal of accreditation on recognized accreditation bodies*. (1) FDA will notify a recognized accreditation body if the accreditation of a third-party certification body it accredited is withdrawn by FDA. Such accreditation body's recognition will remain in effect if, no later than 60 days after withdrawal, the accreditation body conducts a self-assessment under §1.622 and reports the results of the self-assessment to FDA as required by §1.623(b).

(2) FDA may revoke the recognition of an accreditation body whenever FDA determines there is good cause for revocation of recognition under §1.634.

(h) *Public notice of withdrawal accreditation.* FDA will provide notice on the Web site described in § 1.690 of its withdrawal of accreditation of a third-party certification body and provide a description of the basis for withdrawal.

[80 FR 74650, Nov. 27, 2015, as amended at 81 FR 90193, Dec. 14, 2016]

§ 1.665 What if I want to voluntarily relinquish accreditation or do not want to renew accreditation?

(a) *Notice to FDA of intent to relinquish or not to renew accreditation.* A third-party certification body must notify FDA electronically, in English, at least 60 days before voluntarily relinquishing accreditation or before allowing accreditation to expire without seeking renewal. The certification body must provide the name and contact information of the custodian who will maintain the records required under § 1.658(a) after the date of relinquishment or the date accreditation expires, as applicable, and make them available to FDA as required by § 1.658(b) and (c). The contact information for the custodian must include, at a minimum, an email address and the physical address where the records required by § 1.658(a) will be located.

(b) *Notice to recognized accreditation body and eligible entities of intent to relinquish or not to renew accreditation.* No later than 15 business days after notifying FDA under paragraph (a) of this section, the certification body must notify its recognized accreditation body and any eligible entity with current certifications that it intends to relinquish accreditation or to allow its accreditation to expire, specifying the date on which relinquishment or expiration will occur. The recognized accreditation body must establish and maintain records of such notification under § 1.625(a).

(c) *Effect of voluntary relinquishment or expiration of accreditation on food or facility certifications issued to eligible entities.* A food or facility certification issued by a third-party certification body prior to relinquishment or expiration of its accreditation will remain in effect until the certification expires. If FDA has reason to believe that a certification issued for purposes of section 801(q) or 806 of the FD&C Act is not valid or reliable, FDA may refuse to consider the certification in determining the admissibility of the article of food for which the certification was offered or in determining the importer's eligibility for participation in VQIP.

(d) *Public notice of voluntary relinquishment or expiration of accreditation.* FDA will provide notice on the Web site described in § 1.690 of the voluntary relinquishment or expiration of accreditation of a certification body under this subpart.

§ 1.666 How do I request reaccreditation?

(a) *Application following withdrawal.* FDA will reinstate the accreditation of a third-party certification body for which it has withdrawn accreditation:

(1) If, in the case of direct accreditation, FDA determines, based on evidence presented by the third-party certification body, that the third-party certification body satisfies the applicable requirements of this subpart and adequate grounds for withdrawal no longer exist; or

(2) In the case of a third-party certification body accredited by an accreditation body for which recognition has been revoked under § 1.634:

(i) If the third-party certification body becomes accredited by another recognized accreditation body or by FDA through direct accreditation no later than 1 year after withdrawal of accreditation, or the original date of the expiration of accreditation, whichever comes first; or

(ii) Under such conditions as FDA may impose in withdrawing accreditation.

(b) *Application following voluntary relinquishment.* A third-party certification body that previously relinquished its accreditation under § 1.665 may seek accreditation by submitting a new application for accreditation under § 1.660 or, where applicable, § 1.670.

ADDITIONAL PROCEDURES FOR DIRECT ACCREDITATION OF THIRD-PARTY CERTIFICATION BODIES UNDER THIS SUBPART

§ 1.670 How do I apply to FDA for direct accreditation or renewal of direct accreditation?

(a) *Eligibility*. (1) FDA will accept applications from third-party certification bodies for direct accreditation or renewal of direct accreditation only if FDA determines that it has not identified and recognized an accreditation body to meet the requirements of section 808 of the FD&C Act within 2 years after establishing the accredited third-party audits and certification program. Such FDA determination may apply, as appropriate, to specific types of third-party certification bodies, types of expertise, or geographic location; or through identification by FDA of any requirements of section 808 of the FD&C Act not otherwise met by previously recognized accreditation bodies. FDA will only accept applications for direct accreditation and renewal applications that are within the scope of the determination.

(2) FDA may revoke or modify a determination under paragraph (a)(1) of this section if FDA subsequently identifies and recognizes an accreditation body that affects such determination.

(3) FDA will provide notice on the Web site described in § 1.690 of a determination under paragraph (a)(1) of this section and of a revocation or modification of the determination under paragraph (a)(1) of this section, as described in paragraph (a)(2) of this section.

(b) *Application for direct accreditation or renewal of direct accreditation*. (1) A third-party certification body seeking direct accreditation or renewal of direct accreditation must submit an application to FDA, demonstrating that it is within the scope of the determination issued under paragraph (a)(1) of this section, and it meets the eligibility requirements of § 1.640.

(2) Applications and all documents provided as part of the application process must be submitted electronically, in English. An applicant must provide such translation and interpretation services as are needed by FDA to process the application, including during an onsite audit of the applicant.

(3) The application must be signed in the manner designated by FDA by an individual authorized to act on behalf of the applicant for purposes of seeking or renewing direct accreditation.

§ 1.671 How will FDA review my application for direct accreditation or renewal of direct accreditation and what happens once FDA decides on my application?

(a) *Review of a direct accreditation or renewal application*. FDA will examine a third-party certification body's direct accreditation or renewal application for completeness and notify the applicant of any deficiencies. FDA will review applications for direct accreditation and for renewal of direct accreditation on a first in, first out basis according to the date the completed submission is received; however, FDA may prioritize the review of specific applications to meet the needs of the program.

(b) *Evaluation of a direct accreditation or renewal application*. FDA will evaluate any completed application to determine whether the applicant meets the requirements for direct accreditation under this subpart. If FDA does not reach a final decision on a renewal application before the expiration of the direct accreditation, FDA may extend the duration of such direct accreditation for a specified period of time or until the Agency reaches a final decision on the renewal application.

(c) *Notice of approval or denial*. FDA will notify the applicant that its direct accreditation or renewal application has been approved through issuance of or denied.

(d) *Issuance of direct accreditation*. If an application has been approved, the issuance of the direct accreditation that will list any limitations associated with the accreditation.

(e) *Issuance of denial of direct accreditation*. If FDA issues a denial of direct accreditation or denial of a renewal application, the issuance of the denial of direct accreditation will state the basis for such denial and provide the procedures for requesting reconsideration of the application under § 1.691.

(f) *Notice of records custodian after denial of application for renewal of direct*

accreditation. An applicant whose renewal application was denied must notify FDA electronically, in English, within 10 business days of the date of issuance of a denial of a renewal application, of the name and contact information of the custodian who will maintain the records required by §1.658(a) and make them available to FDA as required by §1.658(b) and (c). The contact information for the custodian must include, at a minimum, an email address and the physical address where the records required by §1.658(b) will be located.

(g) *Effect of denial of renewal of direct accreditation on food or facility certifications issued to eligible entities*. A food or facility certification issued by an accredited third-party certification body prior to issuance of the denial of its renewal application will remain in effect until the certification expires. If FDA has reason to believe that a certification issued for purposes of section 801(q) or 806 of the FD&C Act is not valid or reliable, FDA may refuse to consider the certification in determining the admissibility of the article of food for which the certification was offered or in determining the importer's eligibility for participation in VQIP.

(h) *Public notice of denial of renewal of direct accreditation*. FDA will provide notice on the Web site described in §1.690 of the issuance of a denial of renewal application for direct accreditation under this subpart.

§ 1.672 What is the duration of direct accreditation?

FDA will grant direct accreditation of a third-party certification body for a period not to exceed 4 years.

REQUIREMENTS FOR ELIGIBLE ENTITIES UNDER THIS SUBPART

§ 1.680 How and when will FDA monitor eligible entities?

FDA may, at any time, conduct an onsite audit of an eligible entity that has received food or facility certification from an accredited third-party certification body under this subpart. Where FDA determines necessary or appropriate, the unannounced audit may be conducted with or without the accredited third-party certification body or the recognized accreditation body (where applicable) present. An FDA audit conducted under this section will be conducted on an unannounced basis and may be preceded by a request for a 30-day operating schedule.

§ 1.681 How frequently must eligible entities be recertified?

An eligible entity seeking recertification of a food or facility certification under this subpart must apply for recertification prior to the expiration of its certification. For certifications used in meeting the requirements of section 801(q) or 806 of the FD&C Act, FDA may require an eligible entity to apply for recertification at any time FDA determines appropriate under such section.

GENERAL REQUIREMENTS OF THIS SUBPART

§ 1.690 How will FDA make information about recognized accreditation bodies and accredited third-party certification bodies available to the public?

FDA will place on its Web site a registry of recognized accreditation bodies and accredited third-party certification bodies, including the name, contact information, and scope and duration of recognition or accreditation. The registry may provide information on third-party certification bodies accredited by recognized accreditation bodies through links to the Web sites of such recognized accreditation bodies. FDA will also place on its Web site a list of accreditation bodies for which it has denied renewal of recognition, for which FDA has revoked recognition, and that have relinquished their recognition or have allowed their recognition to expire. FDA will also place in its Web site a list of certification bodies whose renewal of accreditation has been denied, for which FDA has withdrawn accreditation, and that have relinquished their accreditations or have allowed their accreditations to expire. FDA will place on its Web site determinations under §1.670(a)(1) and modifications of such determinations under §1.670(a)(2).

§ 1.691 How do I request reconsideration of a denial by FDA of an application or a waiver request?

(a) An accreditation body may seek reconsideration of the denial of an application for recognition, renewal of recognition, or reinstatement of recognition no later than 10 business days after the date of the issuance of such denial.

(b) A third-party certification body may seek reconsideration of the denial of an application for direct accreditation, renewal of direct accreditation, reaccreditation of directly accredited third-party certification body, a request for a waiver of the conflict of interest requirement in § 1.650(b), or a waiver extension no later than 10 business days after the date of the issuance of such denial.

(c) A request to reconsider an application or waiver request under paragraph (a) or (b) of this section must be signed by the requestor or by an individual authorized to act on its behalf in submitting the request for reconsideration. The request must be submitted electronically in English and must comply with the procedures described in the notice.

(d) After completing its review and evaluation of the request for reconsideration, FDA will notify the requestor through the issuance of the recognition, direct accreditation, or waiver upon reconsideration or through the issuance of a denial of the application or waiver request under paragraph (a) or (b) of this section upon reconsideration.

§ 1.692 How do I request internal agency review of a denial of an application or waiver request upon reconsideration?

(a) No later than 10 business days after the date of issuance of a denial of an application or waiver request upon reconsideration under § 1.691, the requestor may seek internal agency review of such denial under § 10.75(c)(1) of this chapter.

(b) The request for internal agency review under paragraph (a) of this section must be signed by the requestor or by an individual authorized to act on its behalf in submitting the request for internal review. The request must be submitted electronically in English to the address specified in the denial upon reconsideration and must comply with procedures it describes.

(c) Under § 10.75(d) of this chapter, internal agency review of such denial must be based on the information in the administrative file, which will include any supporting information submitted under § 1.691(c).

(d) After completing the review and evaluation of the administrative file, FDA will notify the requestor of its decision to overturn the denial and grant the application or waiver request through issuance of an application or waiver request upon reconsideration or to affirm the denial of the application or waiver request upon reconsideration through issuance of a denial of an application or waiver request upon reconsideration.

(e) Issuance by FDA of a denial of an application or waiver request upon reconsideration constitutes final agency action under 5 U.S.C. 702.

§ 1.693 How do I request a regulatory hearing on a revocation of recognition or withdrawal of accreditation?

(a) *Request for hearing on revocation.* No later than 10 business days after the date of issuance of a revocation of recognition of an accreditation body under § 1.634, an individual authorized to act on the accreditation body's behalf may submit a request for a regulatory hearing on the revocation under part 16 of this chapter. The issuance of revocation issued under § 1.634 will contain all of the elements required by § 16.22 of this chapter and will thereby constitute the notice of an opportunity for hearing under part 16 of this chapter.

(b) *Request for hearing on withdrawal.* No later than 10 business days after the date of issuance of a withdrawal of accreditation of a third-party certification body under § 1.664, an individual authorized to act on the third-party certification body's behalf may submit a request for a regulatory hearing on the withdrawal under part 16 of this chapter. The issuance of withdrawal under § 1.664 will contain all of the elements required by § 16.22 of this chapter and will thereby constitute the notice

of opportunity of hearing under part 16 of this chapter.

(c) *Submission of request for regulatory hearing*. The request for a regulatory hearing under paragraph (a) or (b) of this section must be submitted with a written appeal that responds to the basis for the FDA decision, as described in the issuance of revocation or withdrawal, as appropriate, and includes any supporting information upon which the requestor is relying. The request, appeal, and supporting information must be submitted in English to the address specified in the notice and must comply with the procedures it describes.

(d) *Effect of submission of request on FDA decision*. The submission of a request for a regulatory hearing under paragraph (a) or (b) of this section will not operate to delay or stay the effect of a decision by FDA to revoke recognition of an accreditation body or to withdraw accreditation of a third-party certification body unless FDA determines that a delay or a stay is in the public interest.

(e) *Presiding officer*. The presiding officer for a regulatory hearing for a revocation or withdrawal under this subpart will be designated after a request for a regulatory hearing is submitted to FDA.

(f) *Denial of a request for regulatory hearing*. The presiding officer may deny a request for regulatory hearing for a revocation or withdrawal under § 16.26(a) of this chapter when no genuine or substantial issue of fact has been raised.

(g) *Conduct of regulatory hearing*. (1) If the presiding officer grants a request for a regulatory hearing for a revocation or withdrawal, the hearing will be held within 10 business days after the date the request was filed or, if applicable, within a timeframe agreed upon in writing by requestor, the presiding officer, and FDA.

(2) The presiding officer must conduct the regulatory hearing for revocation or withdrawal under part 16 of this chapter, except that, under § 16.5(b) of this chapter, such procedures apply only to the extent that the procedures are supplementary and do not conflict with the procedures specified for regulatory hearings under this subpart. Accordingly, the following requirements of part 16 are inapplicable to regulatory hearings under this subpart: § 16.22 (Initiation of a regulatory hearing); § 16.24(e) (timing) and (f) (contents of notice); § 16.40 (Commissioner); § 16.60(a) (public process); § 16.95(b) (administrative decision and record for decision); and § 16.119 (Reconsideration and stay of action).

(3) A decision by the presiding officer to affirm the revocation of recognition or the withdrawal of accreditation is considered a final agency action under 5 U.S.C. 702.

§ 1.694 Are electronic records created under this subpart subject to the electronic records requirements of part 11 of this chapter?

Records that are established or maintained to satisfy the requirements of this subpart and that meet the definition of electronic records in § 11.3(b)(6) of this chapter are exempt from the requirements of part 11 of this chapter. Records that satisfy the requirements of this subpart, but that also are required under other applicable statutory provisions or regulations, remain subject to part 11 of this chapter.

§ 1.695 Are the records obtained by FDA under this subpart subject to public disclosure?

Records obtained by FDA under this subpart are subject to the disclosure requirements under part 20 of this chapter.

REQUIREMENTS FOR USER FEES UNDER THIS SUBPART

SOURCE: Sections 1.700 through 1.725 appear at 81 FR 90193, Dec. 14, 2016, unless otherwise noted.

§ 1.700 Who is subject to a user fee under this subpart?

(a) Accreditation bodies submitting applications or renewal applications for recognition in the third-party certification program;

(b) Recognized accreditation bodies participating in the third-party certification program;

(c) Third-party certification bodies submitting applications or renewal applications for direct accreditation; and

(d) Accredited third-party certification bodies (whether accredited by recognized accreditation bodies or by FDA through direct accreditation) participating in the third-party certification program.

§ 1.705 What user fees are established under this subpart?

(a) The following application fees:

(1) Accreditation bodies applying for recognition are subject to an application fee for the estimated average cost of the work FDA performs in reviewing and evaluating applications for recognition of accreditation bodies.

(2) Recognized accreditation bodies submitting renewal applications are subject to a renewal application fee for the estimated average cost of the work FDA performs in reviewing and evaluating renewal applications for recognition of accreditation bodies.

(3) Third-party certification bodies applying for direct accreditation are subject to an application fee for the estimated average cost of the work FDA performs in reviewing and evaluating applications for direct accreditation.

(4) Accredited third-party certification bodies applying for renewal of direct accreditation are subject to an application fee for the estimated average cost of the work FDA performs in reviewing and evaluating renewal applications for direct accreditation.

(b) The following annual fees:

(1) Recognized accreditation bodies are subject to an annual fee for the estimated average cost of the work FDA performs to monitor performance of recognized accreditation bodies under § 1.633.

(2) Third-party certification bodies directly accredited by FDA are subject to an annual fee for the estimated average cost of the work FDA performs to monitor directly accredited third-party certification bodies under § 1.662.

(3) Third-party certification bodies accredited by recognized accreditation bodies are subject to an annual fee for the estimated average cost of the work FDA performs to monitor third-party certification bodies that are accredited by a recognized accreditation body under § 1.662.

§ 1.710 How will FDA notify the public about the fee schedule?

FDA will notify the public of the fee schedule annually. The fee notice will be made publicly available prior to the beginning of the fiscal year for which the fees apply, except for the first fiscal year in which this regulation is effective. Each new fee schedule will be adjusted for inflation and improvements in the estimates of the cost to FDA of performing relevant work for the upcoming year.

§ 1.715 When must a user fee required by this subpart be submitted?

(a) Accreditation bodies applying for recognition and third-party certification bodies applying for direct accreditation must submit a fee concurrently with submitting an application or a renewal application.

(b) Accreditation bodies and third-party certification bodies subject to an annual fee must submit payment within 30 days of receiving billing for the fee.

§ 1.720 Are user fees under this subpart refundable?

User fees accompanying completed applications and annual fees under this subpart are not refundable.

§ 1.725 What are the consequences of not paying a user fee under this subpart on time?

(a) An application for recognition or renewal of recognition will not be considered complete for the purposes of § 1.631(a) until the date that FDA receives the application fee. An application for direct accreditation or for renewal of direct accreditation will not be considered complete for the purposes of § 1.671(a) until FDA receives the application fee.

(b) A recognized accreditation body that fails to submit its annual user fee within 30 days of the due date will have its recognition suspended.

(1) FDA will notify the accreditation body electronically that its recognition is suspended. FDA will notify the public of the suspension on the Web site described in § 1.690.

(2) While an accreditation body's recognition is suspended, the accreditation body will not be able to accredit

additional third-party certification bodies. The accreditation of third-party certification bodies that occurred prior to an accreditation body's suspension, as well as food or facility certifications issued by such third-party certification bodies, would remain in effect.

(3) If payment is not received within 90 days of the payment due date, FDA will revoke the accreditation body's recognition under §1.634(a)(4)(iii), and provide notice of such revocation in accordance with §1.634.

(c) An accredited third-party certification body that fails to submit its annual fee within 30 days of the due date will have its accreditation suspended.

(1) FDA will notify the third-party certification body that its accreditation is suspended, electronically and in English. FDA will notify a recognized accreditation body, electronically and in English, if the accreditation of one if its third-party certification bodies is suspended. FDA will notify the public of the suspension on the Web site described in §1.690.

(2) While a third-party certification body's accreditation is suspended, the third-party certification body will not be able to issue food or facility certifications. A food or facility certification issued by a third-party certification body prior to the suspension of the auditor/certification body accreditation will remain in effect.

(3) If payment is not received within 90 days of the payment due date, FDA will withdraw the third-party certification body's accreditation under §1.664(a)(4), and provide notice of such withdrawal in accordance with §1.664.

Subpart N [Reserved]

Subpart O—Sanitary Transportation of Human and Animal Food

SOURCE: 81 FR 20166, Apr. 6, 2016, unless otherwise noted.

GENERAL PROVISIONS

§ 1.900 Who is subject to this subpart?

(a) Except for non-covered businesses as defined in §1.904 and as provided for in paragraph (b) of this section, the requirements of this subpart apply to shippers, receivers, loaders, and carriers engaged in transportation operations whether or not the food is being offered for or enters interstate commerce. The requirements of this subpart apply in addition to any other requirements of this chapter that are applicable to the transportation of food, *e.g.*, in 21 CFR parts 1, 117, 118, 225, 507, and 589.

(b) The requirements of this subpart do not apply to shippers, receivers, loaders, or carriers when they are engaged in transportation operations:

(1) Of food that is transshipped through the United States to another country; or

(2) Of food that is imported for future export, in accordance with section 801(d)(3) of the Federal Food, Drug, and Cosmetic Act, and that is neither consumed nor distributed in the United States; or

(3) Of food when it is located in food facilities as defined in §1.227 of this chapter, 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.*).

§ 1.902 How do the criteria and definitions in this subpart apply under the Federal Food, Drug, and Cosmetic Act?

(a) The criteria and definitions of this subpart apply in determining whether food is adulterated within the meaning of section 402(i) of the Federal Food, Drug, and Cosmetic Act in that the food has been transported or offered for transport by a shipper, carrier by motor vehicle or rail vehicle, loader, or receiver engaged in transportation operations under conditions that are not in compliance with this subpart.

(b) The failure by a shipper, carrier by motor vehicle or rail vehicle, loader, or receiver engaged in transportation operations to comply with the requirements of this subpart is a prohibited act under section 301(hh) of the Federal Food, Drug, and Cosmetic Act.

§ 1.904 What definitions apply to this subpart?

The definitions and interpretations of terms in section 201 of the Federal Food, Drug, and Cosmetic Act are applicable to such terms when used in this part. The following definitions also apply:

Adequate means that which is needed to accomplish the intended purpose in keeping with good public health practice.

Animal food means food for animals other than man, and includes pet food, animal feed, and raw materials and ingredients.

Bulk vehicle means a tank truck, hopper truck, rail tank car, hopper car, cargo tank, portable tank, freight container, or hopper bin, or any other vehicle in which food is shipped in bulk, with the food coming into direct contact with the vehicle.

Carrier means a person who physically moves food by rail or motor vehicle in commerce within the United States. The term carrier does not include any person who transports food while operating as a parcel delivery service.

Cross-contact means the unintentional incorporation of a food allergen as defined in section 201(qq) of the Federal Food, Drug, and Cosmetic Act into food, except animal food.

Farm has the meaning given in § 1.227 of this chapter.

Food not completely enclosed by a container means any food that is placed into a container in such a manner that it is partially open to the surrounding environment. Examples of such containers include an open wooden basket or crate, an open cardboard box, a vented cardboard box with a top, or a vented plastic bag. This term does not include food transported in a bulk vehicle as defined in this subpart.

Full-time equivalent employee is a term used to represent the number of employees of a business entity for the purpose of determining whether the business is a small business. The number of full-time equivalent employees is determined by dividing the total number of hours of salary or wages paid directly to employees of the business entity and of all of its affiliates and subsidiaries by the number of hours of work in 1 year, 2,080 hours (*i.e.*, 40 hours x 52 weeks). If the result is not a whole number, round down to the next lowest whole number.

Loader means a person that loads food onto a motor or rail vehicle during transportation operations.

Non-covered business means a shipper, loader, receiver, or carrier engaged in transportation operations that has less than $500,000, as adjusted for inflation, in average annual revenues, calculated on a rolling basis, during the 3-year period preceding the applicable calendar year. For the purpose of determining an entity's 3-year average revenue threshold as adjusted for inflation, the baseline year for calculating the adjustment for inflation is 2011.

Operating temperature means a temperature sufficient to ensure that under foreseeable circumstances of temperature variation during transport, *e.g.*, seasonal conditions, refrigeration unit defrosting, multiple vehicle loading and unloading stops, the operation will meet the requirements of § 1.908(a)(3).

Pest means any objectionable animals or insects including birds, rodents, flies, and larvae.

Receiver means any person who receives food at a point in the United States after transportation, whether or not that person represents the final point of receipt for the food.

Shipper means a person, *e.g.*, the manufacturer or a freight broker, who arranges for the transportation of food in the United States by a carrier or multiple carriers sequentially.

Small business means a business employing fewer than 500 full-time equivalent employees except that for carriers by motor vehicle that are not also shippers and/or receivers, this term would mean a business subject to § 1.900(a) having less than $27,500,000 in annual receipts.

Transportation means any movement of food in by motor vehicle or rail vehicle in commerce within the United States.

Transportation equipment means equipment used in food transportation operations, *e.g.*, bulk and non-bulk containers, bins, totes, pallets, pumps, fittings, hoses, gaskets, loading systems, and unloading systems. Transportation

equipment also includes a railcar not attached to a locomotive or a trailer not attached to a tractor.

Transportation operations means all activities associated with food transportation that may affect the sanitary condition of food including cleaning, inspection, maintenance, loading and unloading, and operation of vehicles and transportation equipment. Transportation operations do not include any activities associated with the transportation of food that is completely enclosed by a container except a food that requires temperature control for safety, compressed food gases, food contact substances as defined in section 409(h)(6) of the Federal Food, Drug, and Cosmetic Act, human food byproducts transported for use as animal food without further processing, or live food animals except molluscan shellfish. In addition, transportation operations do not include any transportation activities that are performed by a farm.

Vehicle means a land conveyance that is motorized, *e.g.*, a motor vehicle, or that moves on rails, *e.g.*, a railcar, which is used in transportation operations.

VEHICLES AND TRANSPORTATION EQUIPMENT

§ 1.906 What requirements apply to vehicles and transportation equipment?

(a) Vehicles and transportation equipment used in transportation operations must be so designed and of such material and workmanship as to be suitable and adequately cleanable for their intended use to prevent the food they transport from becoming unsafe, *i.e.*, adulterated within the meaning of section 402(a)(1), (2), and (4) of the Federal Food, Drug, and Cosmetic Act during transportation operations.

(b) Vehicles and transportation equipment must be maintained in such a sanitary condition for their intended use as to prevent the food they transport from becoming unsafe during transportation operations.

(c) Vehicles and transportation equipment used in transportation operations for food requiring temperature control for safety must be designed, maintained, and equipped as necessary to provide adequate temperature control to prevent the food from becoming unsafe during transportation operations.

(d) Vehicles and transportation equipment must be stored in a manner that prevents it from harboring pests or becoming contaminated in any other manner that could result in food for which it will be used becoming unsafe during transportation operations.

TRANSPORTATION OPERATIONS

§ 1.908 What requirements apply to transportation operations?

(a) *General requirements.* (1) Unless stated otherwise in this section, the requirements of this section apply to all shippers, carriers, loaders, and receivers engaged in transportation operations. A person may be subject to these requirements in multiple capacities, *e.g.*, the shipper may also be the loader and the carrier, if the person also performs the functions of those respective persons as defined in this subpart. An entity subject to this subpart (shipper, loader, carrier, or receiver) may reassign, in a written agreement, its responsibilities under this subpart to another party subject to this subpart. The written agreement is subject to the records requirements of § 1.912(d).

(2) Responsibility for ensuring that transportation operations are carried out in compliance with all requirements in this subpart must be assigned to competent supervisory personnel.

(3) All transportation operations must be conducted under such conditions and controls necessary to prevent the food from becoming unsafe during transportation operations including:

(i) Taking effective measures such as segregation, isolation, or the use of packaging to protect food from contamination by raw foods and nonfood items in the same load.

(ii) Taking effective measures such as segregation, isolation, or other protective measures, such as hand washing, to protect food transported in bulk vehicles or food not completely enclosed by a container from contamination and cross-contact during transportation operations.

(iii) Taking effective measures to ensure that food that requires temperature control for safety is transported under adequate temperature control.

(4) The type of food, *e.g.*, animal feed, pet food, human food, and its production stage, *e.g.*, raw material, ingredient or finished food, must be considered in determining the necessary conditions and controls for the transportation operation.

(5) Shippers, receivers, loaders, and carriers, which are under the ownership or operational control of a single legal entity, as an alternative to meeting the requirements of paragraphs (b), (d), and (e) of this section may conduct transportation operations in conformance with common, integrated written procedures that ensure the sanitary transportation of food consistent with the requirements of this section. The written procedures are subject to the records requirements of § 1.912(e).

(6) If a shipper, loader, receiver, or carrier becomes aware of an indication of a possible material failure of temperature control or other conditions that may render the food unsafe during transportation, the food shall not be sold or otherwise distributed, and these persons must take appropriate action including, as necessary, communication with other parties to ensure that the food is not sold or otherwise distributed unless a determination is made by a qualified individual that the temperature deviation or other condition did not render the food unsafe.

(b) *Requirements applicable to shippers engaged in transportation operations.* (1) Unless the shipper takes other measures in accordance with paragraph (b)(3) of this section to ensure that vehicles and equipment used in its transportation operations are in appropriate sanitary condition for the transportation of the food, *i.e.*, that will prevent the food from becoming unsafe, the shipper must specify to the carrier and, when necessary, the loader, in writing, all necessary sanitary specifications for the carrier's vehicle and transportation equipment to achieve this purpose, including any specific design specifications and cleaning procedures. One-time notification shall be sufficient unless the design requirements and cleaning procedures required for sanitary transport change based upon the type of food being transported, in which case the shipper shall so notify the carrier in writing before the shipment. The information submitted by the shipper to the carrier is subject to the records requirements in § 1.912(a).

(2) Unless the shipper takes other measures in accordance with paragraph (b)(5) of this section to ensure that adequate temperature control is provided during the transportation of food that requires temperature control for safety under the conditions of shipment, a shipper of such food must specify in writing to the carrier, except a carrier who transports the food in a thermally insulated tank, and, when necessary, the loader, an operating temperature for the transportation operation including, if necessary, the pre-cooling phase. One-time notification shall be sufficient unless a factor, *e.g.*, the conditions of shipment, changes, necessitating a change in the operating temperature, in which case the shipper shall so notify the carrier in writing before the shipment. The information submitted by the shipper to the carrier is subject to the records requirements in § 1.912(a).

(3) A shipper must develop and implement written procedures, subject to the records requirements of § 1.912(a), adequate to ensure that vehicles and equipment used in its transportation operations are in appropriate sanitary condition for the transportation of the food, *i.e.*, will prevent the food from becoming unsafe during the transportation operation. Measures to implement these procedures may be accomplished by the shipper or by the carrier or another party covered by this subpart under a written agreement subject to the records requirements of § 1.912(a).

(4) A shipper of food transported in bulk must develop and implement written procedures, subject to the records requirements of § 1.912(a), adequate to ensure that a previous cargo does not make the food unsafe. Measures to ensure the safety of the food may be accomplished by the shipper or by the carrier or another party covered by this subpart under a written agreement

subject to the records requirements of §1.912(a).

(5) The shipper of food that requires temperature control for safety under the conditions of shipment must develop and implement written procedures, subject to the records requirements of §1.912(a), to ensure that the food is transported under adequate temperature control. Measures to ensure the safety of the food may be accomplished by the shipper or by the carrier or another party covered by this subpart under a written agreement subject to the records requirements of §1.912(a) and must include measures equivalent to those specified for carriers under paragraphs (e)(1) through (3) of this section.

(c) *Requirements applicable to loaders engaged in transportation operations.* (1) Before loading food not completely enclosed by a container onto a vehicle or into transportation equipment the loader must determine, considering, as appropriate, specifications provided by the shipper in accordance with paragraph (b)(1) of this section, that the vehicle or transportation equipment is in appropriate sanitary condition for the transport of the food, *e.g.*, it is in adequate physical condition, and free of visible evidence of pest infestation and previous cargo that could cause the food to become unsafe during transportation. This may be accomplished by any appropriate means.

(2) Before loading food that requires temperature control for safety, the loader must verify, considering, as appropriate, specifications provided by the shipper in accordance with paragraph (b)(2) of this section, that each mechanically refrigerated cold storage compartment or container is adequately prepared for the transportation of such food, including that it has been properly pre-cooled, if necessary, and meets other sanitary conditions for food transportation.

(d) *Requirements applicable to receivers engaged in transportation operations.* Upon receipt of food that requires temperature control for safety under the conditions of shipment, the receiver must take steps to adequately assess that the food was not subjected to significant temperature abuse, such as determining the food's temperature, the ambient temperature of the vehicle and its temperature setting, and conducting a sensory inspection, *e.g.*, for off-odors.

(e) *Requirements applicable to carriers engaged in transportation operations.* When the carrier and shipper have a written agreement that the carrier is responsible, in whole or in part, for sanitary conditions during the transportation operation, the carrier is responsible for the following functions as applicable per the agreement:

(1) A carrier must ensure that vehicles and transportation equipment meet the shipper's specifications and are otherwise appropriate to prevent the food from becoming unsafe during the transportation operation.

(2) A carrier must, once the transportation operation is complete and if requested by the receiver, provide the operating temperature specified by the shipper in accordance with paragraph (b)(2) of this section and, if requested by the shipper or receiver, demonstrate that it has maintained temperature conditions during the transportation operation consistent with the operating temperature specified by the shipper in accordance with paragraph (b)(2) of this section. Such demonstration may be accomplished by any appropriate means agreeable to the carrier and shipper, such as the carrier presenting measurements of the ambient temperature upon loading and unloading or time/temperature data taken during the shipment.

(3) Before offering a vehicle or transportation equipment with an auxiliary refrigeration unit for use for the transportation of food that requires temperature control for safety under the conditions of the shipment during transportation, a carrier must pre-cool each mechanically refrigerated cold storage compartment as specified by the shipper in accordance with paragraph (b)(2) of this section.

(4) If requested by the shipper, a carrier that offers a bulk vehicle for food transportation must provide information to the shipper that identifies the previous cargo transported in the vehicle.

(5) If requested by the shipper, a carrier that offers a bulk vehicle for food

transportation must provide information to the shipper that describes the most recent cleaning of the bulk vehicle.

(6) A carrier must develop and implement written procedures subject to the records requirements of § 1.912(b) that:

(i) Specify practices for cleaning, sanitizing if necessary, and inspecting vehicles and transportation equipment that the carrier provides for use in the transportation of food to maintain the vehicles and the transportation equipment in appropriate sanitary condition as required by § 1.906(b);

(ii) Describe how it will comply with the provisions for temperature control in paragraph (e)(2) of this section, and;

(iii) Describe how it will comply with the provisions for the use of bulk vehicles in paragraphs (e)(4) and (5) of this section.

TRAINING

§ 1.910 What training requirements apply to carriers engaged in transportation operations?

(a) When the carrier and shipper have agreed in a written contract that the carrier is responsible, in whole or in part, for the sanitary conditions during transportation operations, the carrier must provide adequate training to personnel engaged in transportation operations that provides an awareness of potential food safety problems that may occur during food transportation, basic sanitary transportation practices to address those potential problems, and the responsibilities of the carrier under this part. The training must be provided upon hiring and as needed thereafter.

(b) Carriers must establish and maintain records documenting the training described in paragraph (a) of this section. Such records must include the date of the training, the type of training, and the person(s) trained. These records are subject to the records requirements of § 1.912(c).

RECORDS

§ 1.912 What record retention and other records requirements apply to shippers, receivers, loaders, and carriers engaged in transportation operations?

(a) Shippers must retain records:

(1) That demonstrate that they provide specifications and operating temperatures to carriers as required by § 1.908(b)(1) and (2) as a regular part of their transportation operations for a period of 12 months beyond the termination of the agreements with the carriers.

(2) Of written agreements and the written procedures required by § 1.908(b)(3), (4), and (5), for a period of 12 months beyond when the agreements and procedures are in use in their transportation operations.

(b) Carriers must retain records of the written procedures required by § 1.908(e)(6) for a period of 12 months beyond when the agreements and procedures are in use in their transportation operations.

(c) Carriers must retain training records required by § 1.910(b) for a period of 12 months beyond when the person identified in any such records stops performing the duties for which the training was provided.

(d) Any person subject to this subpart must retain any other written agreements assigning tasks in compliance with this subpart for a period of 12 months beyond the termination of the agreements.

(e) Shippers, receivers, loaders, and carriers, which operate under the ownership or control of a single legal entity in accordance with the provisions of § 1.908(a)(5), must retain records of the written procedures for a period of 12 months beyond when the procedures are in use in their transportation operations.

(f) Shippers, receivers, loaders, and carriers must make all records required by this subpart available to a duly authorized individual promptly upon oral or written request.

(g) All records required by this subpart must be kept as original records, true copies (such as photocopies, pictures, scanned copies, microfilm,

microfiche, or other accurate reproductions of the original records), or electronic records.

(h) Records that are established or maintained to satisfy the requirements of this subpart and that meet the definition of electronic records in § 11.3(b)(6) of this chapter are exempt from the requirements of part 11 of this chapter. Records that satisfy the requirements of this subpart, but that also are required under other applicable statutory provisions or regulations, remain subject to part 11 of this chapter.

(i) Except for the written procedures required by § 1.908(e)(6)(i), offsite storage of records is permitted if such records can be retrieved and provided onsite within 24 hours of request for official review. The written procedures required by § 1.908(e)(6)(i) must remain onsite as long as the procedures are in use in transportation operations. Electronic records are considered to be onsite if they are accessible from an onsite location.

(j) All records required by this subpart are subject to the disclosure requirements under part 20 of this chapter.

WAIVERS

§ 1.914 Under what circumstances will we waive a requirement of this subpart?

We will waive any requirement of this subpart with respect to any class of persons, vehicles, food, or nonfood products, when we determine that:

(a) The waiver will not result in the transportation of food under conditions that would be unsafe for human or animal health; and

(b) The waiver will not be contrary to the public interest.

§ 1.916 When will we consider whether to waive a requirement of this subpart?

We will consider whether to waive a requirement of this subpart on our own initiative or on the petition submitted under § 10.30 of this chapter by any person who is subject to the requirements of this subpart with respect to any class of persons, vehicles, food, or nonfood products.

§ 1.918 What must be included in the Statement of Grounds in a petition requesting a waiver?

In addition to the requirements set forth in § 10.30 of this chapter, the Statement of Grounds in a petition requesting a waiver must:

(a) Describe with particularity the waiver requested, including the persons, vehicles, food, or nonfood product(s) to which the waiver would apply and the requirement(s) of this subpart to which the waiver would apply; and

(b) Present information demonstrating that the waiver will not result in the transportation of food under conditions that would be unsafe for human or animal health and will not be contrary to the public interest.

§ 1.920 What information submitted in a petition requesting a waiver or submitted in comments on such a petition is publicly available?

We will presume that information submitted in a petition requesting a waiver and comments submitted on such a petition does not contain information exempt from public disclosure under part 20 of this chapter and would be made public as part of the docket associated with this request.

§ 1.922 Who will respond to a petition requesting a waiver?

The Director or Deputy Directors of the Center for Food Safety and Applied Nutrition (CFSAN) or the Center for Veterinary Medicine (CVM), or the Director, Office of Compliance, CFSAN, or the Director, Office of Surveillance and Compliance, CVM, will respond to a petition requesting a waiver.

§ 1.924 What process applies to a petition requesting a waiver?

(a) In general, the procedures set forth in § 10.30 of this chapter govern our response to a petition requesting a waiver.

(b) Under § 10.30(h)(3) of this chapter, we will publish a notice in the FEDERAL REGISTER, requesting information and views on a filed petition, including information and views from persons who could be affected by the waiver if the petition were to be granted.

(c) Under § 10.30(e)(3) of this chapter, we will respond to the petitioner in writing.

(1) If we grant the petition, either in whole or in part, we will publish a notice in the FEDERAL REGISTER setting forth any waiver and the reasons for such waiver.

(2) If we deny the petition (including partial denials), our written response to the petitioner will explain the reason(s) for the denial.

(d) We will make readily accessible to the public, and periodically update, a list of filed petitions requesting waivers, including the status of each petition (for example, pending, granted, or denied).

§ 1.926 Under what circumstances may we deny a petition requesting a waiver?

We may deny a petition requesting a waiver if the petition does not provide the information required under § 1.918 (including the requirements of § 10.30 of this chapter), or if we determine that the waiver could result in the transportation of food under conditions that would be unsafe for human or animal health, or that the waiver could be contrary to the public interest.

§ 1.928 What process will we follow when waiving a requirement of this subpart on our own initiative?

If we, on our own initiative, determine that a waiver is appropriate, we will publish a notice in the FEDERAL REGISTER setting forth the waiver and the reasons for such waiver.

§ 1.930 When will a waiver that we grant become effective?

Any waiver that we grant will become effective on the date that notice of the waiver is published in the FEDERAL REGISTER.

§ 1.932 Under what circumstances may we modify or revoke a waiver?

We may modify or revoke a waiver if we determine that the waiver could result in the transportation of food under conditions that would be unsafe for human or animal health or that the waiver could be contrary to the public interest.

§ 1.934 What procedures apply if we determine that a waiver should be modified or revoked?

(a) We will provide the following notifications:

(1) We will notify the entity that initially requested the waiver, in writing at the address identified in its petition, if we determine that a waiver granted in response to its petition should be modified or revoked.

(2) We will publish a notice of our determination that a waiver should be modified or revoked in the FEDERAL REGISTER. This notice will establish a public docket so that interested parties may submit written submissions on our determination.

(b) We will consider timely written submissions submitted to the public docket from interested parties.

(c) We will publish a notice of our decision in the FEDERAL REGISTER. The effective date of the decision will be the date of publication of the notice.

Subpart P [Reserved]

Subpart Q—Administrative Detention of Drugs Intended for Human or Animal Use

§ 1.980 Administrative detention of drugs.

(a) *General.* This section sets forth the procedures for detention of drugs believed to be adulterated or misbranded. Administrative detention is intended to protect the public by preventing distribution or use of drugs encountered during inspections that may be adulterated or misbranded, until the Food and Drug Administration (FDA) has had time to consider what action it should take concerning the drugs, and to initiate legal action, if appropriate. Drugs that FDA orders detained may not be used, moved, altered, or tampered with in any manner by any person during the detention period, except as authorized under paragraph (h) of this section, until FDA terminates the detention order under paragraph (j) of this section, or the detention period expires, whichever occurs first.

(b) *Criteria for ordering detention.* Administrative detention of drugs may be ordered in accordance with this section

when an authorized FDA representative, during an inspection under section 704 of the Federal Food, Drug, and Cosmetic Act, has reason to believe that a drug, as defined in section 201(g) of the Federal Food, Drug, and Cosmetic Act, is adulterated or misbranded.

(c) *Detention period.* The detention is to be for a reasonable period that may not exceed 20 calendar days after the detention order is issued, unless the FDA Division Director in whose division the drugs are located determines that a greater period is required to seize the drugs, to institute injunction proceedings, or to evaluate the need for legal action, in which case the Division Director may authorize detention for 10 additional calendar days. The additional 10-calendar-day detention period may be ordered at the time the detention order is issued or at any time thereafter. The entire detention period may not exceed 30 calendar days, except when the detention period is extended under paragraph (g)(6) of this section. An authorized FDA representative may, in accordance with paragraph (j) of this section, terminate a detention before the expiration of the detention period.

(d) *Issuance of detention order.* (1) The detention order must be issued in writing, in the form of a detention notice, signed by the authorized FDA representative who has reason to believe that the drugs are adulterated or misbranded, and issued to the owner, operator, or agent in charge of the place where the drugs are located. If the owner or the user of the drugs is different from the owner, operator, or agent in charge of the place where the drugs are detained, a copy of the detention order must be provided to the owner or user of the drugs if the owner's or user's identity can be readily determined.

(2) If detention of drugs in a vehicle or other carrier is ordered, a copy of the detention order must be provided to the shipper of record and the owner of the vehicle or other carrier, if their identities can be readily determined.

(3) The detention order must include the following information:

(i) A statement that the drugs identified in the order are detained for the period shown;

(ii) A brief, general statement of the reasons for the detention;

(iii) The location of the drugs;

(iv) A statement that these drugs are not to be used, moved, altered, or tampered with in any manner during that period, except as permitted under paragraph (h) of this section, without the written permission of an authorized FDA representative;

(v) Identification of the detained drugs;

(vi) The detention order number;

(vii) The date and hour of the detention order;

(viii) The period of the detention;

(ix) The text of section 304(g) of the Federal Food, Drug, and Cosmetic Act and paragraphs (g)(1) and (g)(2) of this section;

(x) A statement that any informal hearing on an appeal of a detention order must be conducted as a regulatory hearing under part 16 of this chapter, with certain exceptions described in paragraph (g)(3) of this section; and

(xi) The mailing address, telephone number, and name of the FDA Division Director.

(e) *Approval of detention order.* A detention order, before issuance, must be approved by the FDA Division Director in whose division the drugs are located. If prior written approval is not feasible, prior oral approval must be obtained and confirmed by written memorandum within FDA as soon as possible.

(f) *Labeling or marking a detained drug.* An FDA representative issuing a detention order under paragraph (d) of this section must label or mark the drugs with official FDA tags that include the following information:

(1) A statement that the drugs are detained by the U.S. Government in accordance with section 304(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 334(g)).

(2) A statement that the drugs must not be used, moved, altered, or tampered with in any manner for the period shown, without the written permission of an authorized FDA representative, except as authorized in paragraph (h) of this section.

(3) A statement that the violation of a detention order or the removal or alteration of the tag is punishable by fine or imprisonment or both (section 303 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 333)).

(4) The detention order number, the date and hour of the detention order, the detention period, and the name of the FDA representative who issued the detention order.

(g) *Appeal of a detention order*. (1) A person who would be entitled to claim the drugs, if seized, may appeal a detention order. Any appeal must be submitted in writing to the FDA Division Director in whose division the drugs are located within 5 working days of receipt of a detention order. If the appeal includes a request for an informal hearing, as defined in section 201(x) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(x)), the appellant must request either that a hearing be held within 5 working days after the appeal is filed or that the hearing be held at a later date, which must not be later than 20 calendar days after receipt of a detention order.

(2) The appellant of a detention order must state the ownership or proprietary interest the appellant has in the detained drugs. If the detained drugs are located at a place other than an establishment owned or operated by the appellant, the appellant must include documents showing that the appellant would have legitimate authority to claim the drugs if seized.

(3) Any informal hearing on an appeal of a detention order must be conducted as a regulatory hearing under regulation in accordance with part 16 of this chapter, except that:

(i) The detention order under paragraph (d) of this section, rather than the notice under §16.22(a) of this chapter, provides notice of opportunity for a hearing under this section and is part of the administrative record of the regulatory hearing under §16.80(a) of this chapter;

(ii) A request for a hearing under this section should be addressed to the FDA Division Director;

(iii) The last sentence of §16.24(e) of this chapter, stating that a hearing may not be required to be held at a time less than 2 working days after receipt of the request for a hearing, does not apply to a hearing under this section;

(iv) Paragraph (g)(4) of this section, rather than §16.42(a) of this chapter, describes the FDA employees who preside at hearings under this section.

(4) The presiding officer of a regulatory hearing on an appeal of a detention order, who also must decide the appeal, must be an Office of Regulatory Affairs Program Director or another FDA official senior to an FDA Division Director who is permitted by §16.42(a) of this chapter to preside over the hearing.

(5) If the appellant requests a regulatory hearing and requests that the hearing be held within 5 working days after the appeal is filed, the presiding officer must, within 5 working days, hold the hearing and render a decision affirming or revoking the detention.

(6) If the appellant requests a regulatory hearing and requests that the hearing be held at a date later than within 5 working days after the appeal is filed, but not later than 20 calendar days after receipt of a detention order, the presiding officer must hold the hearing at a date agreed upon by FDA and the appellant. The presiding officer must decide whether to affirm or revoke the detention within 5 working days after the conclusion of the hearing. The detention period extends to the date of the decision even if the 5-working-day period for making the decision extends beyond the otherwise applicable 20-calendar-day or 30-calendar-day detention period.

(7) If the appellant appeals the detention order but does not request a regulatory hearing, the presiding officer must render a decision on the appeal, affirming or revoking the detention within 5 working days after the filing of the appeal.

(8) If the presiding officer affirms a detention order, the drugs continue to be detained until FDA terminates the detention under paragraph (j) of this

section or the detention period expires, whichever occurs first.

(9) If the presiding officer revokes a detention order, FDA must terminate the detention under paragraph (j) of this section.

(h) *Movement of detained drugs.* (1) Except as provided in this paragraph, no person may move detained drugs within or from the place where they have been ordered detained until FDA terminates the detention under paragraph (j) of this section or the detention period expires, whichever occurs first.

(2) If detained drugs are not in final form for shipment, the manufacturer may move them within the establishment where they are detained to complete the work needed to put them in final form. As soon as the drugs are moved for the purpose in the preceding sentence, the individual responsible for their movement must orally notify the FDA representative who issued the detention order, or another responsible division office official, of the movement of the drugs. As soon as the drugs are put in final form, they must be segregated from other drugs, and the individual responsible for their movement must orally notify the FDA representative who issued the detention order, or another responsible division office official, of their new location. The drugs put in final form must not be moved further without FDA approval.

(3) The FDA representative who issued the detention order, or another responsible division office official, may approve, in writing, the movement of detained drugs for any of the following purposes:

(i) To prevent interference with an establishment's operations or harm to the drugs;

(ii) To destroy the drugs;

(iii) To bring the drugs into compliance;

(iv) For any other purpose that the FDA representative who issued the detention order, or other responsible division office official, believes is appropriate in the case.

(4) If an FDA representative approves the movement of detained drugs under paragraph (h)(3) of this section, the detained drugs must remain segregated from other drugs and the person responsible for their movement must immediately orally notify the official who approved the movement of the drugs, or another responsible FDA division office official, of the new location of the detained drugs.

(5) Unless otherwise permitted by the FDA representative who is notified of, or who approves, the movement of drugs under this paragraph, the required tags must accompany the drugs during and after movement and must remain with the drugs until FDA terminates the detention or the detention period expires, whichever occurs first.

(i) *Actions involving adulterated or misbranded drugs.* If FDA determines that the detained drugs, including any that have been put in final form, are adulterated or misbranded, or both, it may initiate legal action against the drugs or the responsible individuals, or both, or request that the drugs be destroyed or otherwise brought into compliance with the Federal Food, Drug, and Cosmetic Act under FDA's supervision.

(j) *Detention termination.* If FDA decides to terminate a detention or when the detention period expires, whichever occurs first, an FDA representative authorized to terminate a detention will issue a detention termination notice releasing the drugs to any person who received the original detention order or that person's representative and will remove, or authorize in writing the removal of, the required labels or tags.

(k) *Recordkeeping requirements.* (1) After issuance of a detention order under paragraph (d) of this section, the owner, operator, or agent in charge of any factory, warehouse, other establishment, or consulting laboratory where detained drugs are manufactured, processed, packed, or held, must have, or establish, and maintain adequate records relating to how the detained drugs may have become adulterated or misbranded, records on any distribution of the drugs before and after the detention period, records on the correlation of any in-process detained drugs that are put in final form under paragraph (h) of this section to the completed drugs, records of any changes in, or processing of, the drugs permitted under the detention order, and records of any other movement under paragraph (h) of this section. Records required under this paragraph

must be provided to FDA on request for review and copying. Any FDA request for access to records required under this paragraph must be made at a reasonable time, must state the reason or purpose for the request, and must identify to the fullest extent practicable the information or type of information sought in the records to which access is requested.

(2) Records required under this paragraph must be maintained for a maximum period of 2 years after the issuance of the detention order or for such other shorter period as FDA directs. When FDA terminates the detention or when the detention period expires, whichever occurs first, FDA will advise all persons required under this paragraph to keep records concerning that detention whether further recordkeeping is required for the remainder of the 2-year, or shorter, period. FDA ordinarily will not require further recordkeeping if the Agency determines that the drugs are not adulterated or misbranded or that recordkeeping is not necessary to protect the public health, unless the records are required under other regulations in this chapter (e.g., the good manufacturing practice regulation in part 211 of this chapter).

[79 FR 30719, May 29, 2014, as amended at 82 FR 14144, Mar. 17, 2017; 85 FR 16551, Mar. 24, 2020]

PART 2—GENERAL ADMINISTRATIVE RULINGS AND DECISIONS

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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.

§2.10 Examination and investigation samples.

(a)(1) When any officer or employee of the Department collects a sample of a food, drug, or cosmetic for analysis under the act, the sample shall be designated as an official sample if records or other evidence is obtained by him or any other officer or employee of the Department indicating that the shipment or other lot of the article from which such sample was collected was

introduced or delivered for introduction into interstate commerce, or was in or was received in interstate commerce, or was manufactured within a Territory. Only samples so designated by an officer or employee of the Department shall be considered to be official samples.

(2) For the purpose of determining whether or not a sample is collected for analysis, the term *analysis* includes examinations and tests.

(3) The owner of a food, drug, or cosmetic of which an official sample is collected is the person who owns the shipment or other lot of the article from which the sample is collected.

(b) When an officer or employee of the Department collects an official sample of a food, drug, or cosmetic for analysis under the act, he shall collect at least twice the quantity estimated by him to be sufficient for analysis, unless:

(1) The amount of the article available and reasonably accessible for sampling is less than twice the quantity so estimated, in which case he shall collect as much as is available and reasonably accessible.

(2) The cost of twice the quantity so estimated exceeds $150.

(3) The sample cannot by diligent use of practicable preservation techniques available to the Food and Drug Administration be kept in a state in which it could be readily and meaningfully analyzed in the same manner and for the same purposes as the Food and Drug Administration's analysis.

(4) The sample is collected from a shipment or other lot which is being imported or offered for import into the United States.

(5) The sample is collected from a person named on the label of the article or his agent, and such person is also the owner of the article.

(6) The sample is collected from the owner of the article, or his agent, and such article bears no label or, if it bears a label, no person is named thereon.

In addition to the quantity of sample set forth in this paragraph, the officer or employee shall, if practicable, collect such further amount as he estimates will be sufficient for use as trial exhibits.

(c) After the Food and Drug Administration has completed such analysis of an official sample of a food, drug, or cosmetic as it determines, in the course of analysis and interpretation of analytical results, to be adequate to establish the respects, if any, in which the article is adulterated or misbranded within the meaning of the act, or otherwise subject to the prohibitions of the act, and has reserved an amount of the article it estimates to be adequate for use as exhibits in the trial of any case that may arise under the act based on the sample, a part of the sample, if any remains available, shall be provided for analysis, upon written request, by any person named on the label of the article, or the owner thereof, or the attorney or agent of such person or owner, except when:

(1) After collection, the sample or remaining part thereof has become decomposed or otherwise unfit for analysis, or

(2) The request is not made within a reasonable time before the trial of any case under the act, based on the sample to which such person or owner is a party. The person, owner, attorney, or agent who requests the part of sample shall specify the amount desired. A request from an owner shall be accompanied by a showing of ownership, and a request from an attorney or agent by a showing of authority from such person or owner to receive the part of sample. When two or more requests for parts of the same sample are received the requests shall be complied with in the order in which they were received so long as any part of the sample remains available therefor.

(d) When an official sample of food, drug, or cosmetic is the basis of a notice given under section 305 of the act, or of a case under the act, and the person to whom the notice was given, or any person who is a party to the case, has no right under paragraph (c) of this section to a part of the sample, such person or his attorney or agent may obtain a part of the sample upon request accompanied by a written waiver of right under such paragraph (c) from each person named on the label of the article and owner thereof, who has not

exercised his right under such paragraph (c). The operation of this paragraph shall be subject to the exceptions, terms, and conditions prescribed in paragraph (c) of this section.

(e) The Food and Drug Administration is authorized to destroy:

(1) Any official sample when it determines that no analysis of such sample will be made;

(2) Any official sample or part thereof when it determines that no notice under section 305 of the act, and no case under the act, is or will be based on such sample;

(3) Any official sample or part thereof when the sample was the basis of a notice under section 305 of the act, and when, after opportunity for presentation of views following such notice, it determines that no other such notice, and no case under the act, is or will be based on such sample;

(4) Any official sample or part thereof when the sample was the basis of a case under the act which has gone to final judgment, and when it determines that no other such case is or will be based on such sample;

(5) Any official sample or part thereof if the article is perishable;

(6) Any official sample or part thereof when, after collection, such sample or part has become decomposed or otherwise unfit for analysis;

(7) That part of any official sample which is in excess of three times the quantity it estimates to be sufficient for analysis.

[42 FR 15559, Mar. 22, 1977, as amended at 63 FR 51299, Sept. 25, 1998]

§ 2.19 Methods of analysis.

Where the method of analysis is not prescribed in a regulation, it is the policy of the Food and Drug Administration in its enforcement programs to utilize the methods of analysis of the AOAC INTERNATIONAL (AOAC) as published in the latest edition (13th Ed., 1980) of their publication ''Official Methods of Analysis of the Association of Official Analytical Chemists,'' and the supplements thereto (''Changes in Methods'' as published in the March issues of the ''Journal of the Association of Official Analytical Chemists''), which are incorporated by reference, when available and applicable. Copies are available from the AOAC INTERNATIONAL, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*. In the absence of an AOAC method, the Commissioner will furnish a copy of the particular method, or a reference to the published method, that the Food and Drug Administration will use in its enforcement program. Other methods may be used for quality control, specifications, contracts, surveys, and similar nonregulatory functions, but it is expected that they will be calibrated in terms of the method which the Food and Drug Administration uses in its enforcement program. Use of an AOAC method does not relieve the practioner of the responsibility to demonstrate that he can perform the method properly through the use of positive and negative controls and recovery and reproducibility studies.

[42 FR 15559, Mar. 22, 1977, as amended at 47 FR 946, Jan. 8, 1982; 54 FR 9034, Mar. 3, 1989; 70 FR 40880, July 15, 2005; 70 FR 67651, Nov. 8, 2005]

Subpart B—Human and Animal Foods

§ 2.25 Grain seed treated with poisonous substances; color identification to prevent adulteration of human and animal food.

(a) In recent years there has developed increasing use of poisonous treatments on seed for fungicidal and other purposes. Such treated seed, if consumed, presents a hazard to humans and livestock. It is not unusual for stocks of such treated food seeds to remain on hand after the planting season has passed. Despite the cautions required by the Federal Seed Act (53 Stat. 1275, as amended 72 Stat. 476, 7 U.S.C. 1551 *et seq.*) in the labeling of the treated seed, the Food and Drug Administration has encountered many cases where such surplus stocks of treated wheat, corn, oats, rye, barley, and sorghum seed had been mixed with untreated seed and sent to market for

food or feed use. This has resulted in livestock injury and in legal actions under the Federal Food, Drug, and Cosmetic Act against large quantities of food adulterated through such admixture of poisonous treated seeds with good food. Criminal cases were brought against some firms and individuals. Where the treated seeds are prominently colored, buyers and users or processors of agricultural food seed for food purposes are able to detect the admixture of the poisonous seed and thus reject the lots; but most such buyers, users, and processors do not have the facilities or scientific equipment to determine the presence of the poisonous chemical at the time crops are delivered, in cases where the treated seeds have not been so colored. A suitable color for this use is one that is in sufficient contrast to the natural color of the food seed as to make admixture of treated, denatured seeds with good food easily apparent, and is so applied that it is not readily removed.

(b) On and after December 31, 1964, the Food and Drug Administration will regard as adulterated any interstate shipment of the food seeds wheat, corn, oats, rye, barley, and sorghum bearing a poisonous treatment in excess of a recognized tolerance or treatment for which no tolerance or exemption from tolerance is recognized in regulations promulgated pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act, unless such seeds have been adequately denatured by a suitable color to prevent their subsequent inadvertent use as food for man or feed for animals.

(c) Attention is called to the labeling requirements of the Federal Hazardous Substances Act, where applicable to denatured seeds in packages suitable for household use.

§ 2.35 Use of secondhand containers for the shipment or storage of food and animal feed.

(a) Investigations by the Food and Drug Administration, the National Communicable Disease Center of the U.S. Public Health Service, the Consumer and Marketing Service of the U.S. Department of Agriculture, and by various State public health agencies have revealed practices whereby food and animal feed stored or shipped in secondhand containers have been rendered dangerous to health. Such contamination has been the result of the original use of these containers for the storage and shipment of articles containing or bearing disease organisms or poisonous or deleterious substances.

(b) The Commissioner concludes that such dangerous or potentially dangerous practices include, but are not limited to, the following:

(1) Some vegetable growers and packers employ used poultry crates for shipment of fresh vegetables, including cabbage and celery. Salmonella organisms are commonly present on dressed poultry and in excreta and fluid exudates from dressed birds. Thus wooden crates in which dressed poultry has been iced and packed are potential sources of Salmonella or other enteropathogenic microorganisms that may contaminate fresh vegetables which are frequently consumed without heat treatment.

(2) Some potato growers and producers of animal feeds use secondhand bags for shipment of these articles. Such bags may have originally been used for shipping or storing pesticide-treated seed or other articles bearing or containing poisonous substances. Thus these secondhand bags are potential sources of contamination of the food or animal feed stored or shipped therein.

(c) In a policy statement issued April 11, 1968, the Food and Drug Administration declared adulterated within the meaning of section 402(a) of the Federal Food, Drug, and Cosmetic Act shipments of vegetables or other edible food in used crates or containers that may render the contents injurious to health. This policy statement is extended so that the Food and Drug Administration will regard as adulterated within the meaning of section 402(a) of the act shipments of vegetables, other edible food, or animal feed in used crates, bags, or other containers that may render the contents injurious to health.

Subparts C–E [Reserved]

Subpart F—Caustic Poisons

§ 2.110 Definition of ammonia under Federal Caustic Poison Act.

For the purpose of determining whether an article containing ammonia is subject to the Federal Caustic Poison Act, the ammonia content is to be calculated as NH_3.

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.

(a) As used in this section, *ozone-depleting substance* (ODS) means any class I substance as defined in 40 CFR part 82, appendix A to subpart A, or class II substance as defined in 40 CFR part 82, appendix B to subpart A.

(b) Except as provided in paragraph (c) of this section, any food, drug, device, or cosmetic that is, consists in part of, or is contained in an aerosol product or other pressurized dispenser that releases an ODS is not an essential use of the ODS under the Clean Air Act.

(c) A food, drug, device, or cosmetic that is, consists in part of, or is contained in an aerosol product or other pressurized dispenser that releases an ODS is an essential use of the ODS under the Clean Air Act if paragraph (e) of this section specifies the use of that product as essential. For drugs, including biologics and animal drugs, and for devices, an investigational application or an approved marketing application must be in effect, as applicable.

(d) [Reserved]

(e) The use of ODSs in the following products is essential:

(1) *Metered-dose corticosteroid human drugs for oral inhalation*. Oral pressurized metered-dose inhalers containing the following active moieties:

(i)–(v) [Reserved]

(2) *Metered-dose short-acting adrenergic bronchodilator human drugs for oral inhalation*. Oral pressurized metered-dose inhalers containing the following active moieties:

(i)–(v) [Reserved]

(3) [Reserved]

(4) *Other essential uses*. (i)–(ii) [Reserved]

(iii) Anesthetic drugs for topical use on accessible mucous membranes of humans where a cannula is used for application.

(iv)–(ix) [Reserved]

(f) Any person may file a petition under part 10 of this chapter to request that FDA initiate rulemaking to amend paragraph (e) of this section to add an essential use. FDA may initiate notice-and-comment rulemaking to add an essential use on its own initiative or in response to a petition, if granted.

(1) If the petition is to add use of a noninvestigational product, the petitioner must submit compelling evidence that:

(i) Substantial technical barriers exist to formulating the product without ODSs;

(ii) The product will provide an unavailable important public health benefit; and

(iii) Use of the product does not release cumulatively significant amounts of ODSs into the atmosphere or the release is warranted in view of the unavailable important public health benefit.

(2) If the petition is to add use of an investigational product, the petitioner must submit compelling evidence that:

(i) Substantial technical barriers exist to formulating the investigational product without ODSs;

(ii) A high probability exists that the investigational product will provide an unavailable important public health benefit; and

(iii) Use of the investigational product does not release cumulatively significant amounts of ODSs into the atmosphere or the release is warranted in view of the high probability of an unavailable important public health benefit.

(g) Any person may file a petition under part 10 of this chapter to request that FDA initiate rulemaking to amend paragraph (e) of this section to remove an essential use. FDA may initiate notice-and-comment rulemaking to remove an essential use on its own initiative or in response to a petition, if granted. If the petition is to remove

an essential use from paragraph (e) of this section, the petitioner must submit compelling evidence of any one of the following criteria:

(1) The product using an ODS is no longer being marketed; or

(2) After January 1, 2005, FDA determines that the product using an ODS no longer meets the criteria in paragraph (f) of this section after consultation with a relevant advisory committee(s) and after an open public meeting; or

(3) For individual active moieties marketed as ODS products and represented by one new drug application (NDA):

(i) At least one non-ODS product with the same active moiety is marketed with the same route of administration, for the same indication, and with approximately the same level of convenience of use as the ODS product containing that active moiety;

(ii) Supplies and production capacity for the non-ODS product(s) exist or will exist at levels sufficient to meet patient need;

(iii) Adequate U.S. postmarketing use data is available for the non-ODS product(s); and

(iv) Patients who medically required the ODS product are adequately served by the non-ODS product(s) containing that active moiety and other available products; or

(4) For individual active moieties marketed as ODS products and represented by two or more NDAs:

(i) At least two non-ODS products that contain the same active moiety are being marketed with the same route of delivery, for the same indication, and with approximately the same level of convenience of use as the ODS products; and

(ii) The requirements of paragraphs (g)(3)(ii), (g)(3)(iii), and (g)(3)(iv) of this section are met.

[67 FR 48384, July 24, 2002, as amended at 71 FR 70873, Dec. 7, 2006; 70 FR 17192, Apr. 4, 2005; 75 FR 19241, Apr. 14, 2010; 73 FR 69552, Nov. 19, 2008; 75 FR 19241, Apr. 14, 2010; 81 FR 74302, Oct. 26, 2016]

PART 3—PRODUCT JURISDICTION

Subpart A—Assignment of Agency Component for Review of Premarket Applications

Sec.
3.1 Purpose.
3.2 Definitions.
3.3 Scope.
3.4 Designated agency component.
3.5 Procedures for identifying the designated agency component.
3.6 Product jurisdiction officer.
3.7 Request for designation.
3.8 Letter of designation.
3.9 Effect of letter of designation.
3.10 Stay of review time.

Subpart B [Reserved]

AUTHORITY: 21 U.S.C. 321, 351, 353, 355, 360, 360c–360f, 360h–360j, 360gg–360ss, 360bbb–2, 371(a), 379e, 381, 394; 42 U.S.C. 216, 262, 264.

SOURCE: 56 FR 58756, Nov. 21, 1991, unless otherwise noted.

Subpart A—Assignment of Agency Component for Review of Premarket Applications

§ 3.1 Purpose.

This regulation relates to agency management and organization and has two purposes. The first is to implement section 503(g) of the act, as added by section 16 of the Safe Medical Devices Act of 1990 (Public Law 101–629) and amended by section 204 of the Medical Device User Fee and Modernization Act of 2002 (Public Law 107–250), by specifying how FDA will determine the organizational component within FDA designated to have primary jurisdiction for the premarket review and regulation of products that are comprised of any combination of a drug and a device; a device and a biological; a biological and a drug; or a drug, a device and a biological. This determination will eliminate, in most cases, the need to receive approvals from more than one FDA component for such combination products. The second purpose of this regulation is to enhance the efficiency of agency management and operations by providing procedures for determining which agency component will have primary jurisdiction for any drug, device, or biological product

where such jurisdiction is unclear or in dispute. Nothing in this section prevents FDA from using any agency resources it deems necessary to ensure adequate review of the safety and effectiveness of any product, or the substantial equivalence of any device to a predicate device.

[56 FR 58756, Nov. 21, 1991, as amended at 68 FR 37077, June 23, 2003]

§ 3.2 Definitions.

For the purpose of this part:

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

(b) *Agency component* means the Center for Biologics Evaluation and Research, the Center for Devices and Radiological Health, the Center for Drug Evaluation and Research, or alternative organizational component of the agency.

(c) *Applicant* means any person who submits or plans to submit an application to the Food and Drug Administration for premarket review. For purposes of this section, the terms ''sponsor'' and ''applicant'' have the same meaning.

(d) *Biological product* has the meaning given the term in section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)).

(e) *Combination product* includes:

(1) A product comprised of two or more regulated components, i.e., drug/device, biologic/device, drug/biologic, or drug/device/biologic, that are physically, chemically, or otherwise combined or mixed and produced as a single entity;

(2) Two or more separate products packaged together in a single package or as a unit and comprised of drug and device products, device and biological products, or biological and drug products;

(3) A drug, device, or biological product packaged separately that according to its investigational plan or proposed labeling is intended for use only with an approved individually specified drug, device, or biological product where both are required to achieve the intended use, indication, or effect and where upon approval of the proposed product the labeling of the approved product would need to be changed, e.g., to reflect a change in intended use, dosage form, strength, route of administration, or significant change in dose; or

(4) Any investigational drug, device, or biological product packaged separately that according to its proposed labeling is for use only with another individually specified investigational drug, device, or biological product where both are required to achieve the intended use, indication, or effect.

(f) *Device* has the meaning given the term in section 201(h) of the act.

(g) *Drug* has the meaning given the term in section 201(g)(1) of the act.

(h) *FDA* means Food and Drug Administration.

(i) *Letter of designation* means the written notice issued by the product jurisdiction officer specifying the agency component with primary jurisdiction for a combination product.

(j) *Letter of request* means an applicant's written submission to the product jurisdiction officer seeking the designation of the agency component with primary jurisdiction.

(k) *Mode of action* is the means by which a product achieves an intended therapeutic effect or action. For purposes of this definition, ''therapeutic'' action or effect includes any effect or action of the combination product intended to diagnose, cure, mitigate, treat, or prevent disease, or affect the structure or any function of the body. When making assignments of combination products under this part, the agency will consider three types of mode of action: The actions provided by a biological product, a device, and a drug. Because combination products are comprised of more than one type of regulated article (biological product, device, or drug), and each constituent part contributes a biological product, device, or drug mode of action, combination products will typically have more than one identifiable mode of action.

(1) A constituent part has a biological product mode of action if it acts by means of a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product applicable to the prevention, treatment, or cure of a disease or condition of human

beings, as described in section 351(i) of the Public Health Service Act.

(2) A constituent part has a device mode of action if it meets the definition of device contained in section 201(h)(1) to (h)(3) of the act, it does not have a biological product mode of action, and it does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and is not dependent upon being metabolized for the achievement of its primary intended purposes.

(3) A constituent part has a drug mode of action if it meets the definition of drug contained in section 201(g)(1) of the act and it does not have a biological product or device mode of action.

(l) *Premarket review* includes the examination of data and information in an application for premarket review described in sections 505, 510(k), 513(f), 515, or 520(g) or 520(l) of the act or section 351 of the Public Health Service Act of data and information contained in any investigational new drug (IND) application, investigational device exemption (IDE), new drug application (NDA), biologics license application, device premarket notification, device reclassification petition, and premarket approval application (PMA).

(m) *Primary mode of action* is the single mode of action of a combination product that provides the most important therapeutic action of the combination product. The most important therapeutic action is the mode of action expected to make the greatest contribution to the overall intended therapeutic effects of the combination product.

(n) *Product* means any article that contains any drug as defined in section 201(g)(1) of the act; any device as defined in section 201(h) of the act; or any biologic as defined in section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)).

(o) *Product jurisdiction officer* is the person or persons responsible for designating the component of FDA with primary jurisdiction for the premarket review and regulation of a combination product or any product requiring a jurisdictional designation under this part.

(p) *Sponsor* means ''applicant'' (see § 3.2(c)).

[56 FR 58756, Nov. 21, 1991, as amended at 64 FR 398, Jan. 5, 1999; 64 FR 56447, Oct. 20, 1999; 68 FR 37077, June 23, 2003; 70 FR 49861, Aug. 25, 2005]

§ 3.3 Scope.

This section applies to:

(a) Any combination product, or

(b) Any product where the agency component with primary jurisdiction is unclear or in dispute.

§ 3.4 Designated agency component.

(a) To designate the agency component with primary jurisdiction for the premarket review and regulation of a combination product, the agency shall determine the primary mode of action of the product. Where the primary mode of action is that of:

(1) A drug (other than a biological product), the agency component charged with premarket review of drugs shall have primary jurisdiction;

(2) A device, the agency component charged with premarket review of devices shall have primary jurisdiction;

(3) A biological product, the agency component charged with premarket review of biological products shall have primary jurisdiction.

(b) In some situations, it is not possible to determine, with reasonable certainty, which one mode of action will provide a greater contribution than any other mode of action to the overall therapeutic effects of the combination product. In such a case, the agency will assign the combination product to the agency component that regulates other combination products that present similar questions of safety and effectiveness with regard to the combination product as a whole. When there are no other combination products that present similar questions of safety and effectiveness with regard to the combination product as a whole, the agency will assign the combination product to the agency component with the most expertise related to the most significant safety and effectiveness questions presented by the combination product.

(c) The designation of one agency component as having primary jurisdiction for the premarket review and regulation of a combination product does not preclude consultations by that component with other agency components or, in appropriate cases, the requirement by FDA of separate applications.

[56 FR 58756, Nov. 21, 1991, as amended at 70 FR 49861, Aug. 25, 2005]

§ 3.5 Procedures for identifying the designated agency component.

(a)(1) The Center for Biologics Evaluation and Research, the Center for Devices and Radiological Health, and the Center for Drug Evaluation and Research have entered into agreements clarifying product jurisdictional issues. These guidance documents are on display in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, and are entitled ''Intercenter Agreement Between the Center for Drug Evaluation and Research and the Center for Devices and Radiological Health;'' ''Intercenter Agreement Between the Center for Devices and Radiological Health and the Center for Biologics Evaluation and Research;'' ''Intercenter Agreement Between the Center for Drug Evaluation and Research and the Center for Biologics Evaluation and Research.'' The availability of any amendments to these intercenter agreements will be announced by FEDERAL REGISTER notice.

(2) These guidance documents describe the allocation of responsibility for categories of products or specific products. These intercenter agreements, and any amendments thereto, are nonbinding determinations designed to provide useful guidance to the public.

(3) The sponsor of a premarket application or required investigational filing for a combination or other product covered by these guidance documents may contact the designated agency component identified in the intercenter agreement before submitting an application of premarket review or to confirm coverage and to discuss the application process.

(b) For a combination product not covered by a guidance document or for a product where the agency component with primary jurisdiction is unclear or in dispute, the sponsor of an application for premarket review should follow the procedures set forth in § 3.7 to request a designation of the agency component with primary jurisdiction before submitting the application.

[56 FR 58756, Nov. 21, 1991, as amended at 68 FR 24879, May 9, 2003]

§ 3.6 Product jurisdiction officer.

The Office of Combination Products (Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 5129, Silver Spring, MD 20993–0002, 301–796–8930,, e-mail: *combination@fda.gov*, is the designated product jurisdiction officer.

[68 FR 37077, June 23, 2003, as amended at 71 FR 16033, Mar. 30, 2006; 75 FR 13678, Mar. 23, 2010]

§ 3.7 Request for designation.

(a) Who should file: the sponsor of:

(1) Any combination product the sponsor believes is not covered by an intercenter agreement; or

(2) Any product where the agency component with primary jurisdiction is unclear or in dispute.

(b) When to file: a sponsor should file a request for designation before filing any application for premarket review, whether an application for marketing approval or a required investigational notice. Sponsors are encouraged to file a request for designation as soon as there is sufficient information for the agency to make a determination.

(c) What to file: an original and two copies of the request for designation must be filed. The request for designation must not exceed 15 pages, including attachments, and must set forth:

(1) The identity of the sponsor, including company name and address, establishment registration number, company contact person and telephone number.

(2) A description of the product, including:

(i) Classification, name of the product and all component products, if applicable;

(ii) Common, generic, or usual name of the product and all component products;

(iii) Proprietary name of the product;

(iv) Identification of any component of the product that already has received premarket approval, is marketed as not being subject to premarket approval, or has received an investigational exemption, the identity of the sponsors, and the status of any discussions or agreements between the sponsors regarding the use of this product as a component of a new combination product.

(v) Chemical, physical, or biological composition;

(vi) Status and brief reports of the results of developmental work, including animal testing;

(vii) Description of the manufacturing processes, including the sources of all components;

(viii) Proposed use or indications;

(ix) Description of all known modes of action, the sponsor's identification of the single mode of action that provides the most important therapeutic action of the product, and the basis for that determination.

(x) Schedule and duration of use;

(xi) Dose and route of administration of drug or biologic;

(xii) Description of related products, including the regulatory status of those related products; and

(xiii) Any other relevant information.

(3) The sponsor's recommendation as to which agency component should have primary jurisdiction based on the mode of action that provides the most important therapeutic action of the combination product. If the sponsor cannot determine with reasonable certainty which mode of action provides the most important therapeutic action of the combination product, the sponsor's recommendation must be based on the assignment algorithm set forth in § 3.4(b) and an assessment of the assignment of other combination products the sponsor wishes FDA to consider during the assignment of its combination product.

(d) Where to file: all communications pursuant to this subpart shall be addressed to the attention of the product jurisdiction officer. Such a request, in its mailing cover should be plainly marked ''Request for Designation.'' Concurrent submissions of electronic copies of Requests for Designation may be addressed to *combination@fda.gov*.

[56 FR 58756, Nov. 21, 1991, as amended at 68 FR 37077, June 23, 2003; 70 FR 49861, Aug. 25, 2005]

§ 3.8 Letter of designation.

(a) Each request for designation will be reviewed for completeness within 5 working days of receipt. Any request for designation determined to be incomplete will be returned to the applicant with a request for the missing information. The sponsor of an accepted request for designation will be notified of the filing date.

(b) Within 60 days of the filing date of a request for designation, the product jurisdiction officer will issue a letter of designation to the sponsor, with copies to the centers, specifying the agency component designated to have primary jurisdiction for the premarket review and regulation of the product at issue, and any consulting agency components. The product jurisdiction officer may request a meeting with the sponsor during the review period to discuss the request for designation. If the product jurisdiction officer has not issued a letter of designation within 60 days of the filing date of a request for designation, the sponsor's recommendation of the center with primary jurisdiction, in accordance with § 3.7(c)(3), shall become the designated agency component.

(c) Request for reconsideration by sponsor: If the sponsor disagrees with the designation, it may request the product jurisdiction officer to reconsider the decision by filing, within 15 days of receipt of the letter of designation, a written request for reconsideration not exceeding 5 pages. No new information may be included in a request for reconsideration. The product jurisdiction officer shall review and act on the request in writing within 15 days of its receipt.

§ 3.9 Effect of letter of designation.

(a) The letter of designation constitutes an agency determination that is subject to change only as provided in paragraph (b) of this section.

(b) The product jurisdiction officer may change the designated agency component with the written consent of the sponsor, or without its consent to protect the public health or for other compelling reasons. A sponsor shall be given 30 days written notice of any proposed nonconsensual change in designated agency component. The sponsor may request an additional 30 days to submit written objections, not to exceed 15 pages, to the proposed change, and shall be granted, upon request, a timely meeting with the product jurisdiction officer and appropriate center officials. Within 30 days of receipt of the sponsor's written objections, the product jurisdiction officer shall issue to the sponsor, with copies to appropriate center officials, a written determination setting forth a statement of reasons for the proposed change in designated agency component. A nonconsensual change in the designated agency component requires the concurrence of the Principal Associate Commissioner.

[56 FR 58756, Nov. 21, 1991, as amended at 68 FR 37077, June 23, 2003]

§3.10 Stay of review time.

Any filing with or review by the product jurisdiction officer stays the review clock or other established time periods for agency action for an application for marketing approval or required investigational notice during the pendency of the review by the product jurisdiction officer.

Subpart B [Reserved]

PART 4—REGULATION OF COMBINATION PRODUCTS

Subpart A—Current Good Manufacturing Practice Requirements for Combination Products

Sec.
4.1 What is the scope of this subpart?
4.2 How does FDA define key terms and phrases in this subpart?
4.3 What current good manufacturing practice requirements apply to my combination product?
4.4 How can I comply with these current good manufacturing practice requirements for a co-packaged or single-entity combination product?

Subpart B—Postmarketing Safety Reporting for Combination Products

4.100 What is the scope of this subpart?
4.101 How does FDA define key terms and phrases in this subpart?
4.102 What reports must you submit to FDA for your combination product or constituent part?
4.103 What information must you share with other constituent part applicants for the combination product?
4.104 How and where must you submit postmarketing safety reports for your combination product or constituent part?
4.105 What are the postmarketing safety reporting recordkeeping requirements for your combination product or constituent part?

AUTHORITY: 21 U.S.C. 321, 331, 351, 352, 353, 355, 360, 360b–360f, 360h–360j, 360l, 360hh–360ss, 360aaa–360bbb, 371(a), 372–374, 379e, 381, 383, 394; 42 U.S.C. 216, 262, 263a, 264, 271.

SOURCE: 78 FR 4321, Jan. 22, 2013, unless otherwise noted.

Subpart A—Current Good Manufacturing Practice Requirements for Combination Products

§4.1 What is the scope of this subpart?

This subpart applies to combination products. It establishes which current good manufacturing practice requirements apply to these products. This subpart clarifies the application of current good manufacturing practice regulations to combination products, and provides a regulatory framework for designing and implementing the current good manufacturing practice operating system at facilities that manufacture co-packaged or single-entity combination products.

§4.2 How does FDA define key terms and phrases in this subpart?

The terms listed in this section have the following meanings for purposes of this subpart:

Biological product has the meaning set forth in §3.2(d) of this chapter. A biological product also meets the definitions of either a drug or device as these terms are defined under this section.

Combination product has the meaning set forth in §3.2(e) of this chapter.

Constituent part is a drug, device, or biological product that is part of a combination product.

Co-packaged combination product has the meaning set forth in § 3.2(e)(2) of this chapter.

Current good manufacturing practice operating system means the operating system within an establishment that is designed and implemented to address and meet the current good manufacturing practice requirements for a combination product.

Current good manufacturing practice requirements means the requirements set forth under § 4.3(a) through (d).

Device has the meaning set forth in § 3.2(f) of this chapter. A device that is a constituent part of a combination product is considered a finished device within the meaning of the QS regulation.

Drug has the meaning set forth in § 3.2(g) of this chapter. A drug that is a constituent part of a combination product is considered a drug product within the meaning of the drug CGMPs.

Drug CGMPs refers to the current good manufacturing practice regulations set forth in parts 210 and 211 of this chapter.

HCT/Ps refers to human cell, tissue, and cellular and tissue-based products, as defined in § 1271.3(d) of this chapter. An HCT/P that is not solely regulated under section 361 of the Public Health Service Act may be a constituent part of a combination product. Such an HCT/P is subject to part 1271 of this chapter and is also regulated as a drug, device, and/or biological product.

Manufacture includes, but is not limited to, designing, fabricating, assembling, filling, processing, testing, labeling, packaging, repackaging, holding, and storage.

QS regulation refers to the quality system regulation in part 820 of this chapter.

Single-entity combination product has the meaning set forth in § 3.2(e)(1) of this chapter.

Type of constituent part refers to the category of the constituent part, which can be either a biological product, a device, or a drug, as these terms are defined under this section.

§ 4.3 What current good manufacturing practice requirements apply to my combination product?

If you manufacture a combination product, the requirements listed in this section apply as follows:

(a) The current good manufacturing practice requirements in parts 210 and 211 of this chapter apply to a combination product that includes a drug constituent part;

(b) The current good manufacturing practice requirements in part 820 of this chapter apply to a combination product that includes a device constituent part;

(c) The current good manufacturing practice requirements among the requirements (including standards) for biological products in parts 600 through 680 of this chapter apply to a combination product that includes a biological product constituent part to which those requirements would apply if that constituent part were not part of a combination product; and

(d) The current good tissue practice requirements including donor eligibility requirements for HCT/Ps in part 1271 of this chapter apply to a combination product that includes an HCT/P.

§ 4.4 How can I comply with these current good manufacturing practice requirements for a co-packaged or single-entity combination product?

(a) Under this subpart, for single entity or co-packaged combination products, compliance with all applicable current good manufacturing practice requirements for the combination product shall be achieved through the design and implementation of a current good manufacturing practice operating system that is demonstrated to comply with:

(1) The specifics of each set of current good manufacturing practice regulations listed under § 4.3 as they apply to each constituent part included in the combination product; or

(2) Paragraph (b) of this section.

(b) If you elect to establish a current good manufacturing practice operating system in accordance with paragraph (b) of this section, the following requirements apply:

(1) If the combination product includes a device constituent part and a

drug constituent part, and the current good manufacturing practice operating system has been shown to comply with the drug CGMPs, the following provisions of the QS regulation must also be shown to have been satisfied; upon demonstration that these requirements have been satisfied, no additional showing of compliance with respect to the QS regulation need be made:

(i) Section 820.20 of this chapter. Management responsibility.

(ii) Section 820.30 of this chapter. Design controls.

(iii) Section 820.50 of this chapter. Purchasing controls.

(iv) Section 820.100 of this chapter. Corrective and preventive action.

(v) Section 820.170 of this chapter. Installation.

(vi) Section 820.200 of this chapter. Servicing.

(2) If the combination product includes a device constituent part and a drug constituent part, and the current good manufacturing practice operating system has been shown to comply with the QS regulation, the following provisions of the drug CGMPs must also be shown to have been satisfied; upon demonstration that these requirements have been satisfied, no additional showing of compliance with respect to the drug CGMPs need be made:

(i) Section 211.84 of this chapter. Testing and approval or rejection of components, drug product containers, and closures.

(ii) Section 211.103 of this chapter. Calculation of yield.

(iii) Section 211.132 of this chapter. Tamper-evident packaging requirements for over-the-counter (OTC) human drug products.

(iv) Section 211.137 of this chapter. Expiration dating.

(v) Section 211.165 of this chapter. Testing and release for distribution.

(vi) Section 211.166 of this chapter. Stability testing.

(vii) Section 211.167 of this chapter. Special testing requirements.

(viii) Section 211.170 of this chapter. Reserve samples.

(3) In addition to being shown to comply with the other applicable manufacturing requirements listed under §4.3, if the combination product includes a biological product constituent part, the current good manufacturing practice operating system must also be shown to implement and comply with all manufacturing requirements identified under §4.3(c) that would apply to that biological product if that constituent part were not part of a combination product.

(4) In addition to being shown to comply with the other applicable current good manufacturing practice requirements listed under §4.3, if the combination product includes an HCT/P, the current good manufacturing practice operating system must also be shown to implement and comply with all current good tissue practice requirements identified under §4.3(d) that would apply to that HCT/P if it were not part of a combination product.

(c) During any period in which the manufacture of a constituent part to be included in a co-packaged or single entity combination product occurs at a separate facility from the other constituent part(s) to be included in that single-entity or co-packaged combination product, the current good manufacturing practice operating system for that constituent part at that facility must be demonstrated to comply with all current good manufacturing practice requirements applicable to that type of constituent part.

(d) When two or more types of constituent parts to be included in a single-entity or co-packaged combination product have arrived at the same facility, or the manufacture of these constituent parts is proceeding at the same facility, application of a current good manufacturing process operating system that complies with paragraph (b) of this section may begin.

(e) The requirements set forth in this subpart and in parts 210, 211, 820, 600 through 680, and 1271 of this chapter listed in §4.3, supplement, and do not supersede, each other unless the regulations explicitly provide otherwise. In the event of a conflict between regulations applicable under this subpart to combination products, including their constituent parts, the regulations most specifically applicable to the constituent part in question shall supersede the more general.

Subpart B—Postmarketing Safety Reporting for Combination Products

SOURCE: 81 FR 92624, Dec. 20, 2016, unless otherwise noted.

§ 4.100 What is the scope of this subpart?

(a) This subpart identifies postmarketing safety reporting requirements for combination product applicants and constituent part applicants.

(b) This subpart does not apply to investigational combination products, combination products that have not received marketing authorization, or to persons other than combination product applicants and constituent part applicants.

(c) This subpart supplements and does not supersede other provisions of this chapter, including the provisions in parts 314, 600, 606, 803, and 806 of this chapter, unless a regulation explicitly provides otherwise.

§ 4.101 How does the FDA define key terms and phrases in this subpart?

Abbreviated new drug application (ANDA) has the same meaning given the term ''abbreviated application'' in § 314.3(b) of this chapter.

Agency or we means Food and Drug Administration.

Applicant means, for the purposes of this subpart, a person holding an application under which a combination product or constituent part of a combination product has received marketing authorization (such as approval, licensure, or clearance). For the purposes of this subpart, applicant is used interchangeably with the term ''you.''

Application means, for purposes of this subpart, a BLA, an NDA, an ANDA, or a device application, including all amendments and supplements to them.

Biological product has the meaning given the term in section 351 of the Public Health Service Act (42 U.S.C. 262).

Biological product deviation report (BPDR) is a report as described in §§ 600.14 and 606.171 of this chapter.

Biologics license application (BLA) has the meaning given the term in section 351 of the Public Health Service Act (42 U.S.C. 262) and § 601.2 of this chapter.

Combination product has the meaning given the term in § 3.2(e) of this chapter.

Combination product applicant means an applicant that holds the application(s) for a combination product.

Constituent part has the meaning given the term in § 4.2.

Constituent part applicant means the applicant for a constituent part of a combination product the constituent parts of which are marketed under applications held by different applicants.

Correction or removal report is a report as described in § 806.10 of this chapter.

De novo classification request is a submission requesting *de novo* classification under section 513(f)(2) of the Federal Food, Drug, and Cosmetic Act.

Device has the meaning given the term in section 201(h) of the Federal Food, Drug, and Cosmetic Act.

Device application means a PMA, PDP, premarket notification submission, *de novo* classification request, or HDE.

Drug has the meaning given the term in section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act.

Field alert report is a report as described in § 314.81 of this chapter.

Fifteen-day report is a report required to be submitted within 15 days as described in § 314.80 of this chapter or § 600.80 of this chapter, as well as followup reports to such a report.

Five-day report is a report as described in §§ 803.3 and 803.53 of this chapter, as well as supplemental or followup reports to such a report as described in § 803.56 of this chapter.

Humanitarian device exemption (HDE) has the meaning given the term in § 814.3 of this chapter.

Malfunction report is a report as described in § 803.50 of this chapter as well as supplemental or followup reports to such a report as described in § 803.56 of this chapter.

New drug application (NDA) has the meaning given the term ''application'' in § 314.3(b) of this chapter.

Premarket approval application (PMA) has the meaning given the term in § 814.3 of this chapter.

Premarket notification submission is a submission as described in §807.87 of this chapter.

Product Development Protocol (PDP) is a submission as set forth in section 515(f) of the Federal Food, Drug, and Cosmetic Act.

§4.102 What reports must you submit to FDA for your combination product or constituent part?

(a) *In general.* If you are a constituent part applicant, the reporting requirements applicable to you that are identified in this section apply to your constituent part, and if you are a combination product applicant, the reporting requirements applicable to you that are identified in this section apply to your combination product as a whole.

(b) *Reporting requirements applicable to both combination product applicants and constituent part applicants.* If you are a combination product applicant or constituent part applicant, you must comply with the reporting requirements identified in paragraphs (b)(1), (b)(2), or (b)(3) of this section for your product based on its application type. If you are a combination product applicant, you are required to submit a report as specified in this paragraph unless you have already submitted a report in accordance with paragraph (c) of this section for the same event that: Includes the information required under the applicable regulations identified in this paragraph, is required to be submitted in the same manner under §4.104, and meets the deadlines under the applicable regulations identified in this paragraph.

(1) If your combination product or device constituent part received marketing authorization under a device application, you must comply with the requirements for postmarketing safety reporting described in parts 803 and 806 of this chapter with respect to your product.

(2) If your combination product or drug constituent part received marketing authorization under an NDA or ANDA, you must comply with the requirements for postmarketing safety reporting described in part 314 of this chapter with respect to your product.

(3) If your combination product or biological product constituent part received marketing authorization under a BLA, you must comply with the requirements for postmarketing safety reporting described in parts 600 and 606 of this chapter with respect to your product.

(c) *Reporting requirements applicable only to combination product applicants.* If you are a combination product applicant, in addition to compliance with paragraph (a) of this section, you must also comply with the reporting requirements identified under this paragraph as applicable to your product based on its constituent parts. If you are a combination product applicant, you are required to submit a report as specified in this paragraph unless you have already submitted a report in accordance with paragraph (b) of this section for the same event that: Includes the information required under the applicable regulations for the report identified in this paragraph; is required to be submitted in the same manner under §4.104 of this chapter; and, unless otherwise specified in this paragraph, meets the deadlines under the applicable regulations for the report identified in this paragraph.

(1) If your combination product contains a device constituent part, you must submit:

(i) Five-day reports;

(ii) Malfunction reports; and

(iii) Correction or removal reports, and maintain records as described in §806.20 of this chapter for corrections and removals not required to be reported.

(2) If your combination product contains a drug constituent part, you must submit:

(i) Field alert reports; and

(ii) Fifteen-day reports as described in §314.80 of this chapter, which must be submitted within 30 calendar days instead of 15 calendar days if your combination product received marketing authorization under a device application.

(3) If your combination product contains a biological product constituent part, you must submit:

(i) Biological product deviation reports; and

(ii) Fifteen-day reports as described in § 600.80 of this chapter, which must be submitted within 30 calendar days instead of 15 calendar days if your combination product received marketing authorization under a device application.

(d) *Other reporting requirements for combination product applicants.* (1) If you are the combination product applicant for a combination product that contains a device constituent part and that received marketing authorization under an NDA, ANDA, or BLA, in addition to the information otherwise required in the periodic safety reports you submit under § 314.80 or § 600.80 of this chapter, your periodic safety reports must also include a summary and analysis of the reports identified in paragraphs (c)(1)(i) and (ii) of this section that were submitted during the report interval.

(2) If you are the combination product applicant for a combination product that received marketing authorization under a device application, in addition to the reports required under paragraphs (b) and (c) of this section, you must submit reports regarding postmarketing safety events if notified by the Agency in writing that the Agency requires additional information. We will specify what safety information is needed and will require such information if we determine that protection of the public health requires additional or clarifying safety information for the combination product. In any request under this section, we will state the reason or purpose for the safety information request, specify the due date for submitting the information, and clearly identify the reported event(s) related to our request.

§ 4.103 What information must you share with other constituent part applicants for the combination product?

(a) When you receive information regarding an event that involves a death or serious injury as described in § 803.3 of this chapter, or an adverse experience as described in § 314.80(a) of this chapter or § 600.80(a) of this chapter, associated with the use of the combination product, you must provide the information to the other constituent part applicant(s) for the combination product no later than 5 calendar days of your receipt of the information.

(b) With regard to information you must provide to the other constituent part applicant(s) for the combination product, you must maintain records that include:

(1) A copy of the information you provided,

(2) The date the information was received by you,

(3) The date the information was provided to the other constituent part applicant(s), and

(4) The name and address of the other constituent part applicant(s) to whom you provided the information.

§ 4.104 How and where must you submit postmarketing safety reports for your combination product or constituent part?

(a) If you are a constituent part applicant, you must submit postmarketing safety reports in accordance with the regulations identified in § 4.102(b) that are applicable to your product based on its application type.

(b) If you are a combination product applicant, you must submit postmarketing safety reports required under § 4.102 in the manner specified in the regulation applicable to the type of report, with the following exceptions:

(1) You must submit the postmarketing safety reports identified in § 4.102(c)(1)(i) and (ii) in accordance with § 314.80(g) of this chapter if your combination product received marketing authorization under an NDA or ANDA or in accordance with § 600.80(h) of this chapter if your combination product received marketing authorization under a BLA.

(2) You must submit the postmarketing safety reports identified in § 4.102(c)(2)(ii) and (c)(3)(ii) in accordance with § 803.12(a) of this chapter if your combination product received marketing authorization under a device application.

§ 4.105 What are the postmarketing safety reporting recordkeeping requirements for your combination product or constituent part?

(a) If you are a constituent part applicant:

(1) You must maintain records in accordance with the recordkeeping requirements in the applicable regulation(s) described in § 4.102(b).

(2) You must maintain records required under § 4.103(b) for the longest time period required for records under the postmarketing safety reporting regulations applicable to your product under § 4.102(b).

(b) If you are a combination product applicant, you must maintain records in accordance with the longest time period required for records under the regulations applicable to your product under § 4.102.

PART 5—ORGANIZATION

Subparts A–L [Reserved]

Subpart M—Organization

Sec.
5.1100 Headquarters.
5.1105 Chief Counsel, Food and Drug Administration.
5.1110 FDA Public Information Offices.

AUTHORITY: 5 U.S.C. 552; 21 U.S.C. 301–397.

SOURCE: 77 FR 15962, Mar. 19, 2012, unless otherwise noted.

Subparts A–L [Reserved]

Subpart M—Organization

§ 5.1100 Headquarters.

Office of the Commissioner.[1]
Office of the Chief Counsel.
Office of the Executive Secretariat.
  Freedom of Information Staff.
  Dockets Management Staff.
Office of the Chief Scientist.[1]
Office of Counter-Terrorism and Emerging Threats.
Office of Scientific Integrity.
Office of Regulatory Science and Innovation.
  Division of Science Innovation and Critical Path.
  Division of Scientific Computing and Medical Information.
Office of Scientific Professional Development.
Office of Health Informatics.
Office of Women's Health.
Office of External Affairs.
  Office of Media Affairs.
  Office of Communications.
  Office of Health and Constituent Affairs.
Office of Minority Health.
National Center for Toxicological Research.[2]
  Office of the Center Director.
  Office of Management.
  Office of Research.
  Division of Biochemical Toxicology.
  Division of Genetic and Molecular Toxicology.
  Division of Microbiology.
  Division of Systems Biology.
  Division of Neurotoxicology.
  Division of Bioinformatics and Biostatistics.
  Office of Scientific Coordination.
Office of Foods and Veterinary Medicine.[3]
  Communications and Public Engagement Staff.
  Executive Secretariat Staff.
Office of Resource Planning and Strategic Management.
  Strategic Planning and Budget Formulation Staff.
  Risk Analytics Staff.
Office of Coordinated Outbreak Response and Evaluation Network.[4]
  Prevention Staff.
  Response Staff.
Center for Food Safety and Applied Nutrition.[5]
Office of the Center Director.
  International Affairs Staff.
  Executive Operations Staff.
Office of Management.
  Safety Staff.
  Division of Budget & Planning.
  Division of Program Services.
Office of Analytics and Outreach.
  Food Defense and Emergency Coordination Staff.
  Biostatistics and Bioinformatics Staff.
  Division of Education, Outreach and Information.
  Education and Outreach Branch.
  Information Center Branch.
  Web Branch.
  Division of Public Health Informatics and Analytics.
  Epidemiology and Surveillance Branch.
  Signals Management Branch.
  Consumers Studies Branch.
  Division of Risk and Decision Analysis.
  Risk Analysis Branch.
  Contaminant Assessment Branch.
  Exposure Assessment Branch.
Office of Food Safety.

[1] Mailing address: 10903 New Hampshire Ave., Silver Spring, MD 20993.

[2] Mailing address: Food and Drug Administration, 3900 NCTR Rd., Jefferson, AR 72079.

[3] Mailing address: Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993.

[4] Mailing address: 4300 River Rd., University Station (HFS–015), College Park, MD 20740.

[5] Mailing address: Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740.

Retail Food Production Staff.
Multi-Commodity Foods Staff.
Division of Seafood Science and Technology.
Chemical Hazard Science Branch.
Microbiological Hazards Science Branch.
Division of Food Processing Science & Technology.
Process Engineering Branch.
Food Technology Branch.
Division of Plant and Dairy Food Safety.
Plant Products Branch.
Dairy and Egg Branch.
Division of Seafood Safety.
Shellfish and Aquaculture Policy Branch.
Seafood Processing and Technology Policy Branch.
Division of Produce Safety.
Fresh Produce Branch.
Processed Produce Branch.
Division of Dairy, Egg, and Meat Products.
Milk and Milk Products Branch.
Egg and Meat Products Branch.
Division of Plant Products and Beverages.
Plant Products Branch.
Beverages Branch.
Office of Cosmetics and Colors.
Division of Color Certification and Technology.
Division of Cosmetics.
Office of Regulatory Science.
Division of Analytical Chemistry.
Methods Development Branch.
Spectroscopy and Mass Spectrometry Branch.
Division of Microbiology.
Microbial Methods and Development Branch.
Molecular Methods and Subtyping Branch.
Division of Bioanalytical Chemistry.
Chemical Contaminants Branch.
Bioanalytical Methods Branch.
Office of Food Additive Safety.
Division of Food Contract Notifications.
Division of Biotechnology and GRAS Notice Review.
Division of Petition Review.
Office of Compliance.
Division of Enforcement.
Division of Field Programs and Guidance.
Office of Applied Research and Safety Assessment.
Division of Molecular Biology.
Division of Virulence Assessment.
Virulence Mechanisms Branch.
Immunobiology Branch.
Division of Toxicology.
Office of Regulations, Policy and Social Sciences.
Regulations and Special Government Employee Management Staff.
Division of Social Sciences.
Office of Nutrition and Food Labeling.
Food Labeling and Standards Staff.
Nutrition Programs Staff.
Office of Dietary Supplement Program.
Evaluation and Research Staff.
Regulatory Implementation Staff.
Center for Veterinary Medicine.[6]
Office of the Center Director.
Office of Management.
Program and Resources Management Staff.
Human Capital Management Staff.
Talent Development Staff.
Management Logistics Staff.
Budget Planning and Evaluation Staff.
Office of New Animal Drug Evaluation.
Division of Therapeutic Drugs for Food Animals.
Division of Production Drugs.
Division of Therapeutic Drugs for Non-Food Animals.
Division of Human Food Safety.
Division of Manufacturing Technologies.
Division of Scientific Support.
Division of Generic Animal Drugs.
Division of Business Information Science and Management.
Office of Surveillance and Compliance.
Division of Surveillance.
Division of Animal Feeds.
Division of Compliance.
Division of Veterinary Product Safety.
Office of Research.
Division of Residue Chemistry.
Division of Applied Veterinary Research.
Division of Animal and Food Microbiology.
Office of Minor Use and Minor Species Animal Drug Development.
OFFICE OF MEDICAL PRODUCTS AND TOBACCO
Office of Medical Products and Tobacco—Immediate Office.[7]
Office of Special Medical Programs—Immediate Office.[8]
Advisory Committee Oversight and Management Staff.
Good Clinical Practice Staff.
Office of Pediatric Therapeutics.
Office of Orphan Products Development.
Office of Combination Products.
Center for Biologics Evaluation and Research.[9]
Office of the Center Director.
Executive Operations Staff.
Regulatory Information Management Staff.
Regulations and Policy Staff.
Records Management Staff.
Bioinformatics Support Staff.
Business Operations Staff.
Office of Management.
Planning and Performance Management Staff.

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[6] Mailing address: Food and Drug Administration, 7519 Standish Pl., Rockville MD 20855.

[7] Mailing address: 10903 New Hampshire Ave., Bldg. 1, Silver Spring, MD 20993.

[8] Mailing address: 10903 New Hampshire Ave., Bldg. 32, Silver Spring, MD 20993.

[9] Mailing address: 10903 New Hampshire Ave., Bldg. 71, Silver Spring, MD 20993.

Division of Program Services.
Program Operations Branch.
Program Services Branch.
Division of Budget and Resource Management.
Budget Analysis and Formulation Branch.
Resource Management Branch.
Division of Program Services.
Building Operations Staff.
Program Management Services Branch.
Program Operations Branch.
Division of Scientific Advisors and Consultants.
Division of Veterinary Services.
Office of Compliance and Biologics Quality.
Division of Case Management.
Blood and Tissue Compliance Branch.
Advertising and Promotional Labeling Branch.
Biological Drug and Device Compliance Branch.
Division of Manufacturing and Product Quality.
Product Release Branch.
Manufacturing Review Branch I.
Manufacturing Review Branch II.
Applications Review Branch.
Division of Inspections and Surveillance.
Program Surveillance Branch.
Bioresearch Monitoring Branch.
Division of Biological Standards and Quality Control.
Laboratory of Analytical Chemistry and Blood Related Products.
Quality Assurance Branch.
Laboratory of Microbiology, In-vivo Testing and Standards.
Office of Blood Research and Review.
Administrative Staff.
Policy and Publication Staff.
Regulatory Project Management Staff.
Division of Emerging and Transfusion Transmitted Diseases.
Laboratory of Molecular Virology.
Laboratory of Emerging Pathogens.
Laboratory of Bacterial and Transmissible Spongiform Encephalopathy Agents.
Product Review Branch.
Division of Hematology Clinical Review.
Hematology Product Review Branch.
Clinical Review Branch.
Division of Blood Components and Devices.
Blood and Plasma Branch.
Devices and Review Branch.
Division of Hematology Research and Review.
Laboratory of Cellular Hematology.
Laboratory of Hemostasis.
Laboratory of Plasma Derivatives.
Laboratory of Biochemistry and Vascular Biology.
Office of Vaccine Research and Review.
Program Operations Staff.
Division of Bacterial, Parasitic, and Allergenic Products.
Laboratory of Immunobiochemistry.
Laboratory of Respiratory and Special Pathogens.
Laboratory of Bacterial Polysaccharides.
Laboratory of Mucosal Pathogens and Cellular Immunology.
Division of Viral Products.
Laboratory of Pediatric and Respiratory Viral Diseases.
Laboratory of Hepatitis Viruses.
Laboratory of Retroviruses.
Laboratory of DNA Viruses.
Laboratory of Vector-Borne Diseases.
Laboratory of Method Development.
Laboratory of Immunoregulation.
Division of Vaccines and Related Products Applications.
Clinical Review Branch 1.
Clinical Review Branch 2.
CMC Review Branch 1.
CMC Review Branch 2.
CMC Review Branch 3.
Review Management Support Branch.
Office of Communication, Outreach, and Development.
Division of Disclosure and Oversight Management.
Congressional and Oversight Branch.
Access Litigation and Freedom of Information Branch.
Division of Manufacturers Assistance and Training.
Career Development and Directed Training Branch.
Manufacturers Assistance and Technical Training Branch.
Division of Communication and Consumer Affairs.
Communication Technology Branch.
Consumer Affairs Branch.
Office of Biostatistics and Epidemiology.
Division of Biostatistics.
Vaccine Evaluation Branch.
Therapeutics Evaluation Branch.
Division of Epidemiology.
Pharmacovigilance Branch.
Analytic Epidemiology Branch.
Office of Cellular, Tissue and Gene Therapies.
Regulatory Management Staff.
Division of Cellular and Gene Therapies.
Cell Therapies Branch.
Gene Therapies Branch.
Gene Transfer and Immunogencity Branch.
Tumor Vaccine and Biotechnology Branch.
Cellular and Tissue Therapy Branch.
Division of Clinical Evaluation and Pharmacological Toxicology Review.
General Medicine Branch.
Pharmacology/Toxicology Branch.
Oncology Branch.
Division of Human Tissues.
Human Tissue and Reproduction Branch.
Center for Tobacco Products.[10]
Office of the Center Director.

[10] Mailing address: 10903 New Hampshire Ave., Bldg. 75, Silver Spring, MD 20993.

Office of Management.
Acquisitions and Assistance Staff.
Information and Technology Staff.
Management and Logistics Staff.
Division of Financial Management.
Division of Human Capital.
Office of Regulations.
Office of Science.
Regulatory Science and Management Staff.
Research Staff.
Division of Regulatory Project Management.
Regulatory Project Management Branch I.
Regulatory Project Management Branch II.
Regulatory Project Management Branch III.
Regulatory Project Management Branch IV.
Division of Regulatory Science Informatics.
Division of Product Science.
Division of Individual Health Science.
Division of Population Health Science.
Division of Non-Clinical Science.
Office of Health Communication and Education.
Division of Public Health Education.
Division of Health, Scientific, and Regulatory Communication.
Office of Compliance and Enforcement.
Division of Enforcement and Manufacturing.
Division of Promotion, Advertising and Labeling.
Division of State Programs.
Division of Business Operations.
Center for Drug Evaluation and Research.[11]
Office of the Center Director.
Controlled Substance Staff.
Professional Affairs and Stakeholder Engagement Staff.
Counter-Terrorism and Emergency Coordination Staff.
Drug Shortages Staff.
Office of Regulatory Policy.
Division of Regulatory Policy I.
Division of Regulatory Policy II.
Division of Regulatory Policy III.
Division of Regulatory Policy IV.
Division of Information Disclosure Policy.
Proactive Disclosure Branch.
Freedom of Information Branch.
Office of Management.
Strategic Programs and Initiatives Staff.
Ethics Liaison Staff.
Division of Budget Execution and Resource Management.
Budget Execution Branch.
Acquisitions Support Branch.
Financial Accountability Branch.
Division of Management Services.
Human Capital Management Branch.
Human Capital Programs Branch.
Facilities Operations Branch.
Property and Travel Services Branch.
Leave and Performance Management Branch.
Division of User Fee Management and Budget Formulation.
Generics Branch.
Policy and Operations Branch.
Brands Branch.
Office of Communications.
Division of Online Communications.
Division of Health Communications.
Division of Drug Information.
Office of Compliance.
Program Management and Analysis Staff.
Office of Manufacturing Quality.
Manufacturing Guidance and Policy Staff.
Division of Drug Quality I.
Global Compliance Branch I.
Global Compliance Branch II.
Division of Drug Quality II.
Global Compliance Branch III.
Global Compliance Branch IV.
Office of Unapproved Drugs and Labeling Compliance.
Division of Prescription Drugs.
Prescription Drugs Branch.
Compounding and Pharmacy Practices Branch.
Division of Non-Prescription Drugs and Health Fraud.
Over-the-Counter Drugs Branch.
Health Fraud Branch.
Office of Scientific Investigations.
Policy Staff.
Division of Enforcement and Postmarket Safety.
Compliance Enforcement Branch.
Postmarketing Safety Branch.
Division of Clinical Compliance Evaluation.
Good Clinical Practice Compliance Oversight Branch.
Good Clinical Practice Assessment Branch.
Office of Drug Security, Integrity and Response.
Division of Import Exports and Recalls.
Recalls and Shortages Branch.
Import Export Compliance Branch.
Division of Supply Chain Integrity.
Supply Chain Strategy and Policy Branch.
Supply Chain Response and Enforcement Branch.
Office of Program and Regulatory Operations.
Project Management and Coordination Staff I.
Project Management and Coordination Staff II.
Drug Registration and Listing Staff.
Office of Medical Policy.
Office of Prescription Drug Promotion.
Division of Consumer Drug Promotion.
Division of Professional Drug Promotion.
Office of Medical Policy Initiatives.
Division of Medical Policy Development.
Division of Medical Policy Programs.

[11] Mailing address: 10903 New Hampshire Ave., Bldg. 51, Silver Spring, MD 20993.

Division of Clinical Trial Quality.
Office of Translational Science.
Program Management and Analysis Staff.
Office of Biostatistics.
Division of Biometrics I.
Division of Biometrics II.
Division of Biometrics III.
Division of Biometrics IV.
Division of Biometrics V.
Division of Biometrics VI.
Division of Biometrics VII.
Division of Biometrics VIII.
Office of Clinical Pharmacology.
Division of Clinical Pharmacology I.
Division of Clinical Pharmacology II.
Division of Clinical Pharmacology III.
Division of Clinical Pharmacology IV.
Division of Clinical Pharmacology V.
Division of Pharmacometrics.
Division of Applied Regulatory Science.
Office of Computational Science.
Office of Study Integrity and Surveillance.
Division of New Drug Bioequivalence Evaluation.
Division of Generic Drug Bioequivalence Evaluation.
Office of Executive Programs.
Division of Learning and Organizational Development.
Scientific and Regulatory Education Branch.
Training Design and Delivery Branch.
Leadership and Organizational Development Branch.
Division of Executive Operations.
Division of Advisory Committee and Consultant Management.
Office of Surveillance and Epidemiology.
Regulatory Science Staff.
Regulatory Affairs Staff.
Program Management and Analysis Staff.
Project Management Staff.
Office of Medication Error Prevention and Risk Management.
Division of Medication Error Prevention and Analysis.
Division of Risk Management.
Office of Pharmacovigilance and Epidemiology.
Division of Epidemiology I.
Division of Epidemiology II.
Division of Pharmacovigilance I.
Division of Pharmacovigilance II.
Office of New Drugs.
Program Management and Analysis Staff.
Pharmacology/Toxicology Staff.
Regulatory Affairs Staff.
Office of Drug Evaluation I.
Division of Cardiovascular and Renal Products.
Division of Neurology Products.
Division of Psychiatry Products.
Office of Drug Evaluation II.
Division of Metabolism and Endocrinology Products.
Division of Pulmonary, Allergy, and Rheumatology Products.
Division of Anesthesia, Analgesia, and Addiction Products.
Office of Drug Evaluation III.
Division of Gastroenterology and Inborn Effects Products.
Division of Bone, Reproductive and Urologic Products.
Division of Dermatology and Dental Products.
Office of Antimicrobial Products.
Division of Anti-Infective Products.
Division of Anti-Viral Products.
Division of Transplant and Ophthalmology Products.
Office of Drug Evaluation IV.
Division of Nonprescription Drug Products.
Division of Medical Imaging Products.
Division of Pediatrics and Maternal Health.
Office of Hematology and Oncology Drug Products.
Division of Oncology Products I.
Division of Oncology Products II.
Division of Hematology Products.
Division of Hematology Oncology Toxicology.
Office of Strategic Programs.
Office of Program and Strategic Analysis.
Program Evaluation and Implementation Staff.
Economics Staff.
Performance Analysis and Data Services Staff.
Lean Management Staff.
Office of Business Informatics.
Division of Regulatory Review and Drug Safety Services and Solutions.
Division of Business Management Services and Solutions.
Division of Data Management Services and Solutions.
Division of Drug Quality and Compliance Services and Solutions.
Office of Generic Drugs.
Clinical Safety Surveillance Staff.
Program Management and Analysis Staff.
Communications Staff.
Office of Research and Standards.
Division of Therapeutic Performance.
Division of Quantitative Methods and Modeling.
Office of Bioequivalence.
Division of Bioequivalence I.
Division of Bioequivalence II.
Division of Bioequivalence III.
Division of Clinical Review.
Office of Generic Drug Policy.
Division of Legal and Regulatory Support.
Division of Policy Development.
Office of Regulatory Operations.
Division of Labeling Review.
Division of Filing Review.
Division of Project Management.
Division of Quality Management Systems.
Office of Pharmaceutical Quality.
Scientific Staff.
Program Management and Analysis Staff.

Office of Biotechnology Products.
Division of Biotechnology Review and Research I.
Division of Biotechnology Review and Research II.
Division of Biotechnology Review and Research III.
Division of Biotechnology Review and Research IV.
Office of New Drug Products.
Division of Life Cycle API.
Life Cycle Branch I.
Life Cycle Branch II.
Life Cycle Branch III.
Division of New Drug API.
New Drug Branch I.
New Drug Branch II.
Division of New Drug Products I.
New Drug Products Branch I.
New Drug Products Branch II.
New Drug Products Branch III.
Division of New Drug Products II.
New Drug Products Branch IV.
New Drug Products Branch V.
New Drug Products Branch VI.
Division of Biopharmaceutics.
Biopharmaceutics Branch I.
Biopharmaceutics Branch II.
Biopharmaceutics Branch III.
Office of Policy for Pharmaceutical Quality.
Division of Regulations, Guidance and Standards.
Policy Development and Evaluation Branch I.
Policy Development and Evaluation Branch II.
Compendial Operations and Standards Branch.
Division of Internal Policies and Programs.
Policy Development and Evaluation Branch I.
Policy Development and Evaluation Branch II.
Office of Process and Facilities.
Division of Process Assessment I.
Process Assessment Branch I.
Process Assessment Branch II.
Process Assessment Branch III.
Division of Process Assessment II.
Process Assessment Branch IV.
Process Assessment Branch V.
Process Assessment Branch VI.
Division of Process Assessment III.
Process Assessment Branch VII.
Process Assessment Branch VIII.
Process Assessment Branch IX.
Division of Microbiology Assessment.
Microbiology Assessment Branch I.
Microbiology Assessment Branch II.
Microbiology Assessment Branch III.
Microbiology Assessment Branch IV.
Division of Inspectional Assessment.
Inspectional Assessment Branch I.
Inspectional Assessment Branch II.
Inspectional Assessment Branch III.
Office of Surveillance.
Division of Quality Intelligence, Risk Analysis, and Modeling.
Data Integrity Branch.
Quality Intelligence Branch.
Analysis and Modeling Branch.
Division of Quality Surveillance Assessment.
Quality Deviation and Assessment Branch.
Inspection Assessment Branch.
Office of Testing and Research.
Division of Product Quality Research.
Product Quality Branch I.
Product Quality Branch II.
Division of Pharmaceutical Analysis.
Pharmaceutical Analysis Branch I.
Pharmaceutical Analysis Branch II.
Office of Program and Regulatory Operations.
Division of Regulatory and Business Process Management I.
Regulatory and Business Process Management Branch I.
Regulatory and Business Process Management Branch II.
Division of Regulatory and Business Process Management II.
Regulatory and Business Process Management Branch III.
Regulatory and Business Process Management Branch IV.
Division of Operational Excellence, Learning, and Professional Development.
Learning and Professional Development Branch.
Organizational Excellence Branch.
Office of Lifecycle Drug Products.
Division of Immediate Release Products I.
Immediate Release Branch I.
Immediate Release Branch II.
Immediate Release Branch III.
Division of Immediate Release Products II.
Immediate Release Branch IV.
Immediate Release Branch V.
Immediate Release Branch VI.
Division of Modified Release Products.
Modified Release Branch I.
Modified Release Branch II.
Modified Release Branch III.
Division of Liquid-Based Products.
Liquid-Based Branch I.
Liquid-Based Branch II.
Liquid-Based Branch III.
Division of Post-Marketing Activities I.
Post-Marketing Branch I.
Post-Marketing Branch II.
Division of Post-Marketing Activities II.
Post-Marketing Branch III.
Post-Marketing Branch IV.
Post-Marketing Branch V.
Center for Devices and Radiological Health.[12]
Office of the Center Director.
Regulations Staff.
Office of Management Operations.
Division of Ethics and Management Operations.

[12] Mailing address: 10903 New Hampshire Ave., Bldg. 66, Silver Spring, MD 20993.

Human Resources and Administrative Management Branch.
Integrity, Conference and Committee Management Branch.
Division of Planning, Analysis and Finance and Property.
Planning Branch.
Financial Management Branch.
Office of Compliance.
Program Management Staff.
Division of Bioresearch Monitoring.
Bioresearch Compliance Branch I.
Bioresearch Compliance Branch II.
Division of Analysis and Program Operations.
Quality Management System and Executive Secretary Staff.
Field Inspections Support Branch.
Recall Branch.
Registration and Risk Branch.
Allegations of Regulatory Misconduct Branch.
Division of Manufacturing and Quality.
Physical Medicine, Orthopedic, Neurology, and Dental Devices Branch.
Cardiovascular Devices Branch.
Abdominal and Surgical Devices Branch.
Respiratory, Ear/Nose/Throat, General Hospital, and Ophthalmic Devices Branch.
Division of Premarket and Labeling Compliance.
Surveillance and Enforcement Branch I.
Surveillance and Enforcement Branch II
Division of International Compliance Operations.
Foreign Enforcement Branch.
Imports Branch.
Exports Branch.
Office of Device Evaluation.
Program Management Staff.
Program Operations Staff.
Pre-Market Approval Staff.
Investigational Device Exemption Staff.
Pre-Market Notification Section.
Division of Cardiovascular Devices.
Circulatory Support Devices Branch.
Cardiac Diagnostics Devices Branch.
Implantable Electrophysiology Devices Branch.
Vascular Surgery Devices Branch.
Structural Heart Devices Branch.
Interventional Cardiology Devices Branch.
Cardiac Electrophysiology Devices Branch.
Peripheral Interventional Devices Branch.
Division of Reproductive, Gastro-Renal, and Urological Devices.
Obstetrics/Gynecology Devices Branch.
Urology and Lithotripsy Devices Branch.
Renal Devices Branch.
Gastroenterology Devices Branch.
Division of Orthopedic Devices.
Restorative and Repair Devices Branch.
Joint and Fixation Branch I.
Joint and Fixation Branch II.
Anterior Spine Devices Branch.
Posterior Spine Devices Branch.
Division of Ophthalmic and Ear, Nose, and Throat Devices.
Intraocular and Corneal Implant Devices Branch.
Diagnostic and Surgical Devices Branch.
Contact Lenses and Retinal Devices Branch.
Ear, Nose and Throat Devices Branch.
Division of Anesthesiology, General Hospital, Respiratory Infection Control, and Dental Devices.
General Hospital Devices Branch.
Infection Control Devices Branch.
Dental Devices Branch.
Anesthesiology Devices Branch.
Respiratory Devices Branch.
Division of Neurological and Physical Medicine Devices.
Neurostimulation Devices Branch.
Neurodiagnostic and Neurosurgical Devices Branch.
Physical Medicine Devices Branch.
Division of Surgical Devices.
General Surgery Devices Branch I.
General Surgery Devices Branch II.
Plastic and Reconstructive Surgery Devices Branch I.
Plastic and Reconstructive Surgery Devices Branch II.
Office of Science and Engineering Laboratories.
Division of Biology, Chemistry, and Materials Science.
Division of Biomedical Physics.
Division of Imaging, Diagnostics, and Software Reliability.
Division of Applied Mechanics.
Division of Administrative and Laboratory Support.
Office of Communication and Education.
Program Management Operations Staff.
Digital Communication Media Staff.
Division of Health Communication.
Web Communication Branch.
Strategic Communication Branch.
Division of Industry and Consumer Education.
Postmarket and Consumer Branch.
Premarket Programs Branch.
Division of Information Disclosure.
Freedom of Information Branch A.
Freedom of Information Branch B.
Division of Employee Training and Development.
Employee Development Branch.
Technology and Learning Management Branch.
Office of Surveillance and Biometrics.
Program Management Staff.
Informatics Staff.
Signal Management Staff.
Division of Biostatistics.
Therapeutic Statistics Branch I.
Therapeutic Statistics Branch II.
Therapeutic Statistics Branch III.
Diagnostic Statistics Branch I.
Diagnostic Statistics Branch II.
Division of Postmarket Surveillance.

Product Evaluation Branch I.
Product Evaluation Branch II.
Product Evaluation Branch III.
Information Analysis Branch.
MDR Policy Branch.
Division of Patient Safety Partnership.
Clinical Outreach Branch I.
Clinical Outreach Branch II.
Division of Epidemiology.
Epidemiologic Evaluation and Research Branch I.
Epidemiologic Evaluation and Research Branch II.
Epidemiologic Evaluation and Research Branch III.

Office of In Vitro Diagnostics and Radiological Health.
Division of Chemistry and Toxicology Devices.
Chemistry Branch.
Diabetes Branch.
Toxicology Branch.
Cardio-Renal Diagnostics Branch.
Division of Immunology and Hematology Devices.
Hematology Branch.
Immunology and Flow Cytometry Branch.
Division of Microbiology Devices.
Viral Respiratory and HPV Branch.
General Viral and Hepatitis Branch.
General Bacterial and Antimicrobial Susceptibility Branch.
Bacterial Respiratory and Medical Countermeasures Branch.
Division of Radiological Health.
Magnetic Resonance and Electronic Products Branch.
Diagnostic X-Ray Systems Branch.
Nuclear Medicine and Radiation Therapy Branch.
Mammography, Ultrasound and Imaging Software Branch.
Division of Mammography Quality Standards.
Program Management Branch.
Information Management Branch.
Division of Program Operations and Management.
Division of Molecular Genetics and Pathology.
Molecular Pathology and Cytology Branch.
Molecular Genetics Branch.

Office of Global Regulatory Operations and Policy.[13]

Office of International Programs.[14]

Office of Regulatory Affairs.[15]

Office of the Associate Commissioner for Regulatory Affairs.
Executive Secretariat Staff.
Information Technology Staff.

Office of Resource Management.[16]
Division of Planning Evaluation and Management.
Program Planning and Workforce Management Branch.
Program Evaluation Branch.
Division of Budget Formulation and Execution.
Division of Human Resources Development.
Division of Management Operations.

Office of Criminal Investigations.[17]
Mid-Atlantic Area Office.
Philadelphia Resident Unit.
Midwest Area Office.
Northeast Area Office.
Boston, MA Resident Unit.
Pacific Area Office.
San Francisco, CA Resident Unit.
Southeast Area Office.
San Juan, PR Resident Unit.
Atlanta, GA Resident Unit.
New Orleans, LA Resident Unit.
Southwest Area Office.
Dallas, TX Resident Unit.

Office of Communications and Quality Program Management.
Quality Management Systems Staff.
Project Coordination Staff.
Division of Communications.
Public Affairs and Editorial Services Branch.
Web and Digital Media Strategies Branch.

Office of Partnerships.[18]
Standards Implementation Staff.
Contracts and Grants Staff.

Office of Policy and Risk Management.[19]
Food and Feed Policy Staff.
Medical Products and Tobacco Policy Staff.
Risk Management Staff.
Division of Planning Evaluation and Management.
Program Evaluation Branch.
Work Planning Branch.

Office of Operations.[20]
Audit Staff.

Office of Enforcement and Import Operations.[21]
Division of Enforcement.
Division of Compliance Systems.
Enforcement Systems Branch.
Import Compliance Systems Branch.

[13] Mailing address: 10903 New Hampshire Ave., Bldg. 1, Silver Spring, MD 20993.
[14] Mailing address: 12420 Parklawn Dr., Element Building, Rockville, MD 20857.
[15] Mailing address: 10903 New Hampshire Ave., Bldg. 31, Silver Spring, MD 20993.
[16] Mailing address: 12420 Parklawn Dr., Element Building, Rockville, MD 20857.
[17] Mailing address: 7500 Standish Pl., MPN2 Building, Rockville, MD 20855.
[18] Mailing address: 12420 Parklawn Dr., Element Building, Rockville, MD 20857.
[19] Mailing address: 12420 Parklawn Dr., Element Building, Rockville, MD 20857.
[20] Mailing address: 10903 New Hampshire Ave., Bldg. 31, Silver Spring, MD 20993.
[21] Mailing address: 12420 Parklawn Dr., Element Building, Rockville, MD 20857.

Division of Import Operations.
Import Operations and Maintenance Branch.
Import Program Development and Implementation Branch.
Office of Regulatory Science.[22]
Food and Feed Scientific Staff.
Medical Products and Tobacco Scientific Staff.
Laboratory Operations and Support Staff.
Office of Food and Feed Operations.[23]
Division of Food Defense Targeting.
Division of Food and Feed Program Operations and Inspections.
Food and Feed Program Operations Branch.
Food and Feed Inspection Branch.
Food and Feed Trip Planning Branch.
Office of Medical Products and Tobacco Operations.[24]
Division of Products and Tobacco Program Operations.
Medical Device and Tobacco Program Operations Branch.
Team Biological Branch.
Division of Medical Products and Tobacco Inspections.
Medical Products and Tobacco Inspection Branch.
Drug Inspection Branch.
Medical Products and Tobacco Trip Planning Branch.
Regional Field Office, Northeast Region, Jamaica, NY.[25]
Operations Staff.
Intergovernmental Affairs Staff.
District Office New York.[26]
Domestic Compliance Branch.
Domestic Investigations Branch.
Resident Post Long Island, NY.
Resident Post White Plains, NY.
Resident Post Albany, NY.
Resident Post Binghamton, NY.
Resident Post Rochester, NY.
Resident Post Newburgh, NY.
Resident Post Syracuse, NY.
Import Operations Branch (Downstate).
Resident Post Port Elizabeth, NJ.
Import Operations Branch (Upstate).
Resident Post Champlain, NY.
Resident Post Alexandra Bay, NY.
Resident Post Massena, NY.
Resident Post Ogdensburg, NY.
Northeast Regional Laboratory.[27]
Microbiological Science Branch.
Chemistry Branch 1.
Chemistry Branch 2.
New England District Office.[28]
Compliance Branch.
Investigations Branch.
Resident Post Augusta, ME.
Resident Post Bridgeport, CT.
Resident Post Concord, NH.
Resident Post Hartford, CT.
Resident Post Providence, RI.
Resident Post Worcester, MA.
Resident Post Calais, ME.
Resident Post Houlton, ME.
Resident Post Highgate, VT.
Winchester Engineering and Analytical Center.[29]
Analytical Branch.
Engineering Branch.
Regional Field Office, Southwest Region, Dallas, TX.[30]
State Cooperative Programs Staff.
Resident Post Pharr.
Dallas District Office.[31]
Compliance Branch.
Investigations Branch.
Resident Post Austin, TX.
Resident Post Fort Worth, TX.
Resident Post Houston, TX.
Resident Post San Antonio, TX.
Resident Post Oklahoma City, OK.
Resident Post Little Rock, AR.
Kansas City District Office.[32]
Investigations Branch.
Resident Post Wichita, KS.
Resident Post Omaha, NE.
Resident Post Des Moines, IA.
Resident Post Springfield, MO.
Resident Post St Louis, MO.
Resident Post Davenport, IA.
Compliance Branch.
Denver District Office.[33]
Compliance Branch.
Investigations Branch.
Resident Post Salt Lake City, UT.
Resident Post Albuquerque, NM.
Arkansas Regional Laboratory.[34]
General Chemistry Branch.
Pesticide Chemistry Branch.
Microbiology Branch.

[22] Mailing address: 12420 Parklawn Dr., Element Building, Rockville, MD 20857.
[23] Mailing address: 12420 Parklawn Dr., Element Building, Rockville, MD 20857.
[24] Mailing address: 12420 Parklawn Dr., Element Building, Rockville, MD 20857.
[25] Mailing address: 158–15 Liberty Ave., Jamaica, NY 11433.
[26] Mailing address: 158–15 Liberty Ave., Jamaica, NY 11433.
[27] Mailing address: 158–15 Liberty Ave., Jamaica, NY 11433.
[28] Mailing address: 1 Montvale Ave., 4th Floor, Stoneham, MA 02180–3500.
[29] Mailing address: 109 Holton St., Winchester, MA 01890.
[30] Mailing address: 4040 North Central Expressway, Dallas, TX 75204–3128.
[31] Mailing address: 4040 North Central Expressway, Suite 300, Dallas, TX 75204–3128.
[32] Mailing address: 8050 Marshal Dr., Suite 250, Lenexa, KS 66214.
[33] Mailing address: Sixth Avenue and Kipling Street, Building 20, P.O. Box 25087, Denver, CO 80255–0087—Denver Federal Center.
[34] Mailing address: 3900 NCTR Rd., Bldg. 26, Jefferson, AR 72079.

Southwest Import District Office Dallas, TX.[35]
Compliance Branch.
Investigations Branch.
Resident Post Calexico.
Resident Post Eagle Pass.
Resident Post El Paso Bota.
Resident Post El Paso Bota Westmoreland.
Resident Post El Paso Ysleta Bridge.
Resident Post Houston (SWID).
Resident Post Laredo #2 Bridge.
Resident Post Laredo Columbia Bridge.
Resident Post Laredo World Trade Bridge.
Resident Post Los Tomates.
Resident Post Nogales #1.
Resident Post Nogales #2.
Resident Post Otay Mesa #1.
Resident Post Otay Mesa #2.
Resident Post Pharr.
Resident Post Rio Grande City.
Resident Post San Luis.
Kansas City Laboratory.[36]
Denver Laboratory.[37]

Central Regional Field Office Chicago IL.[38]
State Cooperative Programs Staff I.
State Cooperative Programs Staff II.
Regional Operations Staff.
Baltimore District Office Baltimore, MD.[39]
Compliance Branch.
Investigations Branch.
Resident Post Charleston, WV.
Resident Post Falls Church, VA.
Resident Post Seva.
Resident Post Richmond, VA.
Resident Post Roanoke, VA.
Resident Post Dundalk Marine Terminal, MD.
Resident Post Morgantown, WV.
District Office Cincinnati, OH.[40]
Compliance Branch.
Investigations Branch.
Resident Post Brunswick, OH.
Resident Post Columbus, OH.
Resident Post Toledo, OH.
Resident Post Louisville, KY.
Forensic Chemistry Center.[41]
Inorganic Chemistry Branch.
Organic Chemistry Branch.
District Office Parsippany, NJ.[42]
Compliance Branch.
Investigations Branch.
Resident Post Voorhees, NJ.
Resident Post North Brunswick, NJ.
District Office Philadelphia, PA.[43]
Compliance Branch.
Investigations Branch.
Resident Post Harrisburg, PA.
Resident Post Pittsburgh, PA.
Resident Post Wilkes-Barre, PA.
Resident Post Wilmington, PA.
District Office Chicago, IL.[44]
Compliance Branch.
Investigations Branch.
Resident Post Peoria, IL.
Resident Post Hinsdale, IL.
Resident Post Gurnee, IL.
Resident Post Springfield, IL.
Resident Post O'Hare Airport.
District Office Minneapolis, MN.[45]
Compliance Branch.
Investigations Branch.
Resident Post La Crosse, WI.
Resident Post Green Bay, WI.
Resident Post Milwaukee, WI.
Resident Post Madison, WI.
Resident Post Fargo, ND.
Resident Post Stevens Point, WI.
Resident Post Sioux, SD.
District Office Detroit, MI.[46]
Compliance Branch.
Investigations Branch.
Resident Post Kalamazoo, MI.
Resident Post South Bend, IN.
Resident Post Indianapolis, IN.
Resident Post Evansville, IN.
Resident Post
Philadelphia Laboratory.[47]
Detroit Laboratory.[48]

Southeast Regional Field Office Atlanta, GA.[49]
State Cooperative Programs Staff
Atlanta District Office.[50]
Compliance Branch.

[35] Mailing address: 4040 North Central Expressway, Suite 300, Dallas, TX 75204–3128.

[36] Mailing address: 11510 West 80th St., Lenexa, KS 66214.

[37] Mailing address: Sixth Avenue and Kipling Street, Building 20, Denver, CO 80255–0087—Denver Federal Center.

[38] Mailing address: 20 N. Michigan Ave., Suite 510, Chicago, IL 60602.

[39] Mailing address: 6000 Metro Dr., Suite 101, Baltimore, MD 21215.

[40] Mailing address: 6751 Steger Dr., Cincinnati, OH 45237.

[41] Mailing address: 6751 Steger Dr., Cincinnati, OH 45237.

[42] Mailing address: 10 Waterview Blvd., 3rd Floor, Parsippany, NJ 07054—Waterview Corporate Center.

[43] Mailing address: 200 Chestnut St., Room 900, Philadelphia, PA 19106—U.S. Customs House.

[44] Mailing address: 550 West Jackson Blvd., Suite 1500, Chicago, IL 60661.

[45] Mailing address: 250 Marquette Ave., Suite 600, Minneapolis, MN 55401.

[46] Mailing address: 300 River Pl., Suite 5900, Detroit, MI 48207.

[47] Mailing address: 200 Chestnut St., Room 900, Philadelphia, PA 19106—U.S. Customs House.

[48] Mailing address: 300 River Pl., Suite 5900, Detroit, MI 48207.

[49] Mailing address: 60 Eighth St. NE., Atlanta, GA 30309.

[50] Mailing address: 60 Eighth St. NE., Atlanta, GA 30309.

Investigations Branch.
Resident Post Savannah, GA.
Resident Post Tifton, GA.
Resident Post Charlotte, NC.
Resident Post Greensboro, NC.
Resident Post Greenville, NC.
Resident Post Raleigh, NC.
Resident Post Charleston, SC.
Resident Post Columbia, SC.
Resident Post Greenville, SC.
Resident Post Asheville, NC.
Florida District Office.[51]
Compliance Branch.
Investigations Branch.
Resident Post Jacksonville, FL.
Resident Post Miami, FL.
Resident Post Tallahassee, FL.
Resident Post Tampa, FL.
Resident Post Boca Raton, FL.
Resident Post Ft. Meyers, FL.
Resident Post Port Everglades, FL.
New Orleans, LA, District Office.[52]
Compliance Branch.
Investigations Branch.
Resident Post Baton Rouge, LA.
Resident Post Lafayette, LA.
Resident Post Covington, LA.
Resident Post Jackson, MS.
Resident Post Mobile, AL.
Nashville Branch.
Resident Post Knoxville, TN.
Resident Post Memphis, TN.
Resident Post Birmingham, AL.
Resident Post Montgomery, AL.
San Juan District Office.[53]
Compliance Branch.
Investigations Branch.
Resident Post Aquada, PR.
Resident Post Ponce, PR.
Southeast Regional Laboratory Atlanta, GA.[54]
Chemistry Branch I.
Microbiology Branch.
Atlanta Center for Nutrient Analysis.
Chemistry Branch II.
San Juan Laboratory.[55]
Regional Field Office, Pacific Region, Oakland, CA.[56]
State Cooperative Programs Staff.
District Office San Francisco, CA.[57]
Compliance Branch.
Investigations Branch.
Resident Post Las Vegas, NV.
Resident Post Fresno, CA.
Resident Post Sacramento, CA.
Resident Post Honolulu, HI.
Resident Post San Jose, CA.
Resident Post Stockton, CA.
Resident Post South San Francisco.
District Office Los Angeles, CA.[58]
Compliance Branch.
Import Operations Branch.
Resident Post Los Angeles Airport.
Resident Post Ontario, CA—Import.
Domestic Investigations Branch.
Resident Post Woodland Hills, CA.
Resident Post San Diego, CA.
Resident Post Tempe, AZ.
Resident Post Ontario, CA—Domestic.
District Office Seattle, WA.[59]
Compliance Branch.
Investigations Branch.
Resident Post Anchorage, AK.
Resident Post Boise, ID.
Resident Post Portland, ID.
Resident Post Spokane, WA.
Resident Post Oroville, WA.
Resident Post Portland, OR—Airport.
Resident Post Blaine, WA.
Resident Post Helena, MT.
Resident Post Sweetgrass, MT.
Resident Post Tacoma, WA.
Resident Post Puget Sound, WA.
Pacific Regional Laboratory Southwest.[60]
Food Chemistry Branch.
Drug Chemistry Branch.
Microbiology Branch.
Pacific Regional Laboratory Northwest.[61]
Chemistry Branch.
Microbiology Branch.
Seafood Products Research Center.
Office of Operations.
Office of Business Services.
Business Operations Staff.
Employee Resource and Information Center.
Division of Ethics and Integrity.
Office of Equal Employment Opportunity.
Compliance Staff.
Office of Finance, Budget, and Acquisitions.
Office of Budget.
Division of Budget Formulation.
Division of Budget Execution and Control.
Office of Acquisition and Grant Services.
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Division of Information Technology.
Office of Financial Operations.
Office of Financial Management.
Office of Financial Services.
Office of Human Resources.
Commission Corps Affairs Staff.
Management Analysis Services Staff.
Business Operations Staff.
Division of Workforce Relations.
Division of Policy, Programs, and Executive Resources.
Division of Human Resource Services for Office of the Commissioner/Office of Operations.
Division of Human Resource Services for Office of Foods and Veterinary Medicine/Office of Global Operations and Policy.
Division of Human Resource Services for Office of Medical Products and Tobacco.
FDA University.
Office of Facilities, Engineering and Mission Support Services.
Jefferson Laboratories Complex Staff.
Division of Operations Management and Community Relations.
Division of Planning, Engineering and Safety Management.
Office of Information Management and Technology.
Office of Information Management.
Office of Technology and Delivery.
Division of Infrastructure Operations.
Division of Application Services.
Division of Delivery Management and Support.
Office of Business and Customer Assurance.
Division of Business Partnership and Support.
Division of Management Services.
Office of Enterprise and Portfolio Management.
Office of Safety, Security, and Crisis Management.
Office of Security Operations.
Office of Crisis Management.
Office of Emergency Operations.
Office of Policy, Planning, Legislation, and Analysis.[62]
Management and Operations Staff.
Intergovernment Affairs Staff.
Office of Policy.
Regulations Policy and Management Staff.
Policy Development and Coordination Staff.
Office of Planning.
Planning Staff.
Program Evaluation and Process Improvement Staff.
Economics Staff.
Risk Communication Staff.
Office of Legislation.
Office of Public Health Strategy and Analysis.

[81 FR 78033, Nov. 7, 2016, as amended at 83 FR 13106, Mar. 27, 2018]

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§ 5.1105 Chief Counsel, Food and Drug Administration.

The Office of the Chief Counsel's mailing address is White Oak Bldg. 1, 10903 New Hampshire Ave., Silver Spring, MD 20993.

§ 5.1110 FDA public information offices.

(a) *Division of Dockets Management.* The Division of Dockets Management public room is located in rm. 1061, 5630 Fishers Lane, Rockville, MD 20852, Telephone: 301–827–6860.

(b) *Freedom of Information Staff.* The Freedom of Information Staff's Public Reading Room is located at the address available on the agency's web site at *http://www.fda.gov.*

(c) *Press Relations Staff.* Press offices are located in White Oak Bldg. 1, 10903 New Hampshire Ave., Silver Spring, MD 20993, Telephone: 301–827–6242; and at5001 Campus Dr., College Park, MD 20740, Telephone: 301–436–2335.

[77 FR 15962, Mar. 19, 2012, as amended at 79 FR 68114, Nov. 14, 2014; 81 FR 49895, July 29, 2016]

PART 7—ENFORCEMENT POLICY

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AUTHORITY: 21 U.S.C. 321–393; 42 U.S.C. 241, 262, 263b–263n, 264.

SOURCE: 42 FR 15567, Mar. 22, 1977, unless otherwise noted.

Subpart A—General Provisions

§ 7.1 Scope.

This part governs the practices and procedures applicable to regulatory enforcement actions initiated by the Food and Drug Administration pursuant to the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 *et seq.*) and other laws that it administers. This part also provides guidance for manufacturers and distributors to follow with respect to their voluntary removal or correction of marketed violative products. This part is promulgated to clarify and explain the regulatory practices and procedures of the Food and Drug Administration, enhance public understanding, improve consumer protection, and assure uniform and consistent application of practices and procedures throughout the agency.

[43 FR 26218, June 16, 1978, as amended at 65 FR 56476, Sept. 19, 2000]

§ 7.3 Definitions.

(a) *Agency* means the Food and Drug Administration.

(b) *Citation* or *cite* means a document and any attachments thereto that provide notice to a person against whom criminal prosecution is contemplated of the opportunity to present views to the agency regarding an alleged violation.

(c) *Respondent* means a person named in a notice who presents views concerning an alleged violation either in person, by designated representative, or in writing.

(d) *Responsible individual* includes those in positions of power or authority to detect, prevent, or correct violations of the Federal Food, Drug, and Cosmetic Act.

(e) [Reserved]

(f) *Product* means an article subject to the jurisdiction of the Food and Drug Administration, including any food, drug, and device intended for human or animal use, any cosmetic and biologic intended for human use, any tobacco product intended for human use, and any item subject to a quarantine regulation under part 1240 of this chapter. *Product* does not include an electronic product that emits radiation and is subject to parts 1003 and 1004 of this chapter.

(g) *Recall* means a firm's removal or correction of a marketed product that the Food and Drug Administration considers to be in violation of the laws it administers and against which the agency would initiate legal action, e.g., seizure. *Recall* does not include a market withdrawal or a stock recovery.

(h) *Correction* means repair, modification, adjustment, relabeling, destruction, or inspection (including patient monitoring) of a product without its physical removal to some other location.

(i) *Recalling firm* means the firm that initiates a recall or, in the case of a Food and Drug Administration-requested recall, the firm that has primary responsibility for the manufacture and marketing of the product to be recalled.

(j) *Market withdrawal* means a firm's removal or correction of a distributed product which involves a minor violation that would not be subject to legal action by the Food and Drug Administration or which involves no violation, e.g., normal stock rotation practices, routine equipment adjustments and repairs, etc.

(k) *Stock recovery* means a firm's removal or correction of a product that has not been marketed or that has not left the direct control of the firm, i.e., the product is located on premises owned by, or under the control of, the firm and no portion of the lot has been released for sale or use.

(l) *Recall strategy* means a planned specific course of action to be taken in conducting a specific recall, which addresses the depth of recall, need for public warnings, and extent of effectiveness checks for the recall.

(m) *Recall classification* means the numerical designation, i.e., I, II, or III, assigned by the Food and Drug Administration to a particular product recall to indicate the relative degree of health hazard presented by the product being recalled.

(1) Class I is a situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death.

(2) Class II is a situation in which use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.

(3) Class III is a situation in which use of, or exposure to, a violative product is not likely to cause adverse health consequences.

(n) *Consignee* means anyone who received, purchased, or used the product being recalled.

[42 FR 15567, Mar. 22, 1977, as amended at 43 FR 26218, June 16, 1978; 44 FR 12167, Mar. 6, 1979; 77 FR 5176, Feb. 2, 2012]

§ 7.12 Guaranty.

In case of the giving of a guaranty or undertaking referred to in section 303(c)(2) or (3) of the act, each person signing such guaranty or undertaking shall be considered to have given it.

§ 7.13 Suggested forms of guaranty.

(a) A guaranty or undertaking referred to in section 303(c)(2) of the act may be:

(1) Limited to a specific shipment or other delivery of an article, in which case it may be a part of or attached to the invoice or bill of sale covering such shipment or delivery, or

(2) General and continuing, in which case, in its application to any shipment or other delivery of an article, it shall be considered to have been given at the date such article was shipped or delivered by the person who gives the guaranty or undertaking.

(b) The following are suggested forms of guaranty or undertaking under section 303(c)(2) of the act:

(1) Limited form for use on invoice or bill of sale.

(Name of person giving the guaranty or undertaking) hereby guarantees that no article listed herein is adulterated or misbranded within the meaning of the Federal Food, Drug, and Cosmetic Act, or is an article which may not, under the provisions of section 404, 505, or 512 of the act, be introduced into interstate commerce.

(Signature and post-office address of person giving the guaranty or undertaking.)

(2) General and continuing form.

The article comprising each shipment or other delivery hereafter made by (name of person giving the guaranty or undertaking) to, or in the order of (name and post-office address of person to whom the guaranty or undertaking is given) is hereby guaranteed, as of the date of such shipment or delivery, to be, on such date, not adulterated or misbranded within the meaning of the Federal Food, Drug, and Cosmetic Act, and not an article which may not, under the provisions of section 404, 505, or 512 of the act, be introduced into interstate commerce.

(Signature and post-office address of person giving the guaranty of undertaking.)

(c) The application of a guaranty or undertaking referred to in section 303(c)(2) of the act to any shipment or other delivery of an article shall expire when such article, after shipment or delivery by the person who gave such guaranty or undertaking, becomes adulterated or misbranded within the meaning of the act, or becomes an article which may not, under the provisions of section 404, 505, or 512 of the act, be introduced into interstate commerce.

(d) A guaranty or undertaking referred to in section 303(c)(3) of the act shall state that the shipment or other delivery of the color additive covered thereby was manufactured by a signer thereof. It may be a part of or attached to the invoice or bill of sale covering such color. If such shipment or delivery is from a foreign manufacturer, such guaranty or undertaking shall be signed by such manufacturer and by an agent of such manufacturer who resides in the United States.

(e) The following are suggested forms of guaranty or undertaking under section 303(c)(3) of the act:

(1) For domestic manufacturers:

(Name of manufacturer) hereby guarantees that all color additives listed herein were manufactured by him, and (where color additive regulations require certification) are from batches certified in accordance with the applicable regulations promulgated

under the Federal Food, Drug, and Cosmetic Act.

(Signature and post-office address of manufacturer.)

(2) For foreign manufacturers:

(Name of manufacturer and agent) hereby severally guarantee that all color additives listed herein were manufactured by (name of manufacturer), and (where color additive regulations require certification) are from batches certified in accordance with the applicable regulations promulgated under the Federal Food, Drug, and Cosmetic Act.

(Signature and post-office address of manufacturer.)

(Signature and post-office address of agent.)

(f) For the purpose of a guaranty or undertaking under section 303(c)(3) of the act the manufacturer of a shipment or other delivery of a color additive is the person who packaged such color.

(g) A guaranty or undertaking, if signed by two or more persons, shall state that such persons severally guarantee the article to which it applies.

(h) No representation or suggestion that an article is guaranteed under the act shall be made in labeling.

Subpart B [Reserved]

Subpart C—Recalls (Including Product Corrections)—Guidance on Policy, Procedures, and Industry Responsibilities

SOURCE: 43 FR 26218, June 16, 1978, unless otherwise noted.

§ 7.40 Recall policy.

(a) Recall is an effective method of removing or correcting consumer products that are in violation of laws administered by the Food and Drug Administration. Recall is a voluntary action that takes place because manufacturers and distributors carry out their responsibility to protect the public health and well-being from products that present a risk of injury or gross deception or are otherwise defective. This section and §§ 7.41 through 7.59 recognize the voluntary nature of recall by providing guidance so that responsible firms may effectively discharge their recall responsibilities. These sections also recognize that recall is an alternative to a Food and Drug Administration-initiated court action for removing or correcting violative, distributed products by setting forth specific recall procedures for the Food and Drug Administration to monitor recalls and assess the adequacy of a firm's efforts in recall.

(b) Recall may be undertaken voluntarily and at any time by manufacturers and distributors, or at the request of the Food and Drug Administration. A request by the Food and Drug Administration that a firm recall a product is reserved for urgent situations and is to be directed to the firm that has primary responsibility for the manufacture and marketing of the product that is to be recalled.

(c) Recall is generally more appropriate and affords better protection for consumers than seizure, when many lots of product have been widely distributed. Seizure, multiple seizure, or other court action is indicated when a firm refuses to undertake a recall requested by the Food and Drug Administration, or where the agency has reason to believe that a recall would not be effective, determines that a recall is ineffective, or discovers that a violation is continuing.

[43 FR 26218, June 16, 1978, as amended at 65 FR 56476, Sept. 19, 2000]

§ 7.41 Health hazard evaluation and recall classification.

(a) An evaluation of the health hazard presented by a product being recalled or considered for recall will be conducted by an ad hoc committee of Food and Drug Administration scientists and will take into account, but need not be limited to, the following factors:

(1) Whether any disease or injuries have already occurred from the use of the product.

(2) Whether any existing conditions could contribute to a clinical situation that could expose humans or animals to a health hazard. Any conclusion shall be supported as completely as possible by scientific documentation and/or statements that the conclusion is the opinion of the individual(s) making the health hazard determination.

(3) Assessment of hazard to various segments of the population, e.g., children, surgical patients, pets, livestock,

etc., who are expected to be exposed to the product being considered, with particular attention paid to the hazard to those individuals who may be at greatest risk.

(4) Assessment of the degree of seriousness of the health hazard to which the populations at risk would be exposed.

(5) Assessment of the likelihood of occurrence of the hazard.

(6) Assessment of the consequences (immediate or long-range) of occurrence of the hazard.

(b) On the basis of this determination, the Food and Drug Administration will assign the recall a classification, i.e., Class I, Class II, or Class III, to indicate the relative degree of health hazard of the product being recalled or considered for recall.

§ 7.42 Recall strategy.

(a) *General.* (1) A recall strategy that takes into account the following factors will be developed by the agency for a Food and Drug Administration-requested recall and by the recalling firm for a firm-initiated recall to suit the individual circumstances of the particular recall:

(i) Results of health hazard evaluation.

(ii) Ease in identifying the product.

(iii) Degree to which the product's deficiency is obvious to the consumer or user.

(iv) Degree to which the product remains unused in the market-place.

(v) Continued availability of essential products.

(2) The Food and Drug Administration will review the adequacy of a proposed recall strategy developed by a recalling firm and recommend changes as appropriate. A recalling firm should conduct the recall in accordance with an approved recall strategy but need not delay initiation of a recall pending review of its recall strategy.

(b) *Elements of a recall strategy.* A recall strategy will address the following elements regarding the conduct of the recall:

(1) *Depth of recall.* Depending on the product's degree of hazard and extent of distribution, the recall strategy will specify the level in the distribution chain to which the recall is to extend, as follows:

(i) Consumer or user level, which may vary with product, including any intermediate wholesale or retail level; or

(ii) Retail level, including any intermediate wholesale level; or

(iii) Wholesale level.

(2) *Public warning.* The purpose of a public warning is to alert the public that a product being recalled presents a serious hazard to health. It is reserved for urgent situations where other means for preventing use of the recalled product appear inadequate. The Food and Drug Administration in consultation with the recalling firm will ordinarily issue such publicity. The recalling firm that decides to issue its own public warning is requested to submit its proposed public warning and plan for distribution of the warning for review and comment by the Food and Drug Administration. The recall strategy will specify whether a public warning is needed and whether it will issue as:

(i) General public warning through the general news media, either national or local as appropriate, or

(ii) Public warning through specialized news media, e.g., professional or trade press, or to specific segments of the population such as physicians, hospitals, etc.

(3) *Effectiveness checks.* The purpose of effectiveness checks is to verify that all consignees at the recall depth specified by the strategy have received notification about the recall and have taken appropriate action. The method for contacting consignees may be accomplished by personal visits, telephone calls, letters, or a combination thereof. A guide entitled ''Methods for Conducting Recall Effectiveness Checks'' that describes the use of these different methods is available upon request from the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. The recalling firm will ordinarily be responsible for conducting effectiveness checks, but the Food and Drug Administration will assist in this task where necessary and appropriate. The recall strategy will specify the method(s) to be used for

and the level of effectiveness checks that will be conducted, as follows:

(i) Level A—100 percent of the total number of consignees to be contacted;

(ii) Level B—Some percentage of the total number of consignees to be contacted, which percentage is to be determined on a case-by-case basis, but is greater that 10 percent and less than 100 percent of the total number of consignees;

(iii) Level C—10 percent of the total number of consignees to be contacted;

(iv) Level D—2 percent of the total number of consignees to be contacted; or

(v) Level E—No effectiveness checks.

[43 FR 26218, June 16, 1978, as amended at 46 FR 8455, Jan. 27, 1981; 59 FR 14363, Mar. 28, 1994; 68 FR 24879, May 9, 2003]

§ 7.45 Food and Drug Administration-requested recall.

(a) The Commissioner of Food and Drugs or designee may request a firm to initiate a recall when the following determinations have been made:

(1) That a product that has been distributed presents a risk of illness or injury or gross consumer deception.

(2) That the firm has not initiated a recall of the product.

(3) That an agency action is necessary to protect the public health and welfare.

(b) The Commissioner or his designee will notify the firm of this determination and of the need to begin immediately a recall of the product. Such notification will be by letter or telegram to a responsible official of the firm, but may be preceded by oral communication or by a visit from an authorized representative of the local Food and Drug Administration district office, with formal, written confirmation from the Commissioner or his designee afterward. The notification will specify the violation, the health hazard classification of the violative product, the recall strategy, and other appropriate instructions for conducting the recall.

(c) Upon receipt of a request to recall, the firm may be asked to provide the Food and Drug Administration any or all of the information listed in § 7.46(a). The firm, upon agreeing to the recall request, may also provide other information relevant to the agency's determination of the need for the recall or how the recall should be conducted.

[43 FR 26218, June 16, 1978, as amended at 69 FR 17290, Apr. 2, 2004]

§ 7.46 Firm-initiated recall.

(a) A firm may decide of its own volition and under any circumstances to remove or correct a distributed product. A firm that does so because it believes the product to be violative is requested to notify immediately the appropriate Food and Drug Administration district office listed in § 5.115 of this chapter. Such removal or correction will be considered a recall only if the Food and Drug Administration regards the product as involving a violation that is subject to legal action, e.g., seizure. In such cases, the firm will be asked to provide the Food and Drug Administration the following information:

(1) Identity of the product involved.

(2) Reason for the removal or correction and the date and circumstances under which the product deficiency or possible deficiency was discovered.

(3) Evaluation of the risk associated with the deficiency or possible deficiency.

(4) Total amount of such products produced and/or the timespan of the production.

(5) Total amount of such products estimated to be in distribution channels.

(6) Distribution information, including the number of direct accounts and, where necessary, the identity of the direct accounts.

(7) A copy of the firm's recall communication if any has issued, or a proposed communication if none has issued.

(8) Proposed strategy for conducting the recall.

(9) Name and telephone number of the firm official who should be contacted concerning the recall.

(b) The Food and Drug Administration will review the information submitted, advise the firm of the assigned recall classification, recommend any appropriate changes in the firm's strategy for the recall, and advise the firm that its recall will be placed in the weekly FDA Enforcement Report.

Pending this review, the firm need not delay initiation of its product removal or correction.

(c) A firm may decide to recall a product when informed by the Food and Drug Administration that the agency has determined that the product in question violates the law, but the agency has not specifically requested a recall. The firm's action also is considered a firm-initiated recall and is subject to paragraphs (a) and (b) of this section.

(d) A firm that initiates a removal or correction of its product which the firm believes is a market withdrawal should consult with the appropriate Food and Drug Administration district office when the reason for the removal or correction is not obvious or clearly understood but where it is apparent, e.g., because of complaints or adverse reactions regarding the product, that the product is deficient in some respect. In such cases, the Food and Drug Administration will assist the firm in determining the exact nature of the problem.

§ 7.49 Recall communications.

(a) *General.* A recalling firm is responsible for promptly notifying each of its affected direct accounts about the recall. The format, content, and extent of a recall communication should be commensurate with the hazard of the product being recalled and the strategy developed for that recall. In general terms, the purpose of a recall communication is to convey:

(1) That the product in question is subject to a recall.

(2) That further distribution or use of any remaining product should cease immediately.

(3) Where appropriate, that the direct account should in turn notify its customers who received the product about the recall.

(4) Instructions regarding what to do with the product.

(b) *Implementation.* A recall communication can be accomplished by telegrams, mailgrams, or first class letters conspicuously marked, preferably in bold red type, on the letter and the envelope: ''DRUG [or FOOD, BIOLOGIC, etc.] RECALL [or CORRECTION]''. The letter and the envelope should be also marked: ''URGENT'' for class I and class II recalls and, when appropriate, for class III recalls. Telephone calls or other personal contacts should ordinarily be confirmed by one of the above methods and/or documented in an appropriate manner.

(c) *Contents.* (1) A recall communication should be written in accordance with the following guidelines:

(i) Be brief and to the point;

(ii) Identify clearly the product, size, lot number(s), code(s) or serial number(s) and any other pertinent descriptive information to enable accurate and immediate identification of the product;

(iii) Explain concisely the reason for the recall and the hazard involved, if any;

(iv) Provide specific instructions on what should be done with respect to the recalled products; and

(v) Provide a ready means for the recipient of the communication to report to the recalling firm whether it has any of the product, e.g., by sending a postage-paid, self-addressed postcard or by allowing the recipient to place a collect call to the recalling firm.

(2) The recall communication should not contain irrelevant qualifications, promotional materials, or any other statement that may detract from the message. Where necessary, followup communications should be sent to those who fail to respond to the initial recall communication.

(d) *Responsibility of recipient.* Consignees that receive a recall communication should immediately carry out the instructions set forth by the recalling firm and, where necessary, extend the recall to its consignees in accordance with paragraphs (b) and (c) of this section.

§ 7.50 Public notification of recall.

The Food and Drug Administration will promptly make available to the public in the weekly FDA Enforcement Report a descriptive listing of each new recall according to its classification, whether it was Food and Drug Administration-requested or firm-initiated, and the specific action being taken by the recalling firm. The Food and Drug Administration will intentionally delay public notification of recalls of

certain drugs and devices where the agency determines that public notification may cause unnecessary and harmful anxiety in patients and that initial consultation between patients and their physicians is essential. The report will not include a firm's product removals or corrections which the agency determines to be market withdrawals or stock recoveries. The report, which also includes other Food and Drug Administration regulatory actions, e.g., seizures that were effected and injunctions and prosecutions that were filed, is available upon request from the Office of Public Affairs (HFI–1), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

§ 7.53 Recall status reports.

(a) The recalling firm is requested to submit periodic recall status reports to the appropriate Food and Drug Administration district office so that the agency may assess the progress of the recall. The frequency of such reports will be determined by the relative urgency of the recall and will be specified by the Food and Drug Administration in each recall case; generally the reporting interval will be between 2 and 4 weeks.

(b) Unless otherwise specified or inappropriate in a given recall case, the recall status report should contain the following information:

(1) Number of consignees notified of the recall, and date and method of notification.

(2) Number of consignees responding to the recall communication and quatity of products on hand at the time it was received.

(3) Number of consignees that did not respond (if needed, the identity of nonresponding consignees may be requested by the Food and Drug Administration).

(4) Number of products returned or corrected by each consignee contacted and the quantity of products accounted for.

(5) Number and results of effectiveness checks that were made.

(6) Estimated time frames for completion of the recall.

(c) Recall status reports are to be discontinued when the recall is terminated by the Food and Drug Administration.

§ 7.55 Termination of a recall.

(a) A recall will be terminated when the Food and Drug Administration determines that all reasonable efforts have been made to remove or correct the product in accordance with the recall strategy, and when it is reasonable to assume that the product subject to the recall has been removed and proper disposition or correction has been made commensurate with the degree of hazard of the recalled product. Written notification that a recall is terminated will be issued by the appropriate Food and Drug Administration district office to the recalling firm.

(b) A recalling firm may request termination of its recall by submitting a written request to the appropriate Food and Drug Adminstration district office stating that the recall is effective in accordance with the criteria set forth in paragraph (a) of this section, and by accompanying the request with the most current recall status report and a description of the disposition of the recalled product.

§ 7.59 General industry guidance.

A recall can be disruptive of a firm's operation and business, but there are several steps a prudent firm can take in advance to minimize this disruptive effect. Notwithstanding similar specific requirements for certain products in other parts of this chapter, the following is provided by the Food and Drug Administration as guidance for a firm's consideration:

(a) Prepare and maintain a current written contingency plan for use in initiating and effecting a recall in accordance with §§ 7.40 through 7.49, 7.53, and 7.55.

(b) Use sufficient coding of regulated products to make possible positive lot identification and to facilitate effective recall of all violative lots.

(c) Maintain such product distribution records as are necessary to facilitate location of products that are being recalled. Such records should be maintained for a period of time that exceeds the shelf life and expected use of the product and is at least the length of

time specified in other applicable regulations concerning records retention.

Subpart D [Reserved]

Subpart E—Criminal Violations

§ 7.84 Opportunity for presentation of views before report of criminal violation.

(a)(1) Except as provided in paragraph (a) (2) and (3) of this section, a person against whom criminal prosecution under the Federal Food, Drug, and Cosmetic Act is contemplated by the Commissioner of Food and Drugs shall be given appropriate notice and an opportunity to present information and views to show cause why criminal prosecution should not be recommended to a United States attorney.

(2) Notice and opportunity need not be provided if the Commissioner has reason to believe that they may result in the alteration or destruction of evidence or in the prospective defendant's fleeing to avoid prosecution.

(3) Notice and opportunity need not be provided if the Commissioner contemplates recommending further investigation by the Department of Justice.

(b) If a statute enforced by the Commissioner does not contain a provision for an opportunity to present views, the Commissioner need not, but may in the Commissioner's discretion, provide notice and an opportunity to present views.

(c) If an apparent violation of the Federal Food, Drug, and Cosmetic Act also constitutes a violation of any other Federal statute(s), and the Commissioner contemplates recommending prosecution under such other statute(s) as well, the notice of opportunity to present views will include all violations.

(d) Notice of an opportunity to present views may be by letter, standard form, or other document(s) identifying the products and/or conduct alleged to violate the law. The notice shall—

(1) Be sent by registered or certified mail, telegram, telex, personal delivery, or any other appropriate mode of written communication;

(2) Specify the time and place where those named may present their views;

(3) Summarize the violations that constitute the basis of the contemplated prosecution;

(4) Describe the purpose and procedure of the presentation; and

(5) Furnish a form on which the legal status of any person named in the notice may be designated.

(e) If more than one person is named in a notice, a separate opportunity for presentation of views shall be scheduled on request. Otherwise, the time and place specified in a notice may be changed only upon a showing of reasonable grounds. A request for any change shall be addressed to the Food and Drug Administration office that issued the notice and shall be received in that office at least 3 working days before the date set in the notice.

(f) A person who has received a notice is under no legal obligation to appear or answer in any manner. A person choosing to respond may appear personally, with or without a representative, or may designate a representative to appear for him or her. Alternatively, a person may respond in writing. If a person elects not to respond on or before the time scheduled, the Commissioner will, without further notice, decide whether to recommend criminal prosecution to a United States attorney on the basis of the information available.

(g) If a respondent chooses to appear solely by designated representative, that representative shall present a signed statement of authorization. If a representative appears for more than one respondent, the representative shall submit independent documentation of authority to act for each respondent. If a representative appears without written authorization, the opportunity to present views with respect to that respondent may be provided at that time only if the authenticity of the representative's authority is first verified by telephone or other appropriate means.

[44 FR 12167, Mar. 6, 1979]

§ 7.85 Conduct of a presentation of views before report of criminal violation.

(a) The presentation of views shall be heard by a designated Food and Drug Administration employee. Other Food

and Drug Administration employees may be present.

(b) A presentation of views shall not be open to the public. The agency employee designated to receive views will permit participation of other persons only if they appear with the respondent or the respondent's designated representative, and at the request of, and on behalf of, the respondent.

(c) A respondent may present any information of any kind bearing on the Commissioner's determination to recommend prosecution. Information may include statements of persons appearing on the respondent's behalf, letters, documents, laboratory analyses, if applicable, or other relevant information or arguments. The opportunity to present views shall be informal. The rules of evidence shall not apply. Any information given by a respondent, including statements by the respondent, shall become part of the agency's records concerning the matter and may be used for any official purpose. The Food and Drug Administration is under no obligation to present evidence or witnesses.

(d) If the respondent holds a ''guaranty or undertaking'' as described in section 303(c) of the act (21 U.S.C. 333(c)) that is applicable to the notice, that document, or a verified copy of it, may be presented by the respondent.

(e) A respondent may have an oral presentation recorded and transcribed at his or her expense, in which case a copy of the transcription shall be furnished to the Food and Drug Administration office from which the notice issued. The employee designated to receive views may order a presentation of views recorded and transcribed at agency expense, in which case a copy of such transcription shall be provided to each respondent.

(f) If an oral presentation is not recorded and transcribed, the agency employee designated to receive views shall dictate a written summary of the presentation. A copy of the summary shall be provided to each respondent.

(g) A respondent may comment on the summary or may supplement any response by additional written or documentary evidence. Any comment or addition shall be furnished to the Food and Drug Administration office where the respondent's views were presented. If materials are submitted within 10 calendar days after receipt of the copy of the summary or transcription of the presentation, as applicable, they will be considered before a final decision as to whether or not to recommend prosecution. Any materials received after the supplemental response period generally will be considered only if the final agency decision has not yet been made.

(h)(1) When consideration of a criminal prosecution recommendation involving the same violations is closed by the Commissioner with respect to all persons named in the notice, the Commissioner will so notify each person in writing.

(2) When it is determined that a person named in a notice will not be included in the Commissioner's recommendation for criminal prosecution, the Commissioner will so notify that person, if and when the Commissioner concludes that notification will not prejudice the prosecution of any other person.

(3) When a United States attorney informs the agency that no persons recommended will be prosecuted, the Commissioner will so notify each person in writing, unless the United States attorney has already done so.

(4) When a United States attorney informs the agency of intent to prosecute some, but not all, persons who had been provided an opportunity to present views and were subsequently named in the Commissioner's recommendation for criminal prosecution, the Commissioner, after being advised by the United States attorney that the notification will not prejudice the prosecution of any other person, will so notify those persons eliminated from further consideration, unless the United States attorney has already done so.

[44 FR 12168, Mar. 6, 1979]

§ 7.87 Records related to opportunities for presentation of views conducted before report of criminal violation.

(a) Records related to a section 305 opportunity for presentation of views constitute investigatory records for

law enforcement purposes and may include inter- and intra-agency memorandums.

(1) Notwithstanding the rule established in §20.21 of this chapter, no record related to a section 305 presentation is available for public disclosure until consideration of criminal prosecution has been closed in accordance with paragraph (b) of this section, except as provided in §20.82 of this chapter. Only very rarely and only under circumstances that demonstrate a compelling public interest will the Commissioner exercise, in accordance with §20.82 of this chapter, the authorized discretion to disclose records related to a section 305 presentation before the consideration of criminal prosecution is closed.

(2) After consideration of criminal prosecution is closed, the records are available for public disclosure in response to a request under the Freedom of Information Act, except to the extent that the exemptions from disclosure in subpart D of part 20 of this chapter are applicable. No statements obtained through promises of confidentiality shall be available for public disclosure.

(b) Consideration of criminal prosecution based on a particular section 305 notice of opportunity for presentation of views shall be deemed to be closed within the meaning of this section and §7.85 when a final decision has been made not to recommend criminal prosecution to a United States attorney based on charges set forth in the notice and considered at the presentation, or when such a recommendation has been finally refused by the United States attorney, or when criminal prosecution has been instituted and the matter and all related appeals have been concluded, or when the statute of limitations has run.

(c) Before disclosure of any record specifically reflecting consideration of a possible recommendation for criminal prosecution of any individual, all names and other information that would identify an individual whose prosecution was considered but not recommended, or who was not prosecuted, shall be deleted, unless the Commissioner concludes that there is a compelling public interest in the disclosure of the names.

(d) Names and other information that would identify a Food and Drug Administration employee shall be deleted from records related to a section 305 presentation of views before public disclosure only under §20.32 of this chapter.

[44 FR 12168, Mar. 6, 1979]

PART 10—ADMINISTRATIVE PRACTICES AND PROCEDURES

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AUTHORITY: 5 U.S.C. 551–558, 701–706; 15 U.S.C. 1451–1461; 21 U.S.C. 141–149, 321–397, 467f, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201, 262, 263b, 264.

SOURCE: 44 FR 22323, Apr. 13, 1979, unless otherwise noted.

EDITORIAL NOTE: Nomenclature changes to part 10 appear at 68 FR 24879, May 9, 2003.

Subpart A—General Provisions

§ 10.1 Scope.

(a) Part 10 governs practices and procedures for petitions, hearings, and other administrative proceedings and activities conducted by the Food and Drug Administration under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, and other laws which the Commissioner of Food and Drugs administers.

(b) If a requirement in another part of title 21 differs from a requirement in this part, the requirements of this part apply to the extent that they do not conflict with the other requirements.

(c) References in this part and parts 12, 13, 14, 15, and 16 to regulatory sections of the Code of Federal Regulations are to chapter I of title 21 unless otherwise noted.

(d) References in this part and parts 12, 13, 14, 15, and 16 to *publication*, or to the day or date of publication, or use of the phrase *to publish*, refer to publication in the FEDERAL REGISTER unless otherwise noted.

[44 FR 22323, Apr. 13, 1979, as amended at 54 FR 9034, Mar. 3, 1989; 69 FR 17290, Apr. 2, 2004]

§ 10.3 Definitions.

(a) The following definitions apply in this part and parts 12, 13, 14, 15, 16, and 19:

Act means the Federal Food, Drug, and Cosmetic Act unless otherwise indicated.

Administrative action includes every act, including the refusal or failure to act, involved in the administration of any law by the Commissioner, except that it does not include the referral of apparent violations to U.S. attorneys for the institution of civil or criminal proceedings or an act in preparation of a referral.

Administrative file means the file or files containing all documents pertaining to a particular administrative action, including internal working memoranda, and recommendations.

Administrative record means the documents in the administrative file of a particular administrative action on which the Commissioner relies to support the action.

Agency means the Food and Drug Administration.

Chief Counsel means the Chief Counsel of the Food and Drug Administration.

Commissioner means the Commissioner of Food and Drugs, Food and Drug Administration, U.S. Department of Health and Human Services, or the Commissioner's designee.

Department means the U.S. Department of Health and Human Services.

Division of Dockets Management means the Division of Dockets Management, Office of Management and Operations of the Food and Drug Administration, U.S. Department of Health and Human Services, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Ex parte communication means an oral or written communication not on the public record for which reasonable prior notice to all parties is not given, but does not include requests for status reports on a matter.

FDA means the Food and Drug Administration.

Food and Drug Administration employee or *Food and Drug Administration representative* includes members of the Food and Drug Division of the office of the General Counsel of the Department of Health and Human Services.

Formal evidentiary public hearing means a hearing conducted under part 12.

Interested person or *any person who will be adversely affected* means a person who submits a petition or comment or objection or otherwise asks to participate in an informal or formal administrative proceeding or court action.

Meeting means any oral discussion, whether by telephone or in person.

Office of the Commissioner includes the offices of the Associate Commissioners but not the centers or the regional or district offices.

Order means the final agency disposition, other than the issuance of a regulation, in a proceeding concerning any matter and includes action on a new drug application, new animal drug application, or biological license.

Participant means any person participating in any proceeding, including each party and any other interested person.

Party means the center of the Food and Drug Administration responsible for a matter involved and every person who either has exercised a right to request or has been granted the right by the Commissioner to have a hearing under part 12 or part 16 or who has waived the right to a hearing to obtain the establishment of a Public Board of Inquiry under part 13 and as a result of whose action a hearing or a Public Board of Inquiry has been established.

Person includes an individual, partnership, corporation, association, or other legal entity.

Petition means a petition, application, or other document requesting the Commissioner to establish, amend, or revoke a regulation or order, or to take or not to take any other form of administrative action, under the laws administered by the Food and Drug Administration.

Presiding officer means the Commissioner or the Commissioner's designee or an administrative law judge appointed as provided in 5 U.S.C. 3105.

Proceeding and *administrative proceeding* means any undertaking to issue, amend, or revoke a regulation or order, or to take or refrain from taking any other form of administrative action.

Public advisory committee or *advisory committee* means any committee, board, commission, council, conference, panel, task force, or other similar group, or any subcommittee or other subgroup of an advisory committee, that is not composed wholly of full-time employees of the Federal Government and is established or utilized by the Food and Drug Administration to obtain advice or recommendations.

Public Board of Inquiry or *Board* means an administrative law tribunal constituted under part 13.

Public hearing before a public advisory committee means a hearing conducted under part 14.

Public hearing before a Public Board of Inquiry means a hearing conducted under part 13.

Public hearing before the Commissioner means a hearing conducted under part 15.

Regulations means an agency rule of general or particular applicability and future effect issued under a law administered by the Commissioner or relating to administrative practices and procedures. In accordance with § 10.90(a), each agency regulation will be published in the FEDERAL REGISTER and codified in the Code of Federal Regulations.

Regulatory hearing before the Food and Drug Administration means a hearing conducted under part 16.

Secretary means the Secretary of Health and Human Services.

The laws administered by the Commissioner or *the laws administered by the Food and Drug Administration* means all the laws that the Commissioner is authorized to administer.

(b) A term that is defined in section 201 of the Federal Food, Drug, and Cosmetic Act or part 1 has the same definition in this part.

(c) Words in the singular form include the plural, words in the masculine form include the feminine, and vice versa.

(d) Whenever a reference is made in this part to a person in FDA, e.g., the director of a center, the reference includes all persons to whom that person

has delegated the specific function involved.

[44 FR 22323, Apr. 13, 1979, as amended at 46 FR 8455, Jan. 27, 1981; 50 FR 8994, Mar. 6, 1985; 54 FR 6886, Feb. 15, 1989; 54 FR 9034, Mar. 3, 1989; 59 FR 14363, Mar. 28, 1994; 69 FR 17290, Apr. 2, 2004]

§ 10.10 Summaries of administrative practices and procedures.

To encourage public participation in all agency activities, the Commissioner will prepare for public distribution summaries of FDA administrative practices and procedures in readily understandable terms.

§ 10.19 Waiver, suspension, or modification of procedural requirements.

The Commissioner or a presiding officer may, either voluntarily or at the request of a participant, waive, suspend, or modify any provision in parts 12 through 16 applicable to the conduct of a public hearing by announcement at the hearing or by notice in advance of the hearing if no participant will be prejudiced, the ends of justice will thereby be served, and the action is in accordance with law.

Subpart B—General Administrative Procedures

§ 10.20 Submission of documents to Division of Dockets Management; computation of time; availability for public disclosure.

(a) A submission to the Division of Dockets Management of a petition, comment, objection, notice, compilation of information, or any other document is to be filed in four copies except as otherwise specifically provided in a relevant FEDERAL REGISTER notice or in another section of this chapter. The Division of Dockets Management is the agency custodian of these documents.

(b) A submission is to be signed by the person making it, or by an attorney or other authorized representative of that person. Submissions by trade associations are also subject to the requirements of § 10.105(b).

(c) Information referred to or relied upon in a submission is to be included in full and may not be incorporated by reference, unless previously submitted in the same proceeding.

(1) A copy of an article or other reference or source cited must be included, except where the reference or source is:

(i) A reported Federal court case;

(ii) A Federal law or regulation;

(iii) An FDA document that is routinely publicly available; or

(iv) A recognized medical or scientific textbook that is readily available to the agency.

(2) If a part of the material submitted is in a foreign language, it must be accompanied by an English translation verified to be complete and accurate, together with the name, address, and a brief statement of the qualifications of the person making the translation. A translation of literature or other material in a foreign language is to be accompanied by copies of the original publication.

(3) Where relevant information is contained in a document also containing irrelevant information, the irrelevant information is to be deleted and only the relevant information is to be submitted.

(4) Under § 20.63 (a) and (b), the names and other information that would identify patients or research subjects are to be deleted from any record before it is submitted to the Division of Dockets Management in order to preclude a clearly unwarranted invasion of personal privacy.

(5) Defamatory, scurrilous, or intemperate matter is to be deleted from a record before it is submitted to the Division of Dockets Management.

(6) The failure to comply with the requirements of this part or with § 12.80 or § 13.20 will result in rejection of the submission for filing or, if it is filed, in exclusion from consideration of any portion that fails to comply. If a submission fails to meet any requirement of this section and the deficiency becomes known to the Division of Dockets Management, the Division of Dockets Management shall not file the submission but return it with a copy of the applicable regulations indicating those provisions not complied with. A deficient submission may be corrected or supplemented and subsequently filed. The office of the Division of

Dockets Management does not make decisions regarding the confidentiality of submitted documents.

(d) The filing of a submission means only that the Division of Dockets Management has identified no technical deficiencies in the submission. The filing of a petition does not mean or imply that it meets all applicable requirements or that it contains reasonable grounds for the action requested or that the action requested is in accordance with law.

(e) Except as provided in § 10.31(b), all submissions to the Division of Dockets Management will be considered as submitted on the date they are postmarked or, if delivered in person during regular business hours, on the date on which they are delivered, unless a provision in this part, an applicable FEDERAL REGISTER notice, or an order issued by an administrative law judge specifically states that the documents must be received by a specified date, *e.g.*, § 10.33(g) relating to a petition for reconsideration, in which case they will be submitted on the date received.

(f) All submissions are to be mailed or delivered in person to the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

(g) FDA ordinarily will not acknowledge or give receipt for documents, except:

(1) Documents delivered in person or by certified or registered mail with a return receipt requested; and

(2) Petitions for which acknowledgment of receipt of filing is provided by regulation or by customary practice, e.g., § 10.30(c) relating to a citizen petition.

(h) Saturdays, Sundays, and Federal legal holidays are included in computing the time allowed for the submission of documents, except that when the time for submission expires on a Saturday, Sunday, or Federal legal holiday, the period will be extended to include the next business day.

(i) All submissions to the Division of Dockets Management are representations that, to the best of the knowledge, information, and belief of the person making the submission, the statements made in the submission are true and accurate. All submissions are subject to the False Reports to the Government Act (18 U.S.C. 1001) under which a willfully false statement is a criminal offense.

(j) The availability for public examination and copying of submissions to the Division of Dockets Management is governed by the following rules:

(1) Except to the extent provided in paragraphs (j)(2) and (3) of this section, the following submissions, including all supporting material, will be on public display and will be available for public examination between 9 a.m. and 4 p.m., Monday through Friday. Requests for copies of submissions will be filed and handled in accordance with subpart C of part 20:

(i) Petitions.

(ii) Comments on petitions, on documents published in the FEDERAL REGISTER, and on similar public documents.

(iii) Objections and requests for hearings filed under part 12.

(iv) Material submitted at a hearing under § 12.32(a)(2) and parts 12, 13, and 15.

(v) Material placed on public display under the regulations in this chapter, e.g., agency guidance documents developed under § 10.115.

(2)(i) Material prohibited from public disclosure under § 20.63 (clearly unwarranted invasion of personal privacy) and, except as provided in paragraph (j)(3) of this section, material submitted with objections and requests for hearing filed under part 12, or at a hearing under part 12 or part 13, or an alternative form of public hearing before a public advisory committee or a hearing under § 12.32(a) (2) or (3), of the following types will not be on public display, will not be available for public examination, and will not be available for copying or any other form of verbatim transcription unless it is otherwise available for public disclosure under part 20:

(*a*) Safety and effectiveness information, which includes all studies and tests of an ingredient or product on animals and humans and all studies and tests on the ingredient or product for identity, stability, purity, potency, bioavailability, performance, and usefulness.

(*b*) A protocol for a test or study.

(*c*) Manufacturing methods or processes, including quality control procedures.

(*d*) Production, sales distribution, and similar information, except any compilation of information aggregated and prepared in a way that does not reveal confidential information.

(*e*) Quantitative or semiquantitative formulas.

(*f*) Information on product design or construction.

(ii) Material submitted under paragraph (j)(2) of this section is to be segregated from all other submitted material and clearly so marked. A person who does not agree that a submission is properly subject to paragraph (j)(2) may request a ruling from the Associate Commissioner for Public Affairs whose decision is final, subject to judicial review under § 20.48.

(3) Material listed in paragraph (j)(2)(i) (*a*) and (*b*) of this section may be disclosed under a protective order issued by the administrative law judge or other presiding officer at a hearing referenced in paragraph (j)(2)(i). The administrative law judge or presiding officer shall permit disclosure of the data only in camera and only to the extent necessary for the proper conduct of the hearing. The administrative law judge or presiding officer shall direct to whom the information is to be made available (e.g., to parties or participants, or only to counsel for parties or participants), and persons not specifically permitted access to the data will be excluded from the in camera part of the proceeding. The administrative law judge or other presiding officer may impose other conditions or safeguards. The limited availability of material under this paragraph does not constitute prior disclosure to the public as defined in § 20.81, and no information subject to a particular order is to be submitted to or received or considered by FDA in support of a petition or other request from any other person.

[44 FR 22323, Apr. 13, 1979, as amended at 46 FR 8455, Jan. 27, 1981; 49 FR 7363, Feb. 29, 1984; 54 FR 9034, Mar. 3, 1989; 59 FR 14363, Mar. 28, 1994; 64 FR 69190, Dec. 10, 1999; 65 FR 56477, Sept. 19, 2000; 66 FR 56035, Nov. 6, 2001; 66 FR 66742, Dec. 27, 2001; 68 FR 25285, May 12, 2003; 81 FR 78505, Nov. 8, 2016]

§ 10.25 Initiation of administrative proceedings.

An administrative proceeding may be initiated in the following three ways:

(a) An interested person may petition the Commissioner to issue, amend, or revoke a regulation or order, or to take or refrain from taking any other form of administrative action. A petition must be either:

(1) In the form specified in other applicable FDA regulations, e.g., the form for a color additive petition in § 71.1, for a food additive petition in § 171.1, for a new drug application in § 314.50, for a new animal drug application in § 514.1, or

(2) in the form for a citizen petition in § 10.30.

(b) The Commissioner may initiate a proceeding to issue, amend, or revoke a regulation or order or take or refrain from taking any other form of administrative action. FDA has primary jurisdiction to make the initial determination on issues within its statutory mandate, and will request a court to dismiss, or to hold in abeyance its determination of or refer to the agency for administrative determination, any issue which has not previously been determined by the agency or which, if it has previously been determined, the agency concluded should be reconsidered and subject to a new administrative determination. The Commissioner may utilize any of the procedures established in this part in reviewing and making a determination on any matter initiated under this paragraph.

(c) The Commissioner will institute a proceeding to determine whether to issue, amend, or revoke a regulation or order, or take or refrain from taking any other form of administrative action whenever any court, on its own initiative, holds in abeyance or refers any matter to the agency for an administrative determination and the Commissioner concludes that an administrative determination is feasible within agency priorities and resources.

[44 FR 22323, Apr. 13, 1979, as amended at 54 FR 9034, Mar. 3, 1989]

§ 10.30 Citizen petition.

(a) This section applies to any petition submitted by a person (including a

person who is not a citizen of the United States) except to the extent that other sections of this chapter apply different requirements to a particular matter.

(b) A petition (including any attachments) must be submitted in accordance with § 10.20 and, if applicable, § 10.31. The certification requirement in this section does not apply to petitions subject to the certification requirement of § 10.31. The petition must also be submitted in accordance with the following paragraphs, as applicable:

(1) *Electronic submission*. Petitions (including any attachments) may be electronically submitted in accordance with paragraph (b)(3) of this section and § 10.20 through *http://www.regulations.gov* at Docket No. FDA 2013–S–0610. It is only necessary to submit one copy.

(2) *Mail, delivery services, or other nonelectronic submissions*. A petition (including any attachments), that is not electronically submitted under paragraph (b)(1) of this section, must be submitted in accordance with paragraph (b)(3) and § 10.20 and delivered to this address: Division of Dockets Management, Department of Health and Human Services, Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. It is only necessary to submit two copies.

(3) *Petition format*. A petition submitted under paragraphs (b)(1) or (b)(2) of this section must be in accordance with § 10.20 and in the following format:

CITIZEN PETITION

Date: _____

The undersigned submits this petition under ____ (relevant statutory sections, if known) of the ____ (Federal Food, Drug, and Cosmetic Act or the Public Health Service Act or any other statutory provision for which authority has been delegated to the Commissioner of Food and Drugs) to request the Commissioner of Food and Drugs to____ (issue, amend, or revoke a regulation or order or take or refrain from taking any other form of administrative action).

A. Action Requested

((1) If the petition requests the Commissioner to issue, amend, or revoke a regulation, the exact wording of the existing regulation (if any) and the proposed regulation or amendment requested.)

((2) If the petition requests the Commissioner to issue, amend, or revoke an order, a copy of the exact wording of the citation to the existing order (if any) and the exact wording requested for the proposed order.)

((3) If the petition requests the Commissioner to take or refrain from taking any other form of administrative action, the specific action or relief requested.)

B. Statement of Grounds

(A full statement, in a well-organized format, of the factual and legal grounds on which the petitioner relies, including all relevant information and views on which the petitioner relies, as well as representative information known to the petitioner which is unfavorable to the petitioner's position.)

C. Environmental Impact

(A) Claim for categorical exclusion under §§ 25.30, 25.31, 25.32, 25.33, or § 25.34 of this chapter or an environmental assessment under § 25.40 of this chapter.)

D. Economic Impact

(The following information is to be submitted only when requested by the Commissioner following review of the petition: A statement of the effect of requested action on: (1) Cost (and price) increases to industry, government, and consumers; (2) productivity of wage earners, businesses, or government; (3) competition; (4) supplies of important materials, products, or services; (5) employment; and (6) energy supply or demand.)

E. Certification

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

(Signature) _____

(Name of petitioner) _____

(Mailing address) _____

(Telephone number) _____

(c) A petition that appears to meet the requirements of paragraph (b)(3) of this section, § 10.20, and, if applicable, § 10.31, will be filed by the Division of Dockets Management, stamped with the date of filing, and assigned a unique docket number. The unique docket number identifies the docket file established by the Division of Dockets Management for all submissions relating to the petition, as provided in this part. Subsequent submissions relating to the matter must refer

to the assigned docket number assigned in this paragraph and will be filed in the established docket file. Related petitions may be filed together and given the same docket number. The Division of Dockets Management will promptly notify the petitioner of the filing and unique docket number of the petition.

(d) An interested person may submit comments to the Division of Dockets Management on a filed petition, which comments become part of the docket file. The comments are to specify the docket number of the petition and include, if applicable, the verification under § 10.31, and may support or oppose the petition in whole or in part. A request for alternative or different administrative action must be submitted as a separate petition.

(e)(1) The Commissioner shall, in accordance with paragraph (e)(2), rule upon each petition filed under paragraph (c) of this section, taking into consideration (i) available agency resources for the category of subject matter, (ii) the priority assigned to the petition considering both the category of subject matter involved and the overall work of the agency, and (iii) time requirements established by statute.

(2) Except as provided in paragraphs (e)(4) and (5) of this section, the Commissioner shall furnish a response to each petitioner within 180 days of receipt of the petition. The response will either:

(i) Approve the petition, in which case the Commissioner shall concurrently take appropriate action (e.g., publication of a FEDERAL REGISTER notice) implementing the approval;

(ii) Deny the petition;

(iii) Dismiss the petition if at any time the Commissioner determines that changes in law, facts, or circumstances since the date on which the petition was submitted have rendered the petition moot; or

(iv) Provide a tentative response, indicating why the agency has been unable to reach a decision on the petition, e.g., because of the existence of other agency priorities, or a need for additional information. The tentative response may also indicate the likely ultimate agency response, and may specify when a final response may be furnished.

(3) The Commissioner may grant or deny such a petition, in whole or in part, and may grant such other relief or take other action as the petition warrants. If, at any time, the Commissioner determines that changes in law, facts, or circumstances since the date on which the petition was submitted have rendered the petition moot, the Commissioner may dismiss the petition. The petitioner is to be notified of the Commissioner's decision. The decision will be placed in the public docket file and may also be in the form of a notice published in the FEDERAL REGISTER.

(4) The Commissioner shall furnish a response to each petitioner within 90 days of receipt of a petition filed under section 505(j)(2)(C) of the act. The response will either approve or disapprove the petition. Agency action on a petition shall be governed by § 314.93 of this chapter.

(5) The Commissioner intends to furnish a response to each petitioner within 150 days of receipt of a petition subject to section 505(q) of the Federal Food, Drug, and Cosmetic Act.

(f) If a petition filed under paragraph (c) of this section requests the Commissioner to issue, amend, or revoke a regulation, § 10.40 or § 10.50 also apply.

(g) A petitioner may supplement, amend, or withdraw a petition without Agency approval and without prejudice to resubmission at any time until the Commissioner rules on the petition, unless the petition has been referred for a hearing under parts 12, 13, 14, or 15 of this chapter. After a ruling or referral, a petition may be supplemented, amended, or withdrawn only with the approval of the Commissioner. The Commissioner may approve withdrawal, with or without prejudice against resubmission of the petition.

(h) In reviewing a petition the Commissioner may use the following procedures:

(1) Conferences, meetings, discussions, and correspondence under § 10.65.

(2) A hearing under parts 12, 13, 14, 15, or 16.

(3) A FEDERAL REGISTER notice requesting information and views.

(4) A proposal to issue, amend, or revoke a regulation, in accordance with § 10.40 or § 12.20.

(5) Any other specific public procedure established in this chapter and expressly applicable to the matter.

(i) The record of the administrative proceeding consists of the following:

(1) The petition, including all information on which it relies, filed by the Division of Dockets Management.

(2) All comments received on the petition, including all information submitted as a part of the comments.

(3) If the petition resulted in a proposal to issue, amend, or revoke a regulation, all of the documents specified in § 10.40(g).

(4) The record, consisting of any transcripts, minutes of meetings, reports, FEDERAL REGISTER notices, and other documents resulting from the optional procedures specified in paragraph (h) of this section, except a transcript of a closed portion of a public advisory committee meeting.

(5) The Commissioner's decision on the petition, including all information identified or filed by the Commissioner with the Division of Dockets Management as part of the record supporting the decision.

(6) All documents filed with the Division of Dockets Management under § 10.65(h).

(7) If a petition for reconsideration or for a stay of action is filed under paragraph (j) of this section, the administrative record specified in § 10.33(k) or § 10.35(h).

(j) The administrative record specified in paragraph (i) of this section is the exclusive record for the Commissioner's decision. The record of the administrative proceeding closes on the date of the Commissioner's decision unless some other date is specified. Thereafter any interested person may submit a petition for reconsideration under § 10.33 or a petition for stay of action under § 10.35. A person who wishes to rely upon information or views not included in the administrative record shall submit them to the Commissioner with a new petition to modify the decision in accordance with this section.

(k) This section does not apply to the referral of a matter to a United States attorney for the initiation of court enforcement action and related correspondence, or to requests, suggestions, and recommendations made informally in routine correspondence received by FDA. Routine correspondence does not constitute a petition within the meaning of this section unless it purports to meet the requirements of this section. Action on routine correspondence does not constitute final administrative action subject to judicial review under § 10.45.

(l) The Division of Dockets Management will maintain a chronological list of each petition filed under this section and § 10.85, but not of petitions submitted elsewhere in the agency under § 10.25(a)(1), showing:

(1) The docket number;

(2) The date the petition was filed by the Division of Dockets Management;

(3) The name of the petitioner;

(4) The subject matter involved; and

(5) The disposition of the petition.

[44 FR 22323, Apr. 13, 1979, as amended at 46 FR 8455, Jan. 27, 1981; 50 FR 16656, Apr. 26, 1985; 54 FR 9034, Mar. 3, 1989; 57 FR 17980, Apr. 28, 1992; 59 FR 14364, Mar. 28, 1994; 62 FR 40592, July 29, 1997; 66 FR 6467, Jan. 22, 2001; 66 FR 12848, Mar. 1, 2001; 78 FR 76749, Dec. 19, 2013; 81 FR 78505, Nov. 8, 2016]

§ 10.31 Citizen petitions and petitions for stay of action related to abbreviated new drug applications, certain new drug applications, or certain biologics license applications.

(a) *Applicability*. This section applies to a citizen petition or petition for stay of action that meets all of the following criteria:

(1) The petition requests that the Commissioner take any form of action that could, if taken, delay approval of an abbreviated new drug application submitted under section 505(j) of the Federal Food, Drug, and Cosmetic Act, a new drug application submitted through the pathway described by section 505(b)(2) of the Federal, Food, Drug and Cosmetic Act, or a biologics license application submitted under section 351(k) of the Public Health Service Act.

(2) The petition is submitted on or after September 27, 2007.

(3) The petition is submitted in writing and under § 10.30 (for citizen petitions) or § 10.35 (for petitions for stay of action).

(b) *Date of submission.* A petition subject to this section and submitted in accordance with § 10.20, § 10.30, § 10.31, or § 10.35 is regarded as submitted on the date on which the petition is received by the Division of Dockets Management.

(c) *Certification.* (1) FDA will not consider for review a petition that is subject to this section unless the petition is in writing and contains the following certification:

I certify that, to my best knowledge and belief: (a) this petition includes all information and views upon which the petition relies; (b) this petition includes representative data and/or information known to the petitioner which are unfavorable to the petition; and (c) I have taken reasonable steps to ensure that any representative data and/or information which are unfavorable to the petition were disclosed to me. I further certify that the information upon which I have based the action requested herein first became known to the party on whose behalf this petition is submitted on or about the following date: _____[in the blank space, provide the date on which such information first became known to the person submitting the petition]. If I received or expect to receive payments, including cash and other forms of consideration, to file this information or its contents, I received or expect to receive those payments from the following persons or organizations: _____ [in the blank space, provide the names of such persons or organizations]. I verify under penalty of perjury that the foregoing is true and correct as of the date of the submission of this petition.

(2) The certification in paragraph (c)(1) of this section must contain one or more specific dates (month, day, and year) in the first blank space provided. If different categories of information become known at different times, the certification must contain each estimated relevant date. The information associated with a particular date must be identified.

(d) *Verification.* (1) FDA will not accept for review any supplemental information or comments on a petition that is subject to this section unless the supplemental information or comments are in writing and contain the following verification:

I certify that, to my best knowledge and belief: (a) I have not intentionally delayed submission of this document or its contents; and (b) the information upon which I have based the action requested herein first became known to me on or about _____[in the blank space, provide the date on which such information first became known to the person submitting the document]. If I received or expect to receive payments, including cash and other forms of consideration, to file this information or its contents, I received or expect to receive those payments from the following persons or organizations: _____ [in the blank space, provide the names of such persons or organizations]. I verify under penalty of perjury that the foregoing is true and correct as of the date of the submission of this document.

(2) The verification in paragraph (d)(1) of this section must contain one or more specific dates (month, day, and year) in the first blank space provided. If different categories of information become known at different times, the verification must contain each estimated relevant date. The information associated with a particular date must be identified.

[81 FR 78506, Nov. 8, 2016]

§ 10.33 Administrative reconsideration of action.

(a) The Commissioner may at any time reconsider a matter, on the Commissioner's own initiative or on the petition of an interested person.

(b) An interested person may request reconsideration of part or all of a decision of the Commissioner on a petition submitted under § 10.25. Each request for reconsideration must be submitted in accordance with § 10.20 and in the following form no later than 30 days after the date of the decision involved. The Commissioner may, for good cause, permit a petition to be filed after 30 days. In the case of a decision published in the FEDERAL REGISTER, the day of publication is the day of decision.

(Date) _____

Division of Dockets Management, Food and Drug Administration, Department of Health and Human Services, rm. 1–23, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

PETITION FOR RECONSIDERATION

[Docket No.]

The undersigned submits this petition for reconsideration of the decision of the Commissioner of Food and Drugs in Docket No. ____.

A. Decision involved

(A concise statement of the decision of the Commissioner which the petitioner wishes to have reconsidered.)

B. Action requested

(The decision which the petitioner requests the Commissioner to make upon reconsideration of the matter.)

C. Statement of grounds

(A full statement, in a well-organized format, of the factual and legal grounds upon which the petitioner relies. The grounds must demonstrate that relevant information and views contained in the administrative record were not previously or not adequately considered by the Commissioner.

(No new information or views may be included in a petition for reconsideration.)

(Signature) _____
(Name of petitioner) _____
(Mailing address) _____
(Telephone number) _____

(c) A petition for reconsideration relating to a petition submitted under § 10.25(a)(2) is subject to the requirements of § 10.30 (c) and (d), except that it is filed in the same docket file as the petition to which it relates.

(d) The Commissioner shall promptly review a petition for reconsideration. The Commissioner may grant the petition when the Commissioner determines it is in the public interest and in the interest of justice. The Commissioner shall grant a petition for reconsideration in any proceeding if the Commissioner determines all of the following apply:

(1) The petition demonstrates that relevant information or views contained in the administrative record were not previously or not adequately considered.

(2) The petitioner's position is not frivolous and is being pursued in good faith.

(3) The petitioner has demonstrated sound public policy grounds supporting reconsideration.

(4) Reconsideration is not outweighed by public health or other public interests.

(e) A petition for reconsideration may not be based on information and views not contained in the administrative record on which the decision was made. An interested person who wishes to rely on information or views not included in the administrative record shall submit them with a new petition to modify the decision under § 10.25(a).

(f) The decision on a petition for reconsideration is to be in writing and placed on public display as part of the docket file on the matter in the office of the Division of Dockets Management. A determination to grant reconsideration will be published in the FEDERAL REGISTER if the Commissioner's original decision was so published. Any other determination to grant or deny reconsideration may also be published in the FEDERAL REGISTER.

(g) The Commissioner may consider a petition for reconsideration only before the petitioner brings legal action in the courts to review the action, except that a petition may also be considered if the Commissioner has denied a petition for stay of action and the petitioner has petitioned for judicial review of the Commissioner's action and requested the reviewing court to grant a stay pending consideration of review.

A petition for reconsideration submitted later than 30 days after the date of the decision involved will be denied as untimely unless the Commissioner permits the petition to be filed after 30 days. A petition for reconsideration will be considered as submitted on the day it is received by the Division of Dockets Management.

(h) The Commissioner may initiate the reconsideration of all or part of a matter at any time after it has been decided or action has been taken. If review of the matter is pending in the courts, the Commissioner may request that the court refer the matter back to the agency or hold its review in abeyance pending administrative reconsideration. The administrative record of the proceeding is to include all additional documents relating to such reconsideration.

(i) After determining to reconsider a matter, the Commissioner shall review and rule on the merits of the matter under § 10.30(e). The Commissioner may reaffirm, modify, or overrule the prior decision, in whole or in part, and may grant such other relief or take such other action as is warranted.

(j) The Commissioner's reconsideration of a matter relating to a petition submitted under § 10.25(a)(2) is subject to § 10.30 (f) through (h), (j), and (k).

(k) The record of the administrative proceeding consists of the following:

(1) The record of the original petition specified in § 10.30(i).

(2) The petition for reconsideration, including all information on which it relies, filed by the Division of Dockets Management.

(3) All comments received on the petition, including all information submitted as a part of the comments.

(4) The Commissioner's decision on the petition under paragraph (f) of this section, including all information identified or filed by the Commissioner with the Division of Dockets Management as part of the record supporting the decision.

(5) Any FEDERAL REGISTER notices or other documents resulting from the petition.

(6) All documents filed with the Division of Dockets Management under § 10.65(h).

(7) If the Commissioner reconsiders the matter, the administrative record relating to reconsideration specified in § 10.30(i).

[44 FR 22323, Apr. 13, 1979, as amended at 46 FR 8455, Jan. 27, 1981; 59 FR 14364, Mar. 28, 1994; 66 FR 6467, Jan. 22, 2001; 66 FR 12848, Mar. 1, 2001]

§ 10.35 Administrative stay of action.

(a) The Commissioner may at any time stay or extend the effective date of an action pending or following a decision on any matter.

(b) An interested person may request the Commissioner to stay the effective date of any administrative action. A stay may be requested for a specific time period or for an indefinite time period. A request for stay must be submitted in accordance with § 10.20 and in the following form (except that a request for stay subject to § 10.31 must also include the certification provided in § 10.31(c)) no later than 30 days after the date of the decision involved. The Commissioner may, for good cause, permit a petition to be filed after 30 days. In the case of a decision published in the FEDERAL REGISTER, the day of publication is the date of decision.

(Date) _____

Division of Dockets Management, Food and Drug Administration, Department of Health and Human Services, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

PETITION FOR STAY OF ACTION

The undersigned submits this petition requesting that the Commissioner of Food and Drugs stay the effective date of the following matter.

A. Decision involved

(The specific administrative action being taken by the Commissioner for which a stay is requested, including the docket number or other citation to the action involved.)

B. Action requested

(The length of time for which the stay is requested, which may be for a specific or indefinite time period.)

C. Statement of grounds

(A full statement, in a well-organized format, of the factual and legal grounds upon which the petitioner relies for the stay.)

(Signature) _____

(Name of petitioner) _____
(Mailing address) _____
(Telephone number) _____

(c) A petition for stay of action relating to a petition submitted under §10.25(a)(2) is subject to the requirements of §10.30 (c) and (d), except that it will be filed in the same docket file as the petition to which it relates.

(d) Neither the filing of a petition for a stay of action nor action taken by an interested person in accordance with any other administrative procedure in this part or in any other section of this chapter, e.g., the filing of a citizen petition under §10.30 or a petition for reconsideration under §10.33 or a request for an advisory opinion under §10.85, will stay or otherwise delay any administrative action by the Commissioner, including enforcement action of any kind, unless one of the following applies:

(1) The Commissioner determines that a stay or delay is in the public interest and stays the action.

(2) A statute requires that the matter be stayed.

(3) A court orders that the matter be stayed.

(e) The Commissioner shall promptly review a petition for stay of action. The Commissioner may grant or deny a petition, in whole or in part; and may grant such other relief or take such other action as is warranted by the petition. If, at any time, the Commissioner determines that changes in law, facts, or circumstances since the date on which the petition was submitted have rendered the petition moot, the Commissioner may dismiss the petition. The Commissioner may grant a stay in any proceeding if it is in the public interest and in the interest of justice. The Commissioner shall grant a stay in any proceeding if all of the following apply:

(1) The petitioner will otherwise suffer irreparable injury.

(2) The petitioner's case is not frivolous and is being pursued in good faith.

(3) The petitioner has demonstrated sound public policy grounds supporting the stay.

(4) The delay resulting from the stay is not outweighted by public health or other public interests.

(f) The Commissioner's decision on a petition for stay of action is to be in writing and placed on public display as part of the file on the matter in the office of the Division of Dockets Management. A determination to grant a stay will be published in the FEDERAL REGISTER if the Commissioner's original decision was so published. Any other determination to grant or to deny a stay may also be published in the FEDERAL REGISTER.

(g) A petition for a stay of action submitted later than 30 days after the date of the decision involved will be denied as untimely unless the Commissioner permits the petition to be filed after 30 days. A petition for a stay of action is considered submitted on the day it is received by the Division of Dockets Management.

(h) The record of the administrative proceeding consists of the following:

(1) The record of the proceeding to which the petition for stay of action is directed.

(2) The petition for stay of action, including all information on which it relies, filed by the Division of Dockets Management.

(3) All comments received on the petition, including all information submitted as a part of the comments.

(4) The Commissioner's decision on the petition under paragraph (e) of this section, including all information identified or filed by the Commissioner with the Division of Dockets Management as part of the record supporting the decision.

(5) Any FEDERAL REGISTER notices or other documents resulting from the petition.

(6) All documents filed with the Division of Dockets Management under §10.65(h).

(i) A petitioner may supplement, amend, or withdraw a petition for stay of action in writing without Agency approval and without prejudice to resubmission at any time until the Commissioner rules on the petition, provided the resubmission is made in accordance with paragraph (b) of this section, unless the petition for stay of action has been referred for a hearing

under parts 12, 13, 14, or 15 of this chapter. After a ruling or referral, a petition for stay of action may be supplemented, amended, or withdrawn only with the approval of the Commissioner. The Commissioner may approve withdrawal with or without prejudice against resubmission of the petition for stay of action.

[44 FR 22323, Apr. 13, 1979, as amended at 46 FR 8455, Jan. 27, 1981; 54 FR 9034, Mar. 3, 1989; 59 FR 14364, Mar. 28, 1994; 66 FR 6468, Jan. 22, 2001; 66 FR 12848, Mar. 1, 2001; 81 FR 78506, Nov. 8, 2016]

§ 10.40 Promulgation of regulations for the efficient enforcement of the law.

(a) The Commissioner may propose and promulgate regulations for the efficient enforcement of the laws administered by FDA whenever it is necessary or appropriate to do so. The issuance, amendment, or revocation of a regulation may be initiated in any of the ways specified in § 10.25.

(1) This section applies to any regulation: (i) Not subject to § 10.50 and part 12, or (ii) if it is subject to § 10.50 and part 12, to the extent that those provisions make this section applicable.

(2) A regulation proposed by an interested person in a petition submitted under § 10.25(a) will be published in the FEDERAL REGISTER as a proposal if:

(i) The petition contains facts demonstrating reasonable grounds for the proposal; and

(ii) The petition substantially shows that the proposal is in the public interest and will promote the objectives of the act and the agency.

(3) Two or more alternative proposed regulations may be published on the same subject to obtain comment on the different alternatives.

(4) A regulation proposed by an interested person in a petition submitted under § 10.25(a) may be published together with the Commissioner's preliminary views on the proposal and any alternative proposal.

(b) Except as provided in paragraph (e) of this section, each regulation must be the subject of a notice of proposed rulemaking published in the FEDERAL REGISTER. (1) The notice will contain:

(i) The name of the agency;

(ii) The nature of the action, e.g., proposed rule, or notice;

(iii) A summary in the first paragraph describing the substance of the document in easily understandable terms;

(iv) Relevant dates, e.g., comment closing date, and proposed effective date(s);

(v) The name, business address, and phone number of an agency contact person who can provide further information to the public about the notice;

(vi) An address for submitting written comments;

(vii) Supplementary information about the notice in the form of a preamble that summarizes the proposal and the facts and policy underlying it, includes references to all information on which the Commissioner relies for the proposal (copies or a full list of which are a part of the docket file on the matter in the office of the Division of Dockets Management), and cites the authority under which the regulation is proposed;

(viii) Either the terms or substance of the proposed regulation or a description of the subjects and issues involved;

(ix) A reference to the existence or lack of need for an environmental impact statement under § 25.52 of this chapter; and

(x) The docket number of the matter, which identifies the docket file established by the Division of Dockets Management for all relevant submissions.

(2) The proposal will provide 60 days for comment, although the Commissioner may shorten or lengthen this time period for good cause. In no event is the time for comment to be less than 10 days.

(3) After publication of the proposed rule, any interested person may request the Commissioner to extend the comment period for an additional specified period by submitting a written request to the Division of Dockets Management stating the grounds for the request. The request is submitted under § 10.35 but should be headed ''REQUEST FOR EXTENSION OF COMMENT PERIOD.''

(i) A request must discuss the reason comments could not feasibly be submitted within the time permitted, or

that important new information will shortly be available, or that sound public policy otherwise supports an extension of the time for comment. The Commissioner may grant or deny the request or may grant an extension for a time period different from that requested. An extension may be limited to specific persons who have made and justified the request, but will ordinarily apply to all interested persons.

(ii) A comment time extension of 30 days or longer will be published in the FEDERAL REGISTER and will be applicable to all interested persons. A comment time extension of less than 30 days will be the subject either of a letter or memorandum filed with the Division of Dockets Management or of a notice published in the FEDERAL REGISTER.

(4) A notice of proposed rulemaking will request that four copies of all comments be submitted to the Division of Dockets Management, except that individuals may submit single copies. Comments will be stamped with the date of receipt and will be numbered chronologically.

(5) Persons submitting comments critical of a proposed regulation are encouraged to include their preferred alternative wording.

(c) After the time for comment on a proposed regulation has expired, the Commissioner will review the entire administrative record on the matter, including all comments and, in a notice published in the FEDERAL REGISTER, will terminate the proceeding, issue a new proposal, or promulgate a final regulation.

(1) The quality and persuasiveness of the comments will be the basis for the Commissioner's decision. The number or length of comments will not ordinarily be a significant factor in the decision unless the number of comments is material where the degree of public interest is a legitimate factor for consideration.

(2) The decision of the Commissioner on the matter will be based solely upon the administrative record.

(3) A final regulation published in the FEDERAL REGISTER will have a preamble stating: (i) The name of the agency, (ii) the nature of the action e.g., final rule, notice, (iii) a summary first paragraph describing the substance of the document in easily understandable terms, (iv) relevant dates, e.g., the rule's effective date and comment closing date, if an opportunity for comment is provided, (v) the name, business address, and phone number of an agency contact person who can provide further information to the public about the notice, (vi) an address for the submission of written comments when they are permitted, (vii) supplementary information about the regulation in the body of the preamble that contains references to prior notices relating to the same matter and a summary of each type of comment submitted on the proposal and the Commissioner's conclusions with respect to each. The preamble is to contain a thorough and comprehensible explanation of the reasons for the Commissioner's decision on each issue.

(4) The effective date of a final regulation may not be less than 30 days after the date of publication in the FEDERAL REGISTER, except for:

(i) A regulation that grants an exemption or relieves a restriction; or

(ii) A regulation for which the Commissioner finds, and states in the notice good cause for an earlier effective date.

(d) The provisions for notice and comment in paragraphs (b) and (c) of this section apply only to the extent required by the Administrative Procedure Act (5 U.S.C. 551, 552, and 553). As a matter of discretion, however, the Commissioner may voluntarily follow those provisions in circumstances in which they are not required by the Administrative Procedure Act.

(e) The requirements of notice and public procedure in paragraph (b) of this section do not apply in the following situations:

(1) When the Commissioner determines for good cause that they are impracticable, unnecessary, or contrary to the public interest. In these cases, the notice promulgating the regulation will state the reasons for the determination, and provide an opportunity for comment to determine whether the regulation should subsequently be modified or revoked. A subsequent notice based on those comments may, but

need not, provide additional opportunity for public comment.

(2) Food additive and color additive petitions, which are subject to the provisions of § 12.20(b)(2).

(3) New animal drug regulations, which are promulgated under section 512(i) of the act.

(f) In addition to the notice and public procedure required under paragraph (b) of this section, the Commissioner may also subject a proposed or final regulation, before or after publication in the FEDERAL REGISTER, to the following additional procedures:

(1) Conferences, meetings, discussions, and correspondence under § 10.65.

(2) A hearing under parts 12, 13, 14, or 15.

(3) A notice published in the FEDERAL REGISTER requesting information and views before the Commissioner determines whether to propose a regulation.

(4) A draft of a proposed regulation placed on public display in the office of the Division of Dockets Management. If this procedure is used, the Commissioner shall publish an appropriate notice in the FEDERAL REGISTER stating that the document is available and specifying the time within which comments on the draft proposal may be submitted orally or in writing.

(5) A revised proposal published in the FEDERAL REGISTER, which proposal is subject to all the provisions in this section relating to proposed regulations.

(6) A tentative final regulation or tentative revised final regulation placed on public display in the office of the Division of Dockets Management and, if deemed desirable by the Commissioner, published in the FEDERAL REGISTER. If the tentative regulation is placed on display only, the Commissioner shall publish an appropriate notice in the FEDERAL REGISTER stating that the document is available and specifying the time within which comments may be submitted orally or in writing on the tentative final regulation. The Commissioner shall mail a copy of the tentative final regulation and the FEDERAL REGISTER notice to each person who submitted comments on the proposed regulation if one has been published.

(7) A final regulation published in the FEDERAL REGISTER that provides an opportunity for the submission of further comments, in accordance with paragraph (e)(1) of this section.

(8) Any other public procedure established in this chapter and expressly applicable to the matter.

(g) The record of the administrative proceeding consists of all of the following:

(1) If the regulation was initiated by a petition, the administrative record specified in § 10.30(i).

(2) If a petition for reconsideration or for a stay of action is filed, the administrative record specified in §§ 10.33(k) and 10.35(h).

(3) The proposed rule published in the FEDERAL REGISTER, including all information identified or filed by the Commissioner with the Division of Dockets Management on the proposal.

(4) All comments received on the proposal, including all information submitted as a part of the comments.

(5) The notice promulgating the final regulation, including all information identified or filed by the Commissioner with the Division of Dockets Management as part of the administrative record of the final regulation.

(6) The transcripts, minutes of meetings, reports, FEDERAL REGISTER notices, and other documents resulting from the procedures specified in paragraph (f) of this section, but not the transcript of a closed portion of a public advisory committee meeting.

(7) All documents submitted to the Division of Dockets Management under § 10.65(h).

(h) The record of the administrative proceeding closes on the date of publication of the final regulation in the FEDERAL REGISTER unless some other date is specified. Thereafter, any interested person may submit a petition for reconsideration under § 10.33 or a petition for stay of action under § 10.35. A person who wishes to rely upon information or views not included in the administrative record shall submit it to the Commissioner with a new petition to modify the final regulation.

(i) The Division of Dockets Management shall maintain a chronological list of all regulations proposed and promulgated under this section and § 10.50

(which list will not include regulations resulting from petitions filed and assigned a docket number under § 10.30) showing—

(1) The docket number (for a petition submitted directly to a center, the list also includes the number or other designation assigned by the center, e.g., the number assigned to a food additive petition);

(2) The name of the petitioner, if any;

(3) The subject matter involved; and

(4) The disposition of the petition.

[44 FR 22323, Apr. 13, 1979, as amended at 52 FR 36401, Sept. 29, 1987; 54 FR 9034, Mar. 3, 1989; 56 FR 13758, Apr. 4, 1991; 62 FR 40592, July 29, 1997; 66 FR 6468, Jan. 22, 2001; 66 FR 12848, Mar. 1, 2001]

§ 10.45 Court review of final administrative action; exhaustion of administrative remedies.

(a) This section applies to court review of final administrative action taken by the Commissioner, including action taken under §§ 10.25 through 10.40 and § 16.1(b), except action subject to § 10.50 and part 12.

(b) A request that the Commissioner take or refrain from taking any form of administrative action must first be the subject of a final administrative decision based on a petition submitted under § 10.25(a) or, where applicable, a hearing under § 16.1(b) before any legal action is filed in a court complaining of the action or failure to act. If a court action is filed complaining of the action or failure to act before the submission of the decision on a petition under § 10.25(a) or, where applicable, a hearing under § 16.1(b), the Commissioner shall request dismissal of the court action or referral to the agency for an initial administrative determination on the grounds of a failure to exhaust administrative remedies, the lack of final agency action as required by 5 U.S.C. 701 *et seq.*, and the lack of an actual controversy as required by 28 U.S.C. 2201.

(c) A request that administrative action be stayed must first be the subject of an administrative decision based upon a petition for stay of action submitted under § 10.35 before a request is made that a court stay the action. If a court action is filed requesting a stay of administrative action before the Commissioner's decision on a petition submitted in a timely manner pursuant to § 10.35, the Commissioner shall request dismissal of the court action or referral to the agency for an initial determination on the grounds of a failure to exhaust administrative remedies, the lack of final agency action as required by 5 U.S.C. 701 *et seq.*, and the lack of an actual controversy as required by 28 U.S.C. 2201. If a court action is filed requesting a stay of administrative action after a petition for a stay of action is denied because it was submitted after expiration of the time period provided under § 10.35, or after the time for submitting such a petition has expired, the Commissioner will request dismissal of the court action on the ground of a failure to exhaust administrative remedies.

(d) Unless otherwise provided, the Commissioner's final decision constitutes final agency action (reviewable in the courts under 5 U.S.C. 701 *et seq.* and, where appropriate, 28 U.S.C. 2201) on a petition submitted under § 10.25(a), on a petition for reconsideration submitted under § 10.33, on a petition for stay of action submitted under § 10.35, on an advisory opinion issued under § 10.85, on a matter involving administrative action which is the subject of an opportunity for a hearing under § 16.1(b) of this chapter, or on the issuance of a final regulation published in accordance with § 10.40, except that the agency's response to a petition filed under section 505(j)(2)(C) of the act (21 U.S.C. 355(j)(2)(C)) and § 314.93 of this chapter will not constitute final agency action until any petition for reconsideration submitted by the petitioner is acted on by the Commissioner.

(1) It is the position of FDA except as otherwise provided in paragraph (d)(2) of this section, that:

(i) Final agency action exhausts all administrative remedies and is ripe for preenforcement judicial review as of the date of the final decision, unless applicable law explicitly requires that the petitioner take further action before judicial review is available;

(ii) An interested person is affected by, and thus has standing to obtain judicial review of final agency action; and

(iii) It is not appropriate to move to dismiss a suit for preenforcement judicial review of final agency action on the ground that indispenable parties are not joined or that it is an unconsented suit against the United States if the defect could be cured by amending the complaint.

(2) The Commissioner shall object to judicial review of a matter if:

(i) The matter is committed by law to the discretion of the Commissioner, e.g., a decision to recommend or not to recommend civil or criminal enforcement action under sections 302, 303, and 304 of the act; or

(ii) Review is not sought in a proper court.

(e) An interested person may request judicial review of a final decision of the Commissioner in the courts without first petitioning the Commissioner for reconsideration or for a stay of action, except that in accordance with paragraph (c) of this section, the person shall request a stay by the Commissioner under § 10.35 before requesting a stay by the court.

(f) The Commissioner shall take the position in an action for judicial review under 5 U.S.C. 701 *et seq.*, whether or not it includes a request for a declaratory judgment under 28 U.S.C. 2201, or in any other case in which the validity of administrative action is properly challenged, that the validity of the action must be determined solely on the basis of the administrative record specified in §§ 10.30(i), 10.33(k), 10.35(h), 10.40(g), and 16.80(a) or the administrative record applicable to any decision or action under the regulations referenced in § 16.1(b), and that additional information or views may not be considered. An interested person who wishes to rely upon information or views not included in the administrative record shall submit them to the Commissioner with a new petition to modify the action under § 10.25(a).

(g) The Commissioner requests that all petitions for judicial review of a particular matter be filed in a single U.S. District court. If petitions are filed in more than one jurisdiction, the Commissioner will take appropriate action to prevent a multiplicity of suits in various jurisdictions, such as:

(1) A request for transfer of one or more suits to consolidate separate actions, under 28 U.S.C. 1404(a) or 28 U.S.C. 2112(a);

(2) A request that actions in all but one jurisdiction be stayed pending the conclusion of one proceeding;

(3) A request that all but one action be dismissed pending the conclusion of one proceeding, with the suggestion that the other plaintiffs intervene in that one suit; or

(4) A request that one of the suits be maintained as a class action in behalf of all affected persons.

(h)(1) For the purpose of 28 U.S.C. 2112(a), a copy of any petition filed in any U.S. Court of Appeals challenging a final action of the Commissioner shall be sent by certified mail, return receipt requested, or by personal delivery to the Chief Counsel of FDA. The petition copy shall be time-stamped by the clerk of the court when the original is filed with the court. The petition copy should be addressed to: Office of the Chief Counsel (GCF–1), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. The Chief Counsel requests that the purpose of all petitions mailed or delivered to the Office of Chief Counsel to satisfy 28 U.S.C. 2112(a) be clearly identified in a cover letter.

(2) If the Chief Counsel receives two or more petitions filed in two or more U.S. Courts of Appeals for review of any agency action within 10 days of the effective date of that action for the purpose of judicial review, the Chief Counsel will notify the U.S. Judicial Panel on Multidistrict Litigation of any petitions that were received within the 10-day period, in accordance with the applicable rule of the panel.

(3) For the purpose of determining whether a petition for review has been received within the 10-day period under paragraph (h)(2) of this section, the petition shall be considered to be received on the date of delivery, if personally delivered. If the delivery is accomplished by mail, the date of receipt shall be the date noted on the return receipt card.

(i) Upon judicial review of administrative action under this section:

(1) If a court determines that the administrative record is inadequate to

support the action, the Commissioner shall determine whether to proceed with such action. (i) If the Commissioner decides to proceed with the action, the court will be requested to remand the matter to the agency to reopen the administrative proceeding and record, or on the Commissioner's own initiative the administrative proceeding and record may be reopened upon receipt of the court determination. A reopened administrative proceeding will be conducted under the provisions of this part and in accordance with any directions of the court.

(ii) If the Commissioner concludes that the public interest requires that the action remain in effect pending further administrative proceedings, the court will be requested not to stay the matter in the interim and the Commissioner shall expedite the further administrative proceedings.

(2) If a court determines that the administrative record is adequate, but the rationale for the action must be further explained:

(i) The Commissioner shall request either that further explanation be provided in writing directly to the court without further administrative proceedings, or that the administrative proceeding be reopened in accordance with paragraph (i)(1)(i) of this section; and

(ii) If the Commissioner concludes that the public interest requires that the action remain in effect pending further court or administrative proceedings, the court will be requested not to stay the matter in the interim and the Commissioner shall expedite the further proceedings.

[44 FR 22323, Apr. 13, 1979, as amended at 54 FR 6886, Feb. 15, 1989; 54 FR 9034, Mar. 3, 1989; 57 FR 17980, Apr. 28, 1992; 65 FR 56477, Sept. 19, 2000; 69 FR 31705, June 4, 2004]

§ 10.50 Promulgation of regulations and orders after an opportunity for a formal evidentiary public hearing.

(a) The Commissioner shall promulgate regulations and orders after an opportunity for a formal evidentiary public hearing under part 12 whenever all of the following apply:

(1) The subject matter of the regulation or order is subject by statute to an opportunity for a formal evidentiary public hearing.

(2) The person requesting the hearing has a right to an opportunity for a hearing and submits adequate justification for the hearing as required by §§ 12.20 through 12.22 and other applicable provisions in this chapter, e.g., §§ 314.200, 514.200, and 601.7(a).

(b) The Commissioner may order a formal evidentiary public hearing on any matter whenever it would be in the public interest to do so.

(c) The provisions of the act, and other laws, that afford a person who would be adversely affected by administrative action an opportunity for a formal evidentiary public hearing as listed below. The list imparts no right to a hearing where the statutory section provides no opportunity for a hearing.

(1) Section 401 on any action for the amendment or repeal of any definition and standard of identity for any dairy product (including products regulated under parts 131, 133, and 135 of this chapter) or maple sirup (regulated under § 168.140 of this chapter).

(2) Section 403(j) on regulations for labeling of foods for special dietary uses.

(3) Section 404(a) on regulations for emergency permit control.

(4) Section 406 on tolerances for poisonous substances in food.

(5) Section 409 (c), (d), and (h) on food additive regulations.

(6) Section 501(b) on tests or methods of assay for drugs described in official compendia.

(7) [Reserved]

(8) Section 502(h) on regulations designating requirements for drugs liable to deterioration.

(9) Section 502(n) on prescription drug advertising regulations.

(10)–(11) [Reserved]

(12) Section 512(n)(5) on regulations for animal antibiotic drugs and certification requirements.

(13) Section 721 (b) and (c) on regulations for color additive listing and certification.

(14) Section 4(a) of the Fair Packaging and Labeling Act on food, drug, device, and cosmetic labeling.

(15) Section 5(c) of the Fair Packaging and Labeling Act on additional

economic regulations for food, drugs, devices, and cosmetics.

(16) Section 505 (d) and (e) on new drug applications.

(17) Section 512 (d), (e) and (m) (3) and (4) on new animal drug applications.

(18) Section 515(g) on device premarket approval applications and product development protocols.

(19) Section 351(a) of the Public Health Service Act on a biologics license for a biological product.

(20) Section 306 on debarment, debarment period and considerations, termination of debarment under section 306(d)(3), suspension, and termination of suspension.

[44 FR 22323, Apr. 13, 1979, as amended at 54 FR 9034, Mar. 3, 1989; 58 FR 49190, Sept. 22, 1993; 60 FR 38626, July 27, 1995; 63 FR 26697, May 13, 1998; 64 FR 398, Jan. 5, 1999; 64 FR 56448, Oct. 20, 1999; 67 FR 4906, Feb. 1, 2002]

§ 10.55 Separation of functions; ex parte communications.

(a) This section applies to any matter subject by statute to an opportunity for a formal evidentiary public hearing, as listed in § 10.50(c), and any matter subject to a hearing before a Public Board of Inquiry under part 13.

(b) In the case of a matter listed in § 10.50(c) (1) through (10) and (12) through (15):

(1) An interested person may meet or correspond with any FDA representative concerning a matter prior to publication of a notice announcing a formal evidentiary public hearing or a hearing before a Public Board of Inquiry on the matter; the provisions of § 10.65 apply to the meetings and correspondence; and

(2) Upon publication of a notice announcing a formal evidentiary public hearing or a hearing before a Public Board of Inquiry, the following separation of functions apply:

(i) The center responsible for the matter is, as a party to the hearing, responsible for all investigative functions and for presentation of the position of the center at the hearing and in any pleading or oral argument before the Commissioner. Representatives of the center may not participate or advise in any decision except as witness or counsel in public proceedings. There is to be no other communication between representatives of the center and representatives of the office of the Commissioner concerning the matter before the decision of the Commissioner. The Commissioner may, however, designate representatives of a center to advise the office of the Commissioner, or designate members of that office to advise a center. The designation will be in writing and filed with the Division of Dockets Management no later than the time specified in paragraph (b)(2) of this section for the application of separation of functions. All members of FDA other than representatives of the involved center (except those specifically designated otherwise) shall be available to advise and participate with the office of the Commissioner in its functions relating to the hearing and the final decision.

(ii) The Chief Counsel for FDA shall designate members of the office of General Counsel to advise and participate with the center in its functions in the hearing and members who are to advise the office of the Commissioner in its functions related to the hearing and the final decision. The members of the office of General Counsel designated to advise the center may not participate or advise in any decision of the Commissioner except as counsel in public proceedings. The designation is to be in the form of a memorandum filed with the Division of Dockets Management and made a part of the administrative record in the proceeding. There may be no other communication between those members of the office of General Counsel designated to advise the office of the Commissioner and any other persons in the office of General Counsel or in the involved center with respect to the matter prior to the decision of the Commissioner. The Chief Counsel may assign new attorneys to advise either the center or the office of the Commissioner at any stage of the proceedings. The Chief Counsel will ordinarily advise and participate with the office of the Commissioner in its functions relating to the hearing and the final decision.

(iii) The office of the Commissioner is responsible for the agency review and final decision of the matter, with the advice and participation of anyone in FDA other than representatives of

the involved center and those members of the office of General Counsel designated to assist in the center's functions in the hearing.

(c) In a matter listed in § 10.50(c) (11) and (16) through (19), the provisions relating to separation of functions set forth in §§ 314.200(f), 514.200, and 601.7(a) are applicable before publication of a notice announcing a formal evidentiary public hearing or a hearing before a Public Board of Inquiry. Following publication of the notice of hearing, the rules in paragraph (b)(2) of this section apply.

(d) Except as provided in paragraph (e) of this section, between the date that separation of functions applies under paragraph (b) or (c) of this section and the date of the Commissioner's decision on the matter, communication concerning the matter involved in the hearing will be restricted as follows:

(1) No person outside the agency may have an ex parte communication with the presiding officer or any person representing the office of the Commissioner concerning the matter in the hearing. Neither the presiding officer nor any person representing the office of the Commissioner may have any ex parte communication with a person outside the agency concerning the matter in the hearing. All communications are to be public communications, as witness or counsel, under the applicable provisions of this part.

(2) A participant in the hearing may submit a written communication to the office of the Commissioner with respect to a proposal for settlement. These communications are to be in the form of pleadings, served on all other participants, and filed with the Division of Dockets Management like any other pleading.

(3) A written communication contrary to this section must be immediately served on all other participants and filed with the Division of Dockets Management by the presiding officer at the hearing, or by the Commissioner, depending on who received the communication. An oral communication contrary to this section must be immediately recorded in a written memorandum and similarly served on all other participants and filed with the Division of Dockets Management. A person, including a representative of a participant in the hearing, who is involved in an oral communication contrary to this section, must, if possible, be made available for cross-examination during the hearing with respect to the substance of that conversation. Rebuttal testimony pertinent to a written or oral communication contrary to this section will be permitted. Cross-examination and rebuttal testimony will be transcribed and filed with the Division of Dockets Management.

(e) The prohibitions specified in paragraph (d) of this section apply to a person who knows of a notice of hearing in advance of its publication from the time the knowledge is acquired.

(f) The making of a communication contrary to this section may, consistent with the interests of justice and the policy of the underlying statute, result in a decision adverse to the person knowingly making or causing the making of such a communication.

[44 FR 22323, Apr. 13, 1979, as amended at 50 FR 8994, Mar. 6, 1985; 54 FR 9035, Mar. 3, 1989; 64 FR 398, Jan. 5, 1999]

§ 10.60 Referral by court.

(a) This section applies when a Federal, State, or local court holds in abeyance, or refers to the Commissioner, any matter for an initial administrative determination under § 10.25(c) or § 10.45(b).

(b) The Commissioner shall promptly agree or decline to accept a court referral. Whenever feasible in light of agency priorities and resources, the Commissioner shall agree to accept a referral and shall proceed to determine the matter referred.

(c) In reviewing the matter, the Commissioner may use the following procedures:

(1) Conferences, meetings, discussions, and correspondence under § 10.65.

(2) A hearing under parts 12, 13, 14, 15, or 16.

(3) A notice published in the FEDERAL REGISTER requesting information and views.

(4) Any other public procedure established in other sections of this chapter and expressly applicable to the matter under those provisions.

(d) If the Commissioner's review of the matter results in a proposed rule, the provisions of § 10.40 or § 10.50 also apply.

§ 10.65 Meetings and correspondence.

(a) In addition to public hearings and proceedings established under this part and other sections of this chapter, meetings may be held and correspondence may be exchanged between representatives of FDA and an interested person outside FDA on a matter within the jurisdiction of the laws administered by the Commissioner. Action on meetings and correspondence does not constitute final administrative action subject to judicial review under § 10.45.

(b) The Commissioner may conclude that it would be in the public interest to hold an open public meeting to discuss a matter (or class of matters) pending before FDA, in which any interested person may participate.

(1) The Commissioner shall inform the public of the time and place of the meeting and of the matters to be discussed.

(2) The meeting will be informal, i.e., any interested person may attend and participate in the discussion without prior notice to the agency unless the notice of the meeting specifies otherwise.

(c) Every person outside the Federal Government may request a private meeting with a representative of FDA in agency offices to discuss a matter. FDA will make reasonable efforts to accommodate such requests.

(1) The person requesting a meeting may be accompanied by a reasonable number of employees, consultants, or other persons with whom there is a commercial arrangement within the meaning of § 20.81(a) of this chapter. Neither FDA nor any other person may require the attendance of a person who is not an employee of the executive branch of the Federal Government without the agreement of the person requesting the meeting. Any person may attend by mutual consent of the person requesting the meeting and FDA.

(2) FDA will determine which representatives of the agency will attend the meeting. The person requesting the meeting may request, but not require or preclude, the attendance of a specific FDA employee.

(3) A person who wishes to attend a private meeting, but who is not invited to attend either by the person requesting the meeting or by FDA, or who otherwise cannot attend the meeting, may request a separate meeting with FDA to discuss the same matter or an additional matter.

(d) FDA employees have a responsibility to meet with all segments of the public to promote the objectives of the laws administered by the agency. In pursuing this responsibility, the following general policy applies where agency employees are invited by persons outside the Federal Government to attend or participate in meetings outside agency offices as representatives of the agency.

(1) A person outside the executive branch may invite an agency representative to attend or participate in a meeting outside agency offices. The agency representative is not obligated to attend or participate, but may do so where it is in the public interest and will promote the objectives of the act.

(2) The agency representative may request that the meeting be open if that would be in the public interest. The agency representative may decline to participate in a meeting held as a private meeting if that will best serve the public interest.

(3) An agency representative may not knowingly participate in a meeting that is closed on the basis of gender, race, or religion.

(e) An official transcript, recording, or memorandum summarizing the substance of any meeting described in this section will be prepared by a representative of FDA when the agency determines that such documentation will be useful.

(f) FDA promptly will file in the appropriate administrative file memoranda of meetings prepared by FDA representatives and all correspondence, including any written summary of a meeting from a participant, that relate to a matter pending before the agency.

(g) Representatives of FDA may initiate a meeting or correspondence on any matter concerning the laws administered by the Commissioner. Unless otherwise required by law, meetings

may be public or private at FDA's discretion.

(h) A meeting of an advisory committee is subject to the requirements of part 14 of this chapter.

[66 FR 6468, Jan. 22, 2001]

§ 10.70 Documentation of significant decisions in administrative file.

(a) This section applies to every significant FDA decision on any matter under the laws administered by the Commissioner, whether it is raised formally, for example, by a petition or informally, for example, by correspondence.

(b) FDA employees responsible for handling a matter are responsible for insuring the completeness of the administrative file relating to it. The file must contain:

(1) Appropriate documentation of the basis for the decision, including relevant evaluations, reviews, memoranda, letters, opinions of consultants, minutes of meetings, and other pertinent written documents; and

(2) The recommendations and decisions of individual employees, including supervisory personnel, responsible for handling the matter.

(i) The recommendations and decisions are to reveal significant controversies or differences of opinion and their resolution.

(ii) An agency employee working on a matter and, consistent with the prompt completion of other assignments, an agency employee who has worked on a matter may record individual views on that matter in a written memorandum, which is to be placed in the file.

(c) A written document placed in an administrative file must:

(1) Relate to the factual, scientific, legal or related issues under consideration;

(2) Be dated and signed by the author;

(3) Be directed to the file, to appropriate supervisory personnel, and to other appropriate employees, and show all persons to whom copies were sent;

(4) Avoid defamatory language, intemperate remarks, undocumented charges, or irrelevant matters (e.g., personnel complaints);

(5) If it records the views, analyses, recommendations, or decisions of an agency employee in addition to the author, be given to the other employees; and

(6) Once completed (i.e., typed in final form, dated, and signed) not be altered or removed. Later additions to or revisions of the document must be made in a new document.

(d) Memoranda or other documents that are prepared by agency employees and are not in the administrative file have no status or effect.

(e) FDA employees working on a matter have access to the administrative file on that matter, as appropriate for the conduct of their work. FDA employees who have worked on a matter have access to the administrative file on that matter so long as attention to their assignments is not impeded. Reasonable restrictions may be placed upon access to assure proper cataloging and storage of documents, the availability of the file to others, and the completeness of the file for review.

§ 10.75 Internal agency review of decisions.

(a) A decision of an FDA employee, other than the Commissioner, on a matter, is subject to review by the employee's supervisor under the following circumstances:

(1) At the request of the employee.

(2) On the initiative of the supervisor.

(3) At the request of an interested person outside the agency.

(4) As required by delegations of authority.

(b)(1) The review will be made by consultation between the employee and the supervisor or by review of the administrative file on the matter, or both. The review will ordinarily follow the established agency channels of supervision or review for that matter.

(2) A sponsor, applicant, or manufacturer of a drug or device regulated under the act or the Public Health Service Act (42 U.S.C. 262), may request review of a scientific controversy by an appropriate scientific advisory panel as described in section 505(n) of the act, or an advisory committee as described in section 515(g)(2)(B) of the act. The reason(s) for any denial of a request for

such review shall be briefly set forth in writing to the requester. Persons who receive a Center denial of their request under this section may submit a request for review of the denial. The request should be sent to the Chief Mediator and Ombudsman.

(c) An interested person outside the agency may request internal agency review of a decision through the established agency channels of supervision or review. Personal review of these matters by center directors or the office of the Commissioner will occur for any of the following purposes:

(1) To resolve an issue that cannot be resolved at lower levels within the agency (e.g., between two parts of a center or other component of the agency, between two centers or other components of the agency, or between the agency and an interested person outside the agency).

(2) To review policy matters requiring the attention of center or agency management.

(3) In unusual situations requiring an immediate review in the public interest.

(4) As required by delegations of authority.

(d) Internal agency review of a decision must be based on the information in the administrative file. If an interested person presents new information not in the file, the matter will be returned to the appropriate lower level in the agency for reevaluation based on the new information.

(e) Each request by an interested person for review of a decision within the Center for Devices and Radiological Health shall also comply with § 800.75 of this chapter.

[44 FR 22323, Apr. 13, 1979, as amended at 50 FR 8994, Mar. 6, 1985; 63 FR 63982, Nov. 18, 1998; 84 FR 31477, July 2, 2019]

§ 10.80 Dissemination of draft Federal Register notices and regulations.

(a) A representative of FDA may discuss orally or in writing with an interested person ideas and recommendations for notices or regulations. FDA welcomes assistance in developing ideas for, and in gathering the information to support, notices and regulations.

(b) *Notices and proposed regulations.* (1) Once it is determined that a notice or proposed regulation will be prepared, the general concepts may be discussed by a representative of FDA with an interested person. Details of a draft of a notice or proposed regulation may be discussed with a person outside the executive branch only with the specific permission of the Commissioner. The permission must be in writing and filed with the Division of Dockets Management.

(2) A draft of a notice or proposed regulation or its preamble, or a portion of either, may be furnished to an interested person outside the executive branch only if it is made available to all interested persons by a notice published in the FEDERAL REGISTER. A draft of a notice or proposed regulation made available in this manner may, without the prior permission of the Commissioner, be discussed with an interested person to clarify and resolve questions raised and concerns expressed about the draft.

(c) After publication of a notice or proposed regulation in the FEDERAL REGISTER, and before preparation of a draft of the final notice or regulation, a representative of FDA may discuss the proposal with an interested person as provided in paragraph (b)(2) of this section.

(d) *Final notices and regulations.* (1) Details of a draft of a final notice or regulation may be discussed with an interested person outside the executive branch only with the specific permission of the Commissioner. The permission must be in writing and filed with the Division of Dockets Management.

(2) A draft of a final notice or regulation or its preamble, or any portion of either, may be furnished to an interested person outside the executive branch only if it is made available to all interested persons by a notice published in the FEDERAL REGISTER, except as otherwise provided in paragraphs (g) and (j) of this section. A draft of a final notice or regulation made available to an interested person in this manner may, without the prior permission of the Commissioner, be discussed as provided in paragraph (b)(2) of this section.

(i) The final notice or regulation and its preamble will be prepared solely on the basis of the administrative record.

(ii) If additional technical information from a person outside the executive branch is necessary to draft the final notice or regulation or its preamble, it will be requested by FDA in general terms and furnished directly to the Division of Dockets Management to be included as part of the administrative record.

(iii) If direct discussion by FDA of a draft of a final notice or regulation or its preamble is required with a person outside the executive branch, appropriate protective procedures will be undertaken to make certain that a full and impartial administrative record is established. Such procedures may include either:

(*a*) The scheduling of an open public meeting under § 10.65(b) at which interested persons may participate in review of and comment on the draft document; or

(*b*) The preparation of a tentative final regulation or tentative revised final regulation under § 10.40(f)(6), on which interested persons will be given an additional period of time for oral and written comment.

(e) After a final regulation is published, an FDA representative may discuss any aspect of it with an interested person.

(f) In addition to the requirements of this section, the provisions of § 10.55 apply to the promulgation of a regulation subject to § 10.50 and part 12.

(g) A draft of a final food additive color additive, or new animal drug regulation may be furnished to the petitioner for comment on the technical accuracy of the regulation. Every meeting with a petitioner relating to the draft will be recorded in a written memorandum, and all memoranda and correspondence will be filed with the Division of Dockets Management as part of the administrative record of the regulation under the provisions of § 10.65.

(h) In accordance with 42 U.S.C 263f, the Commissioner shall consult with interested persons and with the Technical Electronic Product Radiation Safety Standards Committee (TEPRSSC) before prescribing any performance standard for an electronic product. Accordingly, the Commissioner shall publish in the FEDERAL REGISTER an announcement when a proposed or final performance standard, including any amendment, is being considered for an electronic product, and any draft of any proposed or final standard will be furnished to an interested person upon request and may be discussed in detail.

(i) The provisions of § 10.65 apply to meetings and correspondence relating to draft notices and regulations.

(j) The provisions of this section restricting discussion and disclosure of draft notices and regulations do not apply to situations covered by §§ 20.83 through 20.89.

[44 FR 22323, Apr. 13, 1979, as amended at 54 FR 9035, Mar. 3, 1989; 64 FR 398, Jan. 5, 1999]

§ 10.85 Advisory opinions.

(a) An interested person may request an advisory opinion from the Commissioner on a matter of general applicability.

(1) The request will be granted whenever feasible.

(2) The request may be denied if:

(i) The request contains incomplete information on which to base an informed advisory opinion;

(ii) The Commissioner concludes that an advisory opinion cannot reasonably be given on the matter involved;

(iii) The matter is adequately covered by a prior advisory opinion or a regulation;

(iv) The request covers a particular product or ingredient or label and does not raise a policy issue of broad applicability; or

(v) The Commissioner otherwise concludes that an advisory opinion would not be in the public interest.

(b) A request for an advisory opinion is to be submitted in accordance with § 10.20, is subject to the provisions of § 10.30 (c) through (l), and must be in the following form:

(Date) _____

Division of Dockets Management, Food and Drug Administration, Department of Health and Human Services, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

REQUEST FOR ADVISORY OPINION

The undersigned submits this request for an advisory opinion of the Commissioner of Food and Drugs with respect to _____ (the general nature of the matter involved).

A. *Issues involved.*

(A concise statement of the issues and questions on which an opinion is requested.)

B. *Statement of facts and law.*

(A full statement of all facts and legal points relevant to the request.)

The undersigned certifies that, to the best of his/her knowledge and belief, this request includes all data, information, and views relevant to the matter, whether favorable or unfavorable to the position of the undersigned, which is the subject of the request.

(Signature) _____
(Person making request) _____
(Mailing address) _____
(Telephone number) _____

(c) The Commissioner may respond to an oral or written request to the agency as a request for an advisory opinion, in which case the request will be filed with the Division of Dockets Management and be subject to this section.

(d) A statement of policy or interpretation made in the following documents, unless subsequently repudiated by the agency or overruled by a court, will constitute an advisory opinion:

(1) Any portion of a FEDERAL REGISTER notice other than the text of a proposed or final regulation, e.g., a notice to manufacturers or a preamble to a proposed or final regulation.

(2) Trade Correspondence (T.C. Nos. 1–431 and 1A–8A) issued by FDA between 1938 and 1946.

(3) Compliance policy guides issued by FDA beginning in 1968 and codified in the Compliance Policy Guides manual.

(4) Other documents specifically identified as advisory opinions, e.g., advisory opinions on the performance standard for diagnostic X-ray systems, issued before July 1, 1975, and filed in a permanent public file for prior advisory opinions maintained by the Division of Freedom of Information (ELEM–1029)'' and adding in its place ''(the Freedom of Information Staff's address is available on the agency's web site at *http://www.fda.gov.*)

(e) An advisory opinion represents the formal position of FDA on a matter and except as provided in paragraph (f) of this section, obligates the agency to follow it until it is amended or revoked. The Commissioner may not recommend legal action against a person or product with respect to an action taken in conformity with an advisory opinion which has not been amended or revoked.

(f) In unusual situations involving an immediate and significant danger to health, the Commissioner may take appropriate civil enforcement action contrary to an advisory opinion before amending or revoking the opinion. This action may be taken only with the approval of the Commissioner, who may not delegate this function. Appropriate amendment or revocation of the advisory opinion involved will be expedited.

(g) An advisory opinion may be amended or revoked at any time after it has been issued. Notice of amendment or revocation will be given in the same manner as notice of the advisory opinion was originally given or in the FEDERAL REGISTER, and will be placed on public display as part of the file on the matter in the office of the Division of Dockets Management. The Division of Dockets Management shall maintain a separate chronological index of all advisory opinions filed. The index will specify the date of the request for the advisory opinion, the date of the opinion, and identification of the appropriate file.

(h) Action undertaken or completed in conformity with an advisory opinion which has subsequently been amended or revoked is acceptable to FDA unless the Commissioner determines that substantial public interest considerations preclude continued acceptance. Whenever possible, an amended or revoked advisory opinion will state when action previously undertaken or completed does not remain acceptable, and any transition period that may be applicable.

(i) An interested person may submit written comments on an advisory opinion or modified advisory opinion. Four copies of any comments are to be sent to the Division of Dockets Management for inclusion in the public file on the advisory opinion. Individuals may submit only one copy. Comments will be considered in determining whether further modification of an advisory opinion is warranted.

(j) An advisory opinion may be used in administrative or court proceedings to illustrate acceptable and unacceptable procedures or standards, but not as a legal requirement.

(k) A statement made or advice provided by an FDA employee constitutes an advisory opinion only if it is issued in writing under this section. A statement or advice given by an FDA employee orally, or given in writing but not under this section or § 10.90, is an informal communication that represents the best judgment of that employee at that time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

[44 FR 22323, Apr. 13, 1979, as amended at 46 FR 8455, Jan. 27, 1981; 59 FR 14364, Mar. 28, 1994; 65 FR 56477, Sept. 19, 2000; 76 FR 31469, June 1, 2011; 79 FR 68114, Nov. 14, 2014]

§ 10.90 Food and Drug Administration regulations, recommendations, and agreements.

(a) *Regulations*. FDA regulations are issued in the FEDERAL REGISTER under § 10.40 or § 10.50 and codified in the Code of Federal Regulations. Regulations may contain provisions that will be enforced as legal requirements, or which are intended only as guidance documents and recommendations, or both. The dissemination of draft notices and regulations is subject to § 10.80.

(b) [Reserved]

(c) *Recommendations*. In addition to the guidance documents subject to § 10.115, FDA often formulates and disseminates recommendations about matters which are authorized by, but do not involve direct regulatory action under, the laws administered by the Commissioner, e.g., model State and local ordinances, or personnel practices for reducing radiation exposure, issued under 42 U.S.C. 243 and 21 U.S.C. 360ii. These recommendations may, in the discretion of the Commissioner, be handled under the procedures established in § 10.115, except that the recommendations will be included in a separate public file of recommendations established by the Division of Dockets Management and will be separated from the guidance documents in the notice of availability published in the FEDERAL REGISTER, or be published in the FEDERAL REGISTER as regulations under paragraph (a) of this section.

(d) *Agreements*. Formal agreements, memoranda of understanding, or other similar written documents executed by FDA and another person will be included in the public file on agreements established by the Division of Freedom of Information (ELEM–1029)'' and adding in its place ''(the Freedom of Information Staff's address is available on the agency's web site at *http://www.fda.gov*) under § 20.108. A document not included in the public file is deemed to be rescinded and has no force or effect whatever.

[44 FR 22323, Apr. 13, 1979, as amended at 54 FR 9035, Mar. 3, 1989; 65 FR 56477, Sept. 19, 2000; 75 FR 16346, Apr. 1, 2010; 79 FR 68114, Nov. 14, 2014]

§ 10.95 Participation in outside standard-setting activities.

(a) *General*. This section applies to participation by FDA employees in standard-setting activities outside the agency. Standard-setting activities include matters such as the development of performance characteristics, testing methodology, manufacturing practices, product standards, scientific protocols, compliance criteria, ingredient specifications, labeling, or other technical or policy criteria. FDA encourages employee participation in outside standard-setting activities that are in the public interest.

(b) *Standard-setting activities by other Federal Government agencies*. (1) An FDA employee may participate in these activities after approval of the activity under procedures specified in the current agency Staff Manual Guide.

(2) Approval forms and all pertinent background information describing the activity will be included in the public file on standard-setting activities established by the Division of Freedom of Information (ELEM–1029)'' and adding in its place ''(the Freedom of Information Staff's address is available on the agency's web site at *http://www.fda.gov*).

(3) If a member of the public is invited by FDA to present views to, or to accompany, the FDA employee at a

meeting, the invitations will be extended to a representative sampling of the public, including consumer groups, industry associations, professional societies, and academic institutions.

(4) An FDA employee appointed as the liaison representative to an activity shall refer all requests for information about or participation in the activity to the group or organization responsible for the activity.

(c) *Standard-setting activities by State and local government agencies and by United Nations organizations and other international organizations and foreign governments pursuant to treaty.* (1) An FDA employee may participate in these activities after approval of the activity under procedures specified in the current agency Staff Manual Guide.

(2) Approval forms and all pertinent background information describing the activity will be included in the public file on standard-setting activities established by the Division of Freedom of Information (ELEM–1029)'' and adding in its place ''(the Freedom of Information Staff's address is available on the agency's web site at *http://www.fda.gov*).

(3) The availability for public disclosure of records relating to the activity will be governed by part 20.

(4) If a member of the public is invited by FDA to present views to, or to accompany, the FDA employee at a meeting, the invitation will be extended to a representative sampling of the public, including consumer groups, industry associations, professional societies, and academic institutions.

(5) An FDA employee appointed as the liaison representative to an activity shall refer all requests for information about or participation in the activity to the group or organization responsible for the activity.

(d) *Standard-setting activities by private groups and organizations.* (1) An FDA employee may engage in these activities after approval of the activity under procedures specified in the current agency Staff Manual Guide. A request for official participation must be made by the group or organization in writing, must describe the scope of the activity, and must demonstrate that the minimum standards set out in paragraph (d)(5) of this section are met. Except as provided in paragraph (d)(7) of this section, a request that is granted will be the subject of a letter from the Commissioner or the center director to the organization stating—

(i) Whether participation by the individual will be as a voting or nonvoting liaison representative;

(ii) That participation by the individual does not connote FDA agreement with, or endorsement of, any decisions reached; and

(iii) That participation by the individual precludes service as the deciding official on the standard involved if it should later come before FDA. The deciding official is the person who signs a document ruling upon the standard.

(2) The letter requesting official FDA participation, the approval form, and the Commissioner's or center director's letter, together with all pertinent background information describing the activities involved, will be included in the public file on standard-setting activities established by the Division of Freedom of Information (ELEM–1029)'' and adding in its place ''(the Freedom of Information Staff's address is available on the agency's web site at *http://www.fda.gov*).

(3) The availability for public disclosure of records relating to the activities will be governed by part 20.

(4) An FDA employee appointed as the liaison representative to an activity shall refer all requests for information about or participation in the activity to the group or organization responsible for the activity.

(5) The following minimum standards apply to an outside private standard-setting activity in which FDA employees participate:

(i) The activity will be based upon consideration of sound scientific and technological information, will permit revision on the basis of new information, and will be designed to protect the public against unsafe, ineffective, or deceptive products or practices.

(ii) The activity and resulting standards will not be designed for the economic benefit of any company, group, or organization, will not be used for such antitrust violations as fixing prices or hindering competition, and

will not involve establishment of certification or specific approval of individual products or services.

(iii) The group or organization responsible for the standard-setting activity must have a procedure by which an interested person will have an opportunity to provide information and views on the activity and standards involved, without the payment of fees, and the information and views will be considered. How this is accomplished, including whether the presentation will be in person or in writing, will be decided by the group or organization responsible for the activity.

(6) Membership of an FDA employee in an organization that also conducts a standard-setting activity does not invoke the provisions of this section unless the employee participates in the standard-setting activity. Participation in a standard-setting activity is subject to this section.

(7) The Commissioner may determine in writing that, because direct involvement by FDA in a particular standard-setting activity is in the public interest and will promote the objectives of the act and the agency, the participation is exempt from the requirements of paragraph (d)(1) (ii) and/or (iii) of this section. This determination will be included in the public file on standard-setting activities established by the Division of Freedom of Information (ELEM–1029)'' and adding in its place ''(the Freedom of Information Staff's address is available on the agency's web site at *http://www.fda.gov*) and in any relevant administrative file. The activity may include the establishment and validation of analytical methods for regulatory use, drafting uniform laws and regulations, and the development of recommendations concerning public health and preventive medicine practices by national and international organizations.

(8) Because of the close daily cooperation between FDA and the associations of State and local government officials listed below in this paragraph, and the large number of agency employees who are members of or work with these associations, participation in the activities of these associations is exempt from paragraphs (d)(1) through (7) of this section, except that a list of the committees and other groups of these associations will be included in the public file on standard-setting activities established by the Division of Freedom of Information (ELEM–1029)'' and adding in its place ''(the Freedom of Information Staff's address is available on the agency's web site at *http://www.fda.gov*).

(i) American Association of Food Hygiene Veterinarians (AAFHV).

(ii) American Public Health Association (APHA).

(iii) Association of American Feed Control Officials, Inc. (AAFCO).

(iv) Association of Food and Drug Officials (AFDO).

(v) AOAC INTERNATIONAL (AOAC).

(vi) Association of State and Territorial Health Officials (ASTHO).

(vii) Conference for Food Protection (CFP).

(viii) Conference of State Health and Environmental Managers (COSHEM).

(ix) Conference of Radiation Control Program Directors (CRCPD).

(x) International Association of Milk, Food, and Environmental Sanitation, Inc. (IAMFES).

(xi) Interstate Shellfish Sanitation Conference (ISSC).

(xii) National Association of Boards of Pharmacy (NABP).

(xiii) National Association of Departments of Agriculture (NADA).

(xiv) National Conference on Interstate Milk Shipments (NCIMS).

(xv) National Conference of Local Environmental Health Administrators (NCLEHA).

(xvi) National Conference on Weights and Measures (NCWW).

(xvii) National Environmental Health Association (NEHA).

(xviii) National Society of Professional Sanitarians (NSPS).

[44 FR 22323, Apr. 13, 1979, as amended at 46 FR 8455, Jan. 27, 1981; 52 FR 35064, Sept. 17, 1987; 54 FR 9035, Mar. 3, 1989; 70 FR 40880, July 15, 2005; 70 FR 67651, Nov. 8, 2005; 76 FR 31469, June 1, 2011; 79 FR 68114, Nov. 14, 2014]

§ 10.100 Public calendar.

(a) *Public calendar.* A public calendar will be prepared and made publicly available by FDA each week showing, to the extent feasible, significant events of the previous week, including

significant meetings with persons outside the executive branch, that involve the representatives of FDA designated under paragraph (c) of this section.

(1) Public calendar entries will include:

(i) Significant meetings with members of the judiciary, representatives of Congress, or staffs of congressional committees when the meeting relates to a pending court case, administrative hearing, or other regulatory action or decision;

(ii) Significant meetings, conferences, seminars, and speeches; and

(iii) Social events sponsored by the regulated industry.

(2) The public calendar will not include reports of meetings that would prejudice law enforcement activities (e.g., a meeting with an informant) or invade privacy (e.g., a meeting with a candidate for possible employment at FDA), meetings with members of the press, or meetings with onsite contractors.

(b) *Calendar entries*. The calendar will specify for each entry the date, person(s), and subject matter involved. If a large number of persons are in attendance, the name of each individual need not be specified. When more than one FDA representative is in attendance, the most senior agency official will report the meeting on the public calendar.

(c) *Affected persons*. The following FDA representatives are subject to the requirements of this section:

(1) Commissioner of Food and Drugs.

(2) Senior Associate Commissioners.

(3) Deputy Commissioners.

(4) Associate Commissioner for Regulatory Affairs.

(5) Center Directors.

(6) Chief Counsel for the Food and Drug Administration.

(d) *Public display*. The public calendar will be placed on public display at the following locations:

(1) Division of Dockets Management.

(2) Office of the Associate Commissioner for Public Affairs.

(3) The FDA home page, to the extent feasible.

[66 FR 6468, Jan. 22, 2001]

§ 10.105 Representation by an organization.

(a) An organization may represent its members by filing petitions, comments, and objections, and otherwise participating in an administrative proceeding subject to this part.

(b) A petition, comment, objection, or other representation by an organization will not abridge the right of a member to take individual action of a similar type, in the member's own name.

(c) It is requested that each organization participating in FDA administrative proceedings file annually with the Division of Dockets Management a current list of all of the members of the organization.

(d) The filing by an organization of an objection or request for hearing under §§ 12.20 through 12.22 does not provide a member a legal right with respect to the objection or request for hearing that the member may individually exercise. A member of an organization wishing to file an objection or request for hearing must do so individually.

(e) In a court proceeding in which an organization participates, the Commissioner will take appropriate legal measures to have the case brought or considered as a class action or otherwise as binding upon all members of the organization except those specifically excluded by name. Regardless of whether the case is brought or considered as a class action or as otherwise binding upon all members of the organization except those specifically excluded by name, the Commissioner will take the position in any subsequent suit involving the same issues and a member of the organization that the issues are precluded from further litigation by the member under the doctrines of collateral estoppel or res judicata.

§ 10.110 Settlement proposals.

At any time in the course of a proceeding subject to this part, a person may propose settlement of the issues involved. A participant in a proceeding will have an opportunity to consider a proposed settlement. Unaccepted proposals of settlement and related matters, e.g., proposed stipulations not

agreed to, will not be admissible in evidence in an FDA administrative proceeding. FDA will oppose the admission in evidence of settlement information in a court proceeding or in another administrative proceeding.

§ 10.115 Good guidance practices.

(a) *What are good guidance practices?* Good guidance practices (GGP's) are FDA's policies and procedures for developing, issuing, and using guidance documents.

(b) *What is a guidance document?* (1) Guidance documents are documents prepared for FDA staff, applicants/sponsors, and the public that describe the agency's interpretation of or policy on a regulatory issue.

(2) Guidance documents include, but are not limited to, documents that relate to: The design, production, labeling, promotion, manufacturing, and testing of regulated products; the processing, content, and evaluation or approval of submissions; and inspection and enforcement policies.

(3) Guidance documents do not include: Documents relating to internal FDA procedures, agency reports, general information documents provided to consumers or health professionals, speeches, journal articles and editorials, media interviews, press materials, warning letters, memoranda of understanding, or other communications directed to individual persons or firms.

(c) *What other terms have a special meaning?* (1) ''Level 1 guidance documents'' include guidance documents that:

(i) Set forth initial interpretations of statutory or regulatory requirements;

(ii) Set forth changes in interpretation or policy that are of more than a minor nature;

(iii) Include complex scientific issues; or

(iv) Cover highly controversial issues.

(2) ''Level 2 guidance documents'' are guidance documents that set forth existing practices or minor changes in interpretation or policy. Level 2 guidance documents include all guidance documents that are not classified as Level 1.

(3) ''You'' refers to all affected parties outside of FDA.

(d) *Are you or FDA required to follow a guidance document?* (1) No. Guidance documents do not establish legally enforceable rights or responsibilities. They do not legally bind the public or FDA.

(2) You may choose to use an approach other than the one set forth in a guidance document. However, your alternative approach must comply with the relevant statutes and regulations. FDA is willing to discuss an alternative approach with you to ensure that it complies with the relevant statutes and regulations.

(3) Although guidance documents do not legally bind FDA, they represent the agency's current thinking. Therefore, FDA employees may depart from guidance documents only with appropriate justification and supervisory concurrence.

(e) *Can FDA use means other than a guidance document to communicate new agency policy or a new regulatory approach to a broad public audience?* The agency may not use documents or other means of communication that are excluded from the definition of guidance document to informally communicate new or different regulatory expectations to a broad public audience for the first time. These GGP's must be followed whenever regulatory expectations that are not readily apparent from the statute or regulations are first communicated to a broad public audience.

(f) *How can you participate in the development and issuance of guidance documents?* (1) You can provide input on guidance documents that FDA is developing under the procedures described in paragraph (g) of this section.

(2) You can suggest areas for guidance document development. Your suggestions should address why a guidance document is necessary.

(3) You can submit drafts of proposed guidance documents for FDA to consider. When you do so, you should mark the document ''Guidance Document Submission'' and submit it to Division of Dockets Management (HFA–305), 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. If you wish to submit

the draft of a proposed guidance document electronically, submit it through *https://www.regulations.gov* at Docket No. FDA–2013–S–0610. It is only necessary to submit one copy.

(4) You can, at any time, suggest that FDA revise or withdraw an already existing guidance document. Your suggestion should address why the guidance document should be revised or withdrawn and, if applicable, how it should be revised.

(5) Once a year, FDA will publish, both in the FEDERAL REGISTER and on the Internet, a list of possible topics for future guidance document development or revision during the next year. You can comment on this list (e.g., by suggesting alternatives or making recommendations on the topics that FDA is considering).

(6) To participate in the development and issuance of guidance documents through one of the mechanisms described in paragraphs (f)(1), (f)(2), or (f)(4) of this section, you should contact the center or office that is responsible for the regulatory activity covered by the guidance document.

(7) If FDA agrees to draft or revise a guidance document, under a suggestion made under paragraphs (f)(1), (f)(2), (f)(3) or (f)(4) of this section, you can participate in the development of that guidance document under the procedures described in paragraph (g) of this section.

(g) *What are FDA's procedures for developing and issuing guidance documents?* (1) FDA's procedures for the development and issuance of Level 1 guidance documents are as follows:

(i) Before FDA prepares a draft of a Level 1 guidance document, FDA can seek or accept early input from individuals or groups outside the agency. For example, FDA can do this by participating in or holding public meetings and workshops.

(ii) After FDA prepares a draft of a Level 1 guidance document, FDA will:

(A) Publish a notice in the FEDERAL REGISTER announcing that the draft guidance document is available;

(B) Post the draft guidance document on the Internet and make it available in hard copy; and

(C) Invite your comment on the draft guidance document. Paragraph (h) of this section tells you how to submit your comments.

(iii) After FDA prepares a draft of a Level 1 guidance document, FDA also can:

(A) Hold public meetings or workshops; or

(B) Present the draft guidance document to an advisory committee for review.

(iv) After providing an opportunity for public comment on a Level 1 guidance document, FDA will:

(A) Review any comments received and prepare the final version of the guidance document that incorporates suggested changes, when appropriate;

(B) Publish a notice in the FEDERAL REGISTER announcing that the guidance document is available;

(C) Post the guidance document on the Internet and make it available in hard copy; and

(D) Implement the guidance document.

(v) After providing an opportunity for comment, FDA may decide that it should issue another draft of the guidance document. In this case, FDA will follow the steps in paragraphs (g)(1)(ii), (g)(1)(iii), and (g)(1)(iv) of this section.

(2) FDA will not seek your comment before it implements a Level 1 guidance document if the agency determines that prior public participation is not feasible or appropriate.

(3) FDA will use the following procedures for developing and issuing Level 1 guidance documents under the circumstances described in paragraph (g)(2) of this section:

(i) After FDA prepares a guidance document, FDA will:

(A) Publish a notice in the FEDERAL REGISTER announcing that the guidance document is available;

(B) Post the guidance document on the Internet and make it available in hard copy;

(C) Immediately implement the guidance document; and

(D) Invite your comment when it issues or publishes the guidance document. Paragraph (h) of this section tells you how to submit your comments.

(ii) If FDA receives comments on the guidance document, FDA will review

those comments and revise the guidance document when appropriate.

(4) FDA will use the following procedures for developing and issuing Level 2 guidance documents:

(i) After it prepares a guidance document, FDA will:

(A) Post the guidance document on the Internet and make it available in hard copy;

(B) Immediately implement the guidance document, unless FDA indicates otherwise when the document is made available; and

(C) Invite your comment on the Level 2 guidance document. Paragraph (h) of this section tells you how to submit your comments.

(ii) If FDA receives comments on the guidance document, FDA will review those comments and revise the document when appropriate. If a version is revised, the new version will be placed on the Internet.

(5) You can comment on any guidance document at any time. Paragraph (h) of this section tells you how to submit your comments. FDA will revise guidance documents in response to your comments when appropriate.

(h) *How should you submit comments on a guidance document?* (1) If you choose to submit comments on any guidance document under paragraph (g) of this section, you must send them to the Division of Dockets Management (HFA–305), 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

(2) Comments should identify the docket number on the guidance document, if such a docket number exists. For documents without a docket number, the title of the guidance document should be included.

(3) Comments will be available to the public in accordance with FDA's regulations on submission of documents to the Division of Dockets Management specified in § 10.20(j).

(i) *What standard elements must FDA include in a guidance document?* (1) A guidance document must:

(i) Include the term ''guidance,''

(ii) Identify the center(s) or office(s) issuing the document,

(iii) Identify the activity to which and the people to whom the document applies,

(iv) Prominently display a statement of the document's nonbinding effect,

(v) Include the date of issuance,

(vi) Note if it is a revision to a previously issued guidance and identify the document that it replaces, and

(vii) Contain the word ''draft'' if the document is a draft guidance.

(2) Guidance documents must not include mandatory language such as ''shall,'' ''must,'' ''required,'' or ''requirement,'' unless FDA is using these words to describe a statutory or regulatory requirement.

(3) When issuing draft guidance documents that are the product of international negotiations (e.g., guidances resulting from the International Conference on Harmonisation), FDA need not apply paragraphs (i)(1) and (i)(2) of this section. However, any final guidance document issued according to this provision must contain the elements in paragraphs (i)(1) and (i)(2) of this section.

(j) *Who, within FDA, can approve issuance of guidance documents?* Each center and office must have written procedures for the approval of guidance documents. Those procedures must ensure that issuance of all documents is approved by appropriate senior FDA officials.

(k) *How will FDA review and revise existing guidance documents?* (1) The agency will periodically review existing guidance documents to determine whether they need to be changed or withdrawn.

(2) When significant changes are made to the statute or regulations, the agency will review and, if appropriate, revise guidance documents relating to that changed statute or regulation.

(3) As discussed in paragraph (f)(3) of this section, you may at any time suggest that FDA revise a guidance document.

(l) *How will FDA ensure that FDA staff are following GGP's?* (1) All current and new FDA employees involved in the development, issuance, or application of guidance documents will be trained regarding the agency's GGP's.

(2) FDA centers and offices will monitor the development and issuance of guidance documents to ensure that GGP's are being followed.

(m) *How can you get copies of FDA's guidance documents?* FDA will make copies available in hard copy and, as feasible, through the Internet.

(n) *How will FDA keep you informed of the guidance documents that are available?* (1) FDA will maintain on the Internet a current list of all guidance documents. New documents will be added to this list within 30 days of issuance.

(2) Once a year, FDA will publish in the FEDERAL REGISTER its comprehensive list of guidance documents. The comprehensive list will identify documents that have been added to the list or withdrawn from the list since the previous comprehensive list.

(3) FDA's guidance document lists will include the name of the guidance document, issuance and revision dates, and information on how to obtain copies of the document.

(o) *What can you do if you believe that someone at FDA is not following these GGP's?* If you believe that someone at FDA did not follow the procedures in this section or that someone at FDA treated a guidance document as a binding requirement, you should contact that person's supervisor in the center or office that issued the guidance document. If the issue cannot be resolved, you should contact the next highest supervisor. You can also contact the center or office ombudsman for assistance in resolving the issue. If you are unable to resolve the issue at the center or office level or if you feel that you are not making progress by going through the chain of command, you may ask the Office of the Chief Mediator and Ombudsman to become involved.

[65 FR 56477, Sept. 19, 2000, as amended at 83 FR 13416, Mar. 29, 2018]

Subpart C—Electronic Media Coverage of Public Administrative Proceedings; Guideline on Policy and Procedures

SOURCE: 49 FR 14726, Apr. 13, 1984, unless otherwise noted.

§ 10.200 Scope.

This guideline describes FDA's policy and procedures applicable to electronic media coverage of agency public administrative proceedings. It is a guideline intended to clarify and explain FDA's policy on the presence and operation of electronic recording equipment at such proceedings and to assure uniform and consistent application of practices and procedures throughout the agency.

§ 10.203 Definitions.

(a) *Public administrative proceeding* as used in this guideline means any FDA proceeding which the public has a right to attend. This includes a formal evidentiary public hearing as set forth in part 12, a public hearing before a Public Board of Inquiry as set forth in part 13, a public hearing before a Public Advisory Committee as set forth in part 14, a public hearing before the Commissioner as set forth in part 15, a regulatory hearing before FDA as set forth in part 16, consumer exchange meetings, and Commissioner's public meetings with health professionals.

(b) *Advance notice* as used in this guideline means written or telephone notification to FDA's Office of Public Affairs (Press Relations Staff) of intent to electronically record an agency public administrative proceeding.

(c) *Electronic recording* as used in this guideline means any visual or audio recording made by videotape recording equipment or moving film camera, and/or other electronic recording equipment.

[49 FR 14726, Apr. 13, 1984, as amended at 54 FR 9035, Mar. 3, 1989]

§ 10.204 General.

(a) FDA has for many years willingly committed itself to a policy of openness. In many instances FDA has sought to make the open portions of agency public administrative proceedings more accessible to public participation. Similarly, FDA has sought, wherever possible, to allow full written media access to its proceedings, so that members of the press would have the opportunity to provide first-hand reports. However, because electronic media coverage presents certain difficulties that are easier to resolve with advance notice to the agency and all participants, FDA believes that codification of its policy will facilitate and further increase media access to its

public administrative proceedings. The agency intends to refer to this guideline when notices of hearing, or individual advisory committee meetings, are published in the FEDERAL REGISTER. Thus, all parties to a proceeding will be on notice that the proceeding may be recorded electronically and any person interested in videotaping or otherwise recording the proceeding will be notified that there are established procedures to be followed.

(b) The designated presiding officer of a public administrative proceeding retains the existing discretionary authority set forth in specific regulations pertaining to each type of administrative proceeding to regulate the conduct of the proceeding over which he or she presides. The responsibilities of the presiding officer, established elsewhere in parts 10 through 16, include an obligation to be concerned with the timely conduct of a hearing, the limited availability of certain witnesses, and reducing disruptions to the proceeding which may occur. Each proceeding varies, and the presiding officer cannot anticipate all that might occur. Discretionary authority to regulate conduct at a proceeding has traditionally been granted to presiding officers to enable them to fulfill their responsibility to maintain a fair and orderly hearing conducted in an expeditious manner.

(c) This guideline provides the presiding officer with a degree of flexibility in that it sets forth the agency's policy as well as the procedures that presiding officers should ordinarily follow, but from which they may depart in particular situations if necessary, subject to the presumption of openness of public proceedings to electronic media coverage. The presiding officer's discretion to establish additional procedures or to limit electronic coverage is to be exercised only in the unusual circumstances defined in this guideline. Even though a presiding officer may establish additional procedures or limits as may be required in a particular situation, he or she will be guided by the policy expressed in this guideline in establishing these conditions. The presiding officer may also be less restrictive, taking into account such factors as the duration of a hearing and the design of the room.

(d) If a portion or all of a proceeding is closed to the public because material is to be discussed that is not disclosable to the public under applicable laws, the proceeding also will be closed to electronic media coverage.

(e) The agency requests advance notice of intent to record a proceeding electronically to facilitate the orderly conduct of the proceeding. Knowledge of anticipated media coverage will allow the presiding officer to make any special arrangements required by the circumstances of the proceeding. The agency believes that this guideline establishes sufficiently specific criteria to promote uniformity.

(f) The agency would like to allow all interested media representatives to videotape a proceeding in which they have an interest. However, should space limitations preclude a multitude of cameras, the presiding officer may require pool sharing. In such a case, pool sharing arrangements of the resulting videotape should be made between those allowed to film and those who were excluded. Arrangements for who is designated to present the pool and a method of distributing the resulting film or tape may be determined by the established networks' pooling system. However, the agency has a strong commitment to ensuring that media representatives other than the major networks also be able to obtain a copy of the tape at cost. FDA is concerned that if the network pool representative wishes to record only a short portion of a proceeding, but an excluded party wishes to record the entire proceeding, confusion will result. The agency expects the interested media representatives to negotiate a suitable agreement among themselves before commencement of the proceeding. For example, the network pool representatives might agree to record a portion of the proceeding up to a break in the proceeding, at which time, while the network representative is disassembling equipment, another media representative might set up to continue recording. If an agreement cannot be reached before the proceeding, the agency will use the time of receipt of any advance notice to determine the representation for each category of media, e.g., one network reporter, one

independent reporter. The agency recommends that parties intending to videotape provide as much advance notice as possible, so that the agency may best respond to the needs of the electronic media.

(g) To ensure the timely conduct of agency hearings and to prevent disruptions, equipment is to be stationary during a proceeding and should be set up and taken down when the proceeding is not in progress. As noted previously, the presiding officer may, at his or her discretion, be less restrictive if appropriate.

(h) The agency recognizes that electronic media representatives may desire only short footage of a proceeding, a facsimile of the proceeding, and/or interview opportunities and may be unnecessarily restricted by requirements for setting up before a proceeding and then waiting until a break in the proceeding before being permitted to take down their equipment. To accommodate this possibility, FDA's Press Relations Staff will attempt to make arrangements to respond to such needs by, for example, requesting that the presiding officer provide a break shortly after commencement of the proceeding to permit take down of equipment.

(i) The agency is making a full commitment to allowing, whenever possible, electronic coverage of its public administrative proceedings subject to the limited restrictions established in this guideline.

§ 10.205 Electronic media coverage of public administrative proceedings.

(a) A person may record electronically any open public administrative proceeding, subject to the procedures specified in this guideline. The procedures include a presumption that agency public proceedings are open to the electronic media. Whenever possible, FDA will permit all interested persons access to record agency public administrative proceedings. Restrictions other than those listed in § 10.206 will be imposed only under exceptional circumstances.

(b) A videotape recording of an FDA public administrative proceeding is not an official record of the proceeding. The only official record is the written transcript of the proceeding, which is taken by the official reporter.

§ 10.206 Procedures for electronic media coverage of agency public administrative proceedings.

(a) To facilitate the agency's response to media needs, a person intending to videotape an FDA public administrative proceeding should, whenever possible, provide advance notice to the Press Relations Staff (HFI–20), Office of Public Affairs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, in writing or by telephone (telephone 301–443–4177), at least 48 hours in advance of the proceeding. The Press Relations Staff will inform the presiding officer that the proceeding will be attended by representatives of the electronic media, and ascertain whether any special provisions in addition to those set forth in this subpart are required by the presiding officer. If so, the Press Relations Staff will function as a liaison between the presiding officer and the person intending to record the proceeding in facilitating any procedures in addition to those outlined in this subpart. The presiding officer will not deny access for failure to provide a 48-hour advance notice. Any advance notice may describe the intended length of recording if known, the amount and type of equipment to be used, and any special needs such as interviews.

(b) Cameras should be completely set up before a proceeding is scheduled to begin or during a break in the proceeding and should remain standing in the area designated for electronic media equipment. Cameras may be taken down only during breaks or after the hearing is over. Roving cameras will not be permitted during the proceeding. Any artificial lighting should be unobtrusive. Microphones, like cameras, should be in place before the start of a proceeding and may be taken down as indicated in this paragraph.

(c) When space in the hearing room is limited, the presiding officer may restrict the number of cameras or the equipment present. Should such a restriction become necessary, the pool arrangements are the responsibility of the participating media. The agency encourages the network pool to make

copies of the tape, film, or other product available at cost to nonpool participants. However, if this is not possible, the agency may need to use the time of receipt of any advance notice to determine the representation for each category, e.g., one network reporter, one independent reporter, etc.

(d) *Off the record* portions of a proceeding may not be videotaped.

(e) Before or during the proceeding, the presiding officer may establish other conditions specific to the proceeding for which the request is being made. These conditions may be more or less restrictive than those stated in this guideline, except that the presiding officer shall observe the agency's presumption of openness of its public proceedings to the electronic media. Only a substantial and clear threat to the agency's interests in order, fairness, and timeliness authorizes the presiding officer to impose additional restrictions. This threat must outweigh the public interest in electronic media coverage of agency proceedings. Additional restrictions shall be narrowly drawn to the particular circumstances. The following factors are listed to assist presiding officers in determining whether the agency's interest is sufficiently compelling to call for the unusual step of imposing additional restrictions. Generally this step is justified when one of the following factors is met:

(1) Electronic recording would result in a substantial likelihood of disruption that clearly cannot be contained by the procedures established in paragraphs (a) through (d) of this section.

(2) Electronic recording would result in a substantial likelihood of prejudicial impact on the fairness of the proceeding or the substantive discussion in a proceeding.

(3) There is a substantial likelihood that a witness' ability to testify may be impaired due to unique personal circumstances such as the age or psychological state of the witness or the particularly personal or private nature of the witness' testimony, if the witness' testimony were electronically recorded.

(f) Before the proceeding, the Press Relations Staff will, upon request, provide written copies of any additional conditions imposed by the presiding officer (as described in paragraph (e) of this section) to requesting members of the media. Any appeals should be made in accordance with paragraph (h) of this section.

(g) The presiding officer retains authority to restrict or discontinue videotaping or other recording of a proceeding, or parts of a proceeding, should such a decision become necessary. The presiding officer's responsibility to conduct the hearing includes the right and duty to remove a source of substantial disruption. In exercising his or her authority, the presiding officer shall observe the presumption that agency public proceedings are open to the electronic media. The presiding officer shall exercise his or her discretion to restrict or discontinue electronic coverage of a public proceeding, or portions of a public proceeding, only if he or she determines that the agency's interest in the fair and orderly administrative process is substantially threatened. A clear and substantial threat to the integrity of agency proceedings must clearly outweigh the public interest in electronic media coverage of the proceedings before additional restrictions are imposed on the electronic media during the course of the proceedings. The factors noted in paragraph (e) of this section indicate the kind of substantial threat to the agency interests that may require imposing additional restrictions during the course of the proceedings. If additional requirements are established during the hearing, the presiding officer shall notify immediately the Deputy Commissioner of Food and Drugs of that fact by telephone and submit a written explanation of the circumstances that necessitated such an action within 24 hours or sooner if requested by the Deputy Commissioner. In the absence or unavailability of the Deputy Commissioner, the presiding officer shall notify the Associate Commissioner for Regulatory Affairs.

(h) A decision by a presiding officer, made either before the proceeding or during the course of a proceeding, to establish requirements in addition to the minimum standards set forth in this guideline may be appealed by any adversely affected person who intends

to record the proceeding electronically. Appeals may be made in writing or by phone to the Deputy Commissioner or, in his or her absence, to the Associate Commissioner for Regulatory Affairs. The filing of an appeal, whether before or during a proceeding, does not require the presiding officer to interrupt the proceeding. However, the Deputy Commissioner or, in his or her absence, the Associate Commissioner for Regulatory Affairs will resolve an appeal as expeditiously as possible so as to preserve, to the extent possible, the reporters' opportunity to record the proceedings.

[49 FR 14726, Apr. 13, 1984, as amended at 54 FR 9035, Mar. 3, 1989]

PART 11—ELECTRONIC RECORDS; ELECTRONIC SIGNATURES

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AUTHORITY: 21 U.S.C. 321–393; 42 U.S.C. 262.

SOURCE: 62 FR 13464, Mar. 20, 1997, unless otherwise noted.

Subpart A—General Provisions

§ 11.1 Scope.

(a) The regulations in this part set forth the criteria under which the agency considers electronic records, electronic signatures, and handwritten signatures executed to electronic records to be trustworthy, reliable, and generally equivalent to paper records and handwritten signatures executed on paper.

(b) This part applies to records in electronic form that are created, modified, maintained, archived, retrieved, or transmitted, under any records requirements set forth in agency regulations. This part also applies to electronic records submitted to the agency under requirements of the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act, even if such records are not specifically identified in agency regulations. However, this part does not apply to paper records that are, or have been, transmitted by electronic means.

(c) Where electronic signatures and their associated electronic records meet the requirements of this part, the agency will consider the electronic signatures to be equivalent to full handwritten signatures, initials, and other general signings as required by agency regulations, unless specifically excepted by regulation(s) effective on or after August 20, 1997.

(d) Electronic records that meet the requirements of this part may be used in lieu of paper records, in accordance with § 11.2, unless paper records are specifically required.

(e) Computer systems (including hardware and software), controls, and attendant documentation maintained under this part shall be readily available for, and subject to, FDA inspection.

(f) This part does not apply to records required to be established or maintained by §§ 1.326 through 1.368 of this chapter. Records that satisfy the requirements of part 1, subpart J of this chapter, but that also are required under other applicable statutory provisions or regulations, remain subject to this part.

(g) This part does not apply to electronic signatures obtained under § 101.11(d) of this chapter.

(h) This part does not apply to electronic signatures obtained under § 101.8(d) of this chapter.

(i) This part does not apply to records required to be established or maintained by part 117 of this chapter. Records that satisfy the requirements of part 117 of this chapter, but that also are required under other applicable statutory provisions or regulations, remain subject to this part.

(j) This part does not apply to records required to be established or

maintained by part 507 of this chapter. Records that satisfy the requirements of part 507 of this chapter, but that also are required under other applicable statutory provisions or regulations, remain subject to this part.

(k) This part does not apply to records required to be established or maintained by part 112 of this chapter. Records that satisfy the requirements of part 112 of this chapter, but that also are required under other applicable statutory provisions or regulations, remain subject to this part.

(l) This part does not apply to records required to be established or maintained by subpart L of part 1 of this chapter. Records that satisfy the requirements of subpart L of part 1 of this chapter, but that also are required under other applicable statutory provisions or regulations, remain subject to this part.

(m) This part does not apply to records required to be established or maintained by subpart M of part 1 of this chapter. Records that satisfy the requirements of subpart M of part 1 of this chapter, but that also are required under other applicable statutory provisions or regulations, remain subject to this part.

(n) This part does not apply to records required to be established or maintained by subpart O of part 1 of this chapter. Records that satisfy the requirements of subpart O of part 1 of this chapter, but that also are required under other applicable statutory provisions or regulations, remain subject to this part.

(o) This part does not apply to records required to be established or maintained by part 121 of this chapter. Records that satisfy the requirements of part 121 of this chapter, but that also are required under other applicable statutory provisions or regulations, remain subject to this part.

[62 FR 13464, Mar. 20, 1997, as amended at 69 FR 71655, Dec. 9, 2004; 79 FR 71253, 71291, Dec. 1, 2014; 80 FR 71253, June 19, 2015; 80 FR 56144, 56336, Sept. 17, 2015; 80 FR 74352, 74547, 74667, Nov. 27, 2015; 81 FR 20170, Apr. 6, 2016; 81 FR 34218, May 27, 2016]

§ 11.2 Implementation.

(a) For records required to be maintained but not submitted to the agency, persons may use electronic records in lieu of paper records or electronic signatures in lieu of traditional signatures, in whole or in part, provided that the requirements of this part are met.

(b) For records submitted to the agency, persons may use electronic records in lieu of paper records or electronic signatures in lieu of traditional signatures, in whole or in part, provided that:

(1) The requirements of this part are met; and

(2) The document or parts of a document to be submitted have been identified in public docket No. 92S–0251 as being the type of submission the agency accepts in electronic form. This docket will identify specifically what types of documents or parts of documents are acceptable for submission in electronic form without paper records and the agency receiving unit(s) (e.g., specific center, office, division, branch) to which such submissions may be made. Documents to agency receiving unit(s) not specified in the public docket will not be considered as official if they are submitted in electronic form; paper forms of such documents will be considered as official and must accompany any electronic records. Persons are expected to consult with the intended agency receiving unit for details on how (e.g., method of transmission, media, file formats, and technical protocols) and whether to proceed with the electronic submission.

§ 11.3 Definitions.

(a) The definitions and interpretations of terms contained in section 201 of the act apply to those terms when used in this part.

(b) The following definitions of terms also apply to this part:

(1) *Act* means the Federal Food, Drug, and Cosmetic Act (secs. 201–903 (21 U.S.C. 321–393)).

(2) *Agency* means the Food and Drug Administration.

(3) *Biometrics* means a method of verifying an individual's identity based on measurement of the individual's physical feature(s) or repeatable action(s) where those features and/or actions are both unique to that individual and measurable.

(4) *Closed system* means an environment in which system access is controlled by persons who are responsible for the content of electronic records that are on the system.

(5) *Digital signature* means an electronic signature based upon cryptographic methods of originator authentication, computed by using a set of rules and a set of parameters such that the identity of the signer and the integrity of the data can be verified.

(6) *Electronic record* means any combination of text, graphics, data, audio, pictorial, or other information representation in digital form that is created, modified, maintained, archived, retrieved, or distributed by a computer system.

(7) *Electronic signature* means a computer data compilation of any symbol or series of symbols executed, adopted, or authorized by an individual to be the legally binding equivalent of the individual's handwritten signature.

(8) *Handwritten signature* means the scripted name or legal mark of an individual handwritten by that individual and executed or adopted with the present intention to authenticate a writing in a permanent form. The act of signing with a writing or marking instrument such as a pen or stylus is preserved. The scripted name or legal mark, while conventionally applied to paper, may also be applied to other devices that capture the name or mark.

(9) *Open system* means an environment in which system access is not controlled by persons who are responsible for the content of electronic records that are on the system.

Subpart B—Electronic Records

§ 11.10 Controls for closed systems.

Persons who use closed systems to create, modify, maintain, or transmit electronic records shall employ procedures and controls designed to ensure the authenticity, integrity, and, when appropriate, the confidentiality of electronic records, and to ensure that the signer cannot readily repudiate the signed record as not genuine. Such procedures and controls shall include the following:

(a) Validation of systems to ensure accuracy, reliability, consistent intended performance, and the ability to discern invalid or altered records.

(b) The ability to generate accurate and complete copies of records in both human readable and electronic form suitable for inspection, review, and copying by the agency. Persons should contact the agency if there are any questions regarding the ability of the agency to perform such review and copying of the electronic records.

(c) Protection of records to enable their accurate and ready retrieval throughout the records retention period.

(d) Limiting system access to authorized individuals.

(e) Use of secure, computer-generated, time-stamped audit trails to independently record the date and time of operator entries and actions that create, modify, or delete electronic records. Record changes shall not obscure previously recorded information. Such audit trail documentation shall be retained for a period at least as long as that required for the subject electronic records and shall be available for agency review and copying.

(f) Use of operational system checks to enforce permitted sequencing of steps and events, as appropriate.

(g) Use of authority checks to ensure that only authorized individuals can use the system, electronically sign a record, access the operation or computer system input or output device, alter a record, or perform the operation at hand.

(h) Use of device (e.g., terminal) checks to determine, as appropriate, the validity of the source of data input or operational instruction.

(i) Determination that persons who develop, maintain, or use electronic record/electronic signature systems have the education, training, and experience to perform their assigned tasks.

(j) The establishment of, and adherence to, written policies that hold individuals accountable and responsible for actions initiated under their electronic signatures, in order to deter record and signature falsification.

(k) Use of appropriate controls over systems documentation including:

(1) Adequate controls over the distribution of, access to, and use of documentation for system operation and maintenance.

(2) Revision and change control procedures to maintain an audit trail that documents time-sequenced development and modification of systems documentation.

§ 11.30 Controls for open systems.

Persons who use open systems to create, modify, maintain, or transmit electronic records shall employ procedures and controls designed to ensure the authenticity, integrity, and, as appropriate, the confidentiality of electronic records from the point of their creation to the point of their receipt. Such procedures and controls shall include those identified in § 11.10, as appropriate, and additional measures such as document encryption and use of appropriate digital signature standards to ensure, as necessary under the circumstances, record authenticity, integrity, and confidentiality.

§ 11.50 Signature manifestations.

(a) Signed electronic records shall contain information associated with the signing that clearly indicates all of the following:

(1) The printed name of the signer;

(2) The date and time when the signature was executed; and

(3) The meaning (such as review, approval, responsibility, or authorship) associated with the signature.

(b) The items identified in paragraphs (a)(1), (a)(2), and (a)(3) of this section shall be subject to the same controls as for electronic records and shall be included as part of any human readable form of the electronic record (such as electronic display or printout).

§ 11.70 Signature/record linking.

Electronic signatures and handwritten signatures executed to electronic records shall be linked to their respective electronic records to ensure that the signatures cannot be excised, copied, or otherwise transferred to falsify an electronic record by ordinary means.

Subpart C—Electronic Signatures

§ 11.100 General requirements.

(a) Each electronic signature shall be unique to one individual and shall not be reused by, or reassigned to, anyone else.

(b) Before an organization establishes, assigns, certifies, or otherwise sanctions an individual's electronic signature, or any element of such electronic signature, the organization shall verify the identity of the individual.

(c) Persons using electronic signatures shall, prior to or at the time of such use, certify to the agency that the electronic signatures in their system, used on or after August 20, 1997, are intended to be the legally binding equivalent of traditional handwritten signatures.

(1) The certification shall be submitted in paper form and signed with a traditional handwritten signature, to the Office of Regional Operations (HFC–100), 5600 Fishers Lane, Rockville, MD 20857.

(2) Persons using electronic signatures shall, upon agency request, provide additional certification or testimony that a specific electronic signature is the legally binding equivalent of the signer's handwritten signature.

§ 11.200 Electronic signature components and controls.

(a) Electronic signatures that are not based upon biometrics shall:

(1) Employ at least two distinct identification components such as an identification code and password.

(i) When an individual executes a series of signings during a single, continuous period of controlled system access, the first signing shall be executed using all electronic signature components; subsequent signings shall be executed using at least one electronic signature component that is only executable by, and designed to be used only by, the individual.

(ii) When an individual executes one or more signings not performed during a single, continuous period of controlled system access, each signing shall be executed using all of the electronic signature components.

(2) Be used only by their genuine owners; and

(3) Be administered and executed to ensure that attempted use of an individual's electronic signature by anyone other than its genuine owner requires collaboration of two or more individuals.

(b) Electronic signatures based upon biometrics shall be designed to ensure that they cannot be used by anyone other than their genuine owners.

§ 11.300 Controls for identification codes/passwords.

Persons who use electronic signatures based upon use of identification codes in combination with passwords shall employ controls to ensure their security and integrity. Such controls shall include:

(a) Maintaining the uniqueness of each combined identification code and password, such that no two individuals have the same combination of identification code and password.

(b) Ensuring that identification code and password issuances are periodically checked, recalled, or revised (e.g., to cover such events as password aging).

(c) Following loss management procedures to electronically deauthorize lost, stolen, missing, or otherwise potentially compromised tokens, cards, and other devices that bear or generate identification code or password information, and to issue temporary or permanent replacements using suitable, rigorous controls.

(d) Use of transaction safeguards to prevent unauthorized use of passwords and/or identification codes, and to detect and report in an immediate and urgent manner any attempts at their unauthorized use to the system security unit, and, as appropriate, to organizational management.

(e) Initial and periodic testing of devices, such as tokens or cards, that bear or generate identification code or password information to ensure that they function properly and have not been altered in an unauthorized manner.

PART 12—FORMAL EVIDENTIARY PUBLIC HEARING

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AUTHORITY: 21 U.S.C. 141–149, 321–393, 467f, 679, 821, 1034; 42 U.S.C. 201, 262, 263b–263n, 264; 15 U.S.C. 1451–1461; 5 U.S.C. 551–558, 701–721; 28 U.S.C. 2112.

SOURCE: 44 FR 22339, Apr. 13, 1979, unless otherwise noted.

Subpart A—General Provisions

§ 12.1 Scope.

The procedures in this part apply when—

(a) A person has a right to an opportunity for a hearing under the laws specified in § 10.50; or

(b) The Commissioner concludes that it is in the public interest to hold a formal evidentiary public hearing on any matter before FDA.

Subpart B—Initiation of Proceedings

§ 12.20 Initiation of a hearing involving the issuance, amendment, or revocation of a regulation.

(a) A proceeding under section 409(f), 502(n), 512(n)(5), 701(e), or 721(d) of the act or section 4 or 5 of the Fair Packaging and Labeling Act may be initiated—

(1) By the Commissioner on the Commissioner's own initiative, e.g., as provided in § 170.15 for food additives; or

(2) By a petition—

(i) In the form specified elsewhere in this chapter, e.g., the form for a color additive petition in § 71.1; or

(ii) If no form is specified, by a petition under § 10.30.

(b) If the Commissioner receives a petition under paragraph (a)(2) of this section, the Commissioner will—

(1) If it involves any matter subject to section 701(e) of the act or section 4 or 5 of the Fair Packaging and Labeling Act, and meets the requirements for filing, follow the provisions of § 10.40 (b) through (f);

(2) If it involves a color additive or food additive, and meets the requirements for filing in §§ 71.1 and 71.2, or in §§ 171.1, 171.6, 171.7, and 171.100, publish a notice of filing of the petition within 30 days after the petition is filed instead of a notice of proposed rulemaking.

(c) [Reserved]

(d) The notice promulgating the regulation will describe how to submit objections and requests for hearing.

(e) On or before the 30th day after the date of publication of a final regulation, or of a notice withdrawing a proposal initiated by a petition under § 10.25(a), a person may submit to the Commissioner written objections and a request for a hearing. The 30-day period may not be extended except that additional information supporting an objection may be received after 30 days upon a showing of inadvertent omission and hardship, and if review of the objection and request for hearing will not thereby be impeded. If, after a final color additive regulation is published, a petition or proposal relating to the regulation is referred to an advisory committee in accordance with section 721(b)(5)(C) of the act, objections and requests for a hearing may be submitted on or before the 30th day after the date on which the order confirming or modifying the Commissioner's previous order is published.

[44 FR 22339, Apr. 13, 1979, as amended at 64 FR 399, Jan. 5, 1999]

§ 12.21 Initiation of a hearing involving the issuance, amendment, or revocation of an order.

(a) A proceeding under section 505 (d) or (e), 512 (d), (e), (m) (3) or (4), of section 515(g)(1) of the act, or section 351(a) of the Public Health Service Act, may be initiated—

(1) By the Commissioner on the Commissioner's own initiative;

(2) By a petition in the form specified elsewhere in this chapter, e.g., § 314.50 for new drug applications, § 514.1 for new animal drug applications, § 514.2 for applications for animal feeds, or § 601.3 for licenses for biologic products; or

(3) By a petition under § 10.30.

(b) A notice of opportunity for hearing on a proposal to deny or revoke approval of all or part of an order will be published together with an explanation of the grounds for the proposed action. The notice will describe how to submit requests for hearing. A person subject to the notice has 30 days after its issuance to request a hearing. The 30-day period may not be extended.

(c) The Commissioner may use an optional procedure specified in § 10.30(h) to consider issuing, amending, or revoking an order.

(d) In a proceeding under sections 505(e), 512(e) or (m), or 515(e) of the act in which a party wishes to apply for reimbursement of certain expenses under the Equal Access to Justice Act (5 U.S.C. 504 and 504 note), FDA will follow the Department of Health and Human Services' regulations in 45 CFR part 13.

[44 FR 22339, Apr. 13, 1979, as amended at 47 FR 25734, June 15, 1982; 54 FR 9035, Mar. 3, 1989]

§ 12.22 Filing objections and requests for a hearing on a regulation or order.

(a) Objections and requests for a hearing under § 12.20(d) must be submitted to the Division of Dockets Management and will be accepted for filing if they meet the following conditions:

(1) They are submitted within the time specified in § 12.20(e).

(2) Each objection is separately numbered.

(3) Each objection specifies with particularity the provision of the regulation or proposed order objected to.

(4) Each objection on which a hearing is requested specifically so states. Failure to request a hearing on an objection constitutes a waiver of the right to a hearing on that objection.

(5) Each objection for which a hearing is requested includes a detailed description and analysis of the factual information to be presented in support of the objection. Failure to include a description and analysis for an objection constitutes a waiver of the right to a hearing on that objection. The description and analysis may be used only for the purpose of determining whether a hearing has been justified under § 12.24, and do not limit the evidence that may be presented if a hearing is granted.

(i) A copy of any report, article, survey, or other written document relied upon must be submitted, except if the document is—

(*a*) An FDA document that is routinely publicly available; or

(*b*) A recognized medical or scientific textbook that is readily available to the agency.

(ii) A summary of the nondocumentary testimony to be presented by any witnesses relied upon must be submitted.

(b) Requests for hearing submitted under § 12.21 will be submitted to the Division of Dockets Management and will be accepted for filing if they meet the following conditions:

(1) They are submitted on or before the 30th day after the date of publication of the notice of opportunity for hearing.

(2) They comply with §§ 314.200, 514.200, or 601.7(a).

(c) If an objection or request for a public hearing fails to meet the requirements of this section and the deficiency becomes known to the Division of Dockets Management, the Division of Dockets Management shall return it with a copy of the applicable regulations, indicating those provisions not complied with. A deficient objection or request for a hearing may be supplemented and subsequently filed if submitted within the 30-day time period specified in § 12.20(e) or § 12.21(b).

(d) If another person objects to a regulation issued in response to a petition submitted under § 12.20(a)(2), the petitioner may submit a written reply to the Division of Dockets Management.

[44 FR 22339, Apr. 13, 1979, as amended at 54 FR 9035, Mar. 3, 1989; 64 FR 69190, Dec. 10, 1999]

§ 12.23 Notice of filing of objections.

As soon as practicable after the expiration of the time for filing objections to and requests for hearing on agency action involving the issuance, amendment, or revocation of a regulation under sections 502(n), 701(e), or 721(d) of the act or sections 4 or 5 of the Fair Packaging and Labeling Act, the Commissioner shall publish a notice in the FEDERAL REGISTER specifying those parts of the regulation that have been stayed by the filing of proper objections and, if no objections have been filed, stating that fact. The notice does not constitute a determination that a hearing is justified on any objections or requests for hearing that have been filed. When to do so will cause no undue delay, the notice required by this section may be combined with the notices described in §§ 12.28 and 12.35.

§ 12.24 Ruling on objections and requests for hearing.

(a) As soon as possible the Commissioner will review all objections and requests for hearing filed under § 12.22 and determine—

(1) Whether the regulation should be modified or revoked under § 12.26;

(2) Whether a hearing has been justified; and

(3) Whether, if requested, a hearing before a Public Board of Inquiry under part 13 or before a public advisory committee under part 14 or before the Commissioner under part 15 has been justified.

(b) A request for a hearing will be granted if the material submitted shows the following:

(1) There is a genuine and substantial issue of fact for resolution at a hearing. A hearing will not be granted on issues of policy or law.

(2) The factual issue can be resolved by available and specifically identified reliable evidence. A hearing will not be granted on the basis of mere allegations or denials or general descriptions of positions and contentions.

(3) The data and information submitted, if established at a hearing, would be adequate to justify resolution of the factual issue in the way sought by the person. A hearing will be denied if the Commissioner concludes that the data and information submitted are insufficient to justify the factual determination urged, even if accurate.

(4) Resolution of the factual issue in the way sought by the person is adequate to justify the action requested. A hearing will not be granted on factual issues that are not determinative with respect to the action requested, e.g., if the Commissioner concludes that the action would be the same even if the factual issue were resolved in the way sought, or if a request is made that a final regulation include a provision not reasonably encompassed by the proposal. A hearing will be granted upon proper objection and request when a food standard or other regulation is shown to have the effect of excluding or otherwise affecting a product or ingredient.

(5) The action requested is not inconsistent with any provision in the act or any regulation in this chapter particularizing statutory standards. The proper procedure in those circumstances is for the person requesting the hearing to petition for an amendment or waiver of the regulation involved.

(6) The requirements in other applicable regulations, e.g., §§ 10.20, 12.21, 12.22, 314.200, 514.200, and 601.7(a), and in the notice promulgating the final regulation or the notice of opportunity for hearing are met.

(c) In making the determination in paragraph (a) of this section, the Commissioner may use any of the optional procedures specified in § 10.30(h) or in other applicable regulations, e.g., §§ 314.200, 514.200, and 601.7(a).

(d) If it is uncertain whether a hearing has been justified under the principles in paragraph (b) of this section, and the Commissioner concludes that summary decision against the person requesting a hearing should be considered, the Commissioner may serve upon the person by registered mail a proposed order denying a hearing. The person has 30 days after receipt of the proposed order to demonstrate that the submission justifies a hearing.

[44 FR 22339, Apr. 13, 1979, as amended at 54 FR 9035, Mar. 3, 1989; 64 FR 399, Jan. 5, 1999]

§ 12.26 Modification or revocation of regulation or order.

If the Commissioner determines upon review of an objection or request for

hearing that the regulation or order should be modified or revoked, the Commissioner will promptly take such action by notice in the FEDERAL REGISTER. Further objections to or requests for hearing on the modification or revocation may be submitted under §§ 12.20 through 12.22 but no further issue may be taken with other provisions in the regulation or order. Objections and requests for hearing that are not affected by the modification or revocation will remain on file and be acted upon in due course.

§ 12.28 Denial of hearing in whole or in part.

If the Commissioner determines upon review of the objections or requests for hearing that a hearing is not justified, in whole or in part, a notice of the determination will be published.

(a) The notice will state whether the hearing is denied in whole or in part. If the hearing is denied in part, the notice will be combined with the notice of hearing required by § 12.35, and will specify the objections and requests for hearing that have been granted and denied.

(1) Any denial will be explained. A denial based on an analysis of the information submitted to justify a hearing will explain the inadequacy of the information.

(2) The notice will confirm or modify or stay the effective date of the regulation or order involved.

(b) The record of the administrative proceeding relating to denial of a public hearing in whole or in part on an objection or request for hearing consists of the following:

(1) If the proceeding involves a regulation—

(i) The documents specified in § 10.40(g);

(ii) The objections and requests for hearing filed by the Division of Dockets Management;

(iii) If the proceeding involves a color additive regulation referred to an advisory committee in accordance with section 721(b)(5)(C) of the act, the committee's report and the record of the committee's proceeding; and

(iv) The notice denying a formal evidentiary public hearing.

(2) If the proceeding involves an order—

(i) The notice of opportunity for hearing;

(ii) The requests for hearing filed by the Division of Dockets Management;

(iii) The transcripts, minutes of meetings, reports, FEDERAL REGISTER notices, and other documents constituting the record of any of the optional procedures specified in § 12.24(c) used by the Commissioner, but not the transcript of a closed portion of a public advisory committee meeting; and

(iv) The notice denying the hearing.

(c) The record specified in paragraph (b) of this section is the exclusive record for the Commissioner's decision on the complete or partial denial of a hearing. The record of the proceeding will be closed as of the date of the Commissioner's decision unless another date is specified. A person who requested and was denied a hearing may submit a petition for reconsideration under § 10.33 or a petition for stay of action under § 10.35. A person who wishes to rely upon information or views not included in the administrative record shall submit them to the Commissioner with a petition under § 10.25(a) to modify the final regulation or order.

(d) Denial of a request for a hearing in whole or in part is final agency action reviewable in the courts, under the statutory provisions governing the matter involved, as of the date of publication of the denial in the FEDERAL REGISTER.

(1) Before requesting a court for a stay of action pending review, a person shall first submit a petition for a stay of action under § 10.35.

(2) Under 28 U.S.C. 2112(a), FDA will request consolidation of all petitions on a particular matter.

(3) The time for filing a petition for judicial review of a denial of a hearing on an objection or issue begins on the date the denial is published in the FEDERAL REGISTER, (i) When an objection or issues relates to a regulation, if a hearing is denied on all objections and issues concerning a part of the proposal the effectiveness of which has not been deferred pending a hearing on other parts of the proposal; or (ii) when an issue relates to an order, if a hearing is

denied on all issues relating to a particular new drug application, new animal drug application, device premarket approval application or product development protocol, or biologics license. The failure to file a petition for judicial review within the period established in the statutory provision governing the matter involved constitutes a waiver of the right to judicial review of the objection or issue, regardless whether a hearing has been granted on other objections and issues.

§ 12.30 Judicial review after waiver of hearing on a regulation.

(a) A person with a right to submit objections and a request for hearing under § 12.20(d) may submit objections and waive the right to a hearing. The waiver may be either an explicit statement, or a failure to request a hearing, as provided in 12.22(a)(4).

(b) If a person waives the right to a hearing, the Commissioner will rule upon the person's objections under §§ 12.24 through 12.28. As a matter of discretion, the Commissioner may also order a hearing on the matter under any of the provisions of this part.

(c) If the Commissioner rules adversely on a person's objection, the person may petition for judicial review in a U.S. Court of Appeals under the act.

(1) The record for judicial review is the record designated in § 12.28(b)(1).

(2) The time for filing a petition for judicial review begins as of the date of publication of the Commissioner's ruling on the objections.

§ 12.32 Request for alternative form of hearing.

(a) A person with a right to request a hearing may waive that right and request one of the following alternatives:

(1) A hearing before a Public Board of Inquiry under part 13.

(2) A hearing before a public advisory committee under part 14.

(3) A hearing before the Commissioner under part 15.

(b) The request—

(1) May be on the person's own initiative or at the suggestion of the Commissioner.

(2) Must be submitted in the form of a citizen petition under § 10.30 before publication of a notice of hearing under § 12.35 or a denial of hearing under § 12.28; and

(3) Must be—

(i) In lieu of a request for a hearing under this part; or

(ii) If submitted after or with a request for hearing, in the form of a waiver of the right to request a hearing conditioned on an alternative form of hearing. Upon acceptance by the Commissioner, the waiver becomes binding and may be withdrawn only by waiving any right to any form of hearing unless the Commissioner determines otherwise.

(c) When more than one person requests and justifies a hearing under this part, an alternative form of hearing may by used only if all the persons concur and waive their right to request a hearing under this part.

(d) The Commissioner will determine whether an alternative form of hearing should be used, and if so, which alternative is acceptable, after considering the requests submitted and the appropriateness of the alternatives for the issues raised in the objections. The Commissioner's acceptance is binding unless, for good cause, the Commissioner determines otherwise.

(e) The Commissioner will publish a notice of an alternative form of hearing setting forth the following information:

(1) The regulation or order that is the subject of the hearing.

(2) A statement specifying any part of the regulation or order that has been stayed by operation of law or in the Commissioner's discretion.

(3) The time, date, and place of the hearing, or a statment that such information will be contained in a later notice.

(4) The parties to the hearing.

(5) The issues at the hearing. The statement of issues determines the scope of the hearing.

(6) If the hearing will be conducted by a Public Board of Inquiry, the time within which—

(i) The parties should submit nominees for the Board under § 13.10(b);

(ii) A notice of participation under § 12.45 should be filed; and

(iii) Participants should submit written information under § 13.25. The notice will list the contents of the portions of the administrative record relevant to the issues at the hearing before the Board. The portions listed will be placed on public display in the office of the Division of Dockets Management before the notice is published. Additional copies of material already submitted under § 13.25 need not be included with any later submissions.

(f)(1) The decision of a hearing before a Public Board of Inquiry or a public advisory committee under this section has legal status of and will be handled as an initial decision under § 12.120.

(2) The decision of a public hearing before the Commissioner under this section will be issued as a final order. The final order will have the same content as an initial decision, as specified in § 12.120 (b) and (c).

(3) Thereafter, the participants in the proceeding may pursue the administrative and court remedies specified in §§ 12.120 through 12.159.

(g) If a hearing before a public advisory committee or a hearing before the Commissioner is used as an alternative form of hearing, all submissions will be made to the Division of Dockets Management, and § 10.20(j) governs their availability for public examination and copying.

(h) This section does not affect the right to an opportunity for a hearing before a public advisory committee under section 515(g)(2) of the act regarding device premarket approval applications and product development protocols. Advisory committee hearing procedures are found in part 14.

§ 12.35 Notice of hearing; stay of action.

(a) If the Commissioner determines upon review of the objections and requests for hearing that a hearing is justified on any issue, the Commissioner will publish a notice setting forth the following:

(1) The regulation or order that is the subject of the hearing.

(2) A statement specifying any part of the regulation or order that has been stayed by operation of law or in the Commissioner's discretion.

(3) The parties to the hearing.

(4) The issues of fact on which a hearing has been justified.

(5) A statement of any objections or requests for hearing for which a hearing has not been justified, which are subject to § 12.28.

(6) The presiding officer, or a statement that the presiding officer will be designated in a later notice.

(7) The time within which notices of participation should be filed under § 12.45.

(8) The date, time, and place of the prehearing conference, or a statement that the date, time, and place will be announced in a later notice. The prehearing conference may not commence until after the time expires for filing the notice of participation required by § 12.45(a).

(9) The time within which participants should submit written information and views under § 12.85. The notice will list the contents of the portions of the administrative record relevant to the issues at the hearing. The portions listed will be placed on public display in the office of the Division of Dockets Management before the notice is published. Additional copies of material already submitted under § 12.85 need not be included with any later submissions.

(b) The statement of the issues determines the scope of the hearing and the matters on which evidence may be introduced. The issues may be revised by the presiding officer. A participant may obtain interlocutory review by the Commissioner of a decision by the presiding officer to revise the issues to include an issue on which the Commissioner has not granted a hearing or to eliminate an issue on which a hearing has been granted.

(c) A hearing is deemed to begin on the date of publication of the notice of hearing.

[44 FR 22339, Apr. 13, 1979, as amended at 47 FR 26375, June 18, 1982]

§ 12.37 Effective date of a regulation.

(a) If no objections are filed and no hearing is requested on a regulation under § 12.20(e), the regulation is effective on the date specified in the regulation as promulgated.

(b) The Commissioner shall publish a confirmation of the effective date of

the regulation. The FEDERAL REGISTER document confirming the effective date of the regulation may extend the time for compliance with the regulation.

§ 12.38 Effective date of an order.

(a) If a person who is subject to a notice of opportunity for hearing under § 12.21(b) does not request a hearing, the Commissioner will—

(1) Publish a final order denying or withdrawing approval of an NDA, NADA, device premarket approval application, or biologics license, in whole or in part, or revoking a device product development protocol or notice of completion, or declaring that such a protocol has not been completed, and stating the effective date of the order; and

(2) If the order involves withdrawal of approval of an NADA, forthwith revoke, in whole or in part, the applicable regulation, under section 512(i) of the act.

(b) If a person who is subject to a notice of opportunity for hearing under § 12.21(b) requests a hearing and others do not, the Commissioner may issue a final order covering all the drug or device products at once or may issue more than one final order covering different drug or device products at different times.

Subpart C—Appearance and Participation

§ 12.40 Appearance.

(a) A person who has filed a notice of participation under § 12.45 may appear in person or by counsel or other representative in any hearing and, subject to § 12.89, may be heard concerning all relevant issues.

(b) The presiding officer may strike a person's appearance for violation of the rules of conduct in § 12.90.

§ 12.45 Notice of participation.

(a) Within 30 days after publication of the notice of hearing under § 12.35, a person desiring to participate in a hearing is to file with the Division of Dockets Management under § 10.20 a notice of participation in the following form:

(Date)

Division of Dockets Management, Food and Drug Administration, Department of Health and Human Services, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

NOTICE OF PARTICIPATION

Docket No. ____

Under 21 CFR part 12, please enter the participation of:

(Name) _____
(Street address) _____
(City and State) _____
(Telephone number) _____

Service on the above will be accepted by:

(Name) _____
(Street address) _____
(City and State) _____
(Telephone number) _____

The following statements are made as part of this notice of participation:

A. *Specific interests.* (A statement of the specific interest of the person in the proceeding, including the specific issues of fact concerning which the person desires to be heard. This part need not be completed by a party to the proceeding.)

B. *Commitment to participate.* (A statement that the person will present documentary evidence or testimony at the hearing and will comply with the requirements of 21 CFR 12.85, or, in the case of a hearing before a Public Board of Inquiry, with the requirements of 21 CFR 13.25.)

(Signed) _____

(b) An amendment to a notice of participation should be filed with the Division of Dockets Management and served on all participants.

(c) No person may participate in a hearing who has not filed a written notice of participation or whose participation has been stricken under paragraph (e) of this section.

(d) The presiding officer may permit the late filing of a notice of participation upon a showing of good cause.

(e) The presiding officer may strike the participation of a person for nonparticipation in the hearing or failure to comply with any requirement of this subpart, e.g., disclosure of information as required by § 12.85 or the prehearing order issued under § 12.92. Any person whose participation is stricken may petition the Commissioner for interlocutory review.

[44 FR 22339, Apr. 13, 1979, as amended at 46 FR 8456, Jan. 27, 1981; 59 FR 14364, Mar. 28, 1994; 68 FR 24879, May 9, 2003]

§ 12.50 Advice on public participation in hearings.

(a) *Designated agency contact.* All inquiries from the public about scheduling, location, and general procedures should be addressed to the Deputy Commissioner for Policy (HF–22), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or telephone 301–443–3480. The staff of the Associate Commissioner for Regulatory Affairs will attempt to respond promptly to all inquiries from members of the public, as well as to simple requests for information from participants in hearings.

(b) *Hearing schedule changes.* Requests by hearing participants for changes in the schedule of a hearing or for filing documents, briefs, or other pleadings should be made in writing directly to the Administrative Law Judge (HF–3), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

(c) *Legal advice to individuals.* FDA does not have the resources to provide legal advice to members of the public concerning participation in hearings. Furthermore, to do so would compromise the independence of the Commissioner's office and invite charges of improper interference in the hearing process. Accordingly, the Deputy Commissioner for Policy (HF–22) will not answer questions about the strengths or weaknesses of a party's position at a hearing, litigation strategy, or similar matters.

(d) *Role of the office of the Chief Counsel.* Under no circumstances will the office of the Chief Counsel of FDA directly provide advice about a hearing to any person who is participating or may participate in the hearing. In every hearing, certain attorneys in the office are designated to represent the center or centers whose action is the subject of the hearing. Other members of the office, including ordinarily the Chief Counsel, are designated to advise the Commissioner on a final decision in the matter. It is not compatible with these functions, nor would it be professionally responsible, for the attorneys in the office of the Chief Counsel also to advise other participants in a hearing, or for any attorney who may be called on to advise the Commissioner to respond to inquiries from other participants in the hearing, for such participants may be urging views contrary to those of the center involved or to what may ultimately be the final conclusions of the Commissioner. Accordingly, members of the office of the Chief Counsel, other than the attorneys responsible for representing the center whose action is the subject of the hearing, will not answer questions about the hearing from any participant or potential participant.

(e) *Communication between participants and attorneys.* Participants in a hearing may communicate with the attorneys responsible for representing the center whose action is the subject of the hearing, in the same way that they may communicate with counsel for any other party in interest about the presentation of matters at the hearing. It would be inappropriate to bar discussion of such matters as stipulations of fact, joint presentation of witnesses, or possible settlement of hearing issues. Members of the public, including participants at hearings, are advised, however, that all such communications, including those by telephone, will be recorded in memoranda that can be filed with the Division of Dockets Management.

[44 FR 22329, Apr. 13, 1979, as amended at 50 FR 8994, Mar. 6, 1985; 54 FR 9035, Mar. 3, 1989; 58 FR 17096, Apr. 1, 1993]

Subpart D—Presiding Officer

§ 12.60 Presiding officer.

The presiding officer in a hearing will be the Commissioner, a member of the Commissioner's office to whom the responsibility for the matter involved has been delegated, or an administrative law judge qualified under 5 U.S.C. 3105.

§ 12.62 Commencement of functions.

The functions of the presiding officer begin upon designation and end upon the filing of the initial decision.

§ 12.70 Authority of presiding officer.

The presiding officer has all powers necessary to conduct a fair, expeditious, and orderly hearing, including the power to—

(a) Specify and change the date, time, and place of oral hearings and conferences;

(b) Establish the procedures for use in developing evidentiary facts, including the procedures in § 12.92(b) and to rule on the need for oral testimony and cross-examination under § 12.87(b);

(c) Prepare statements of the areas of factual disagreement among the participants;

(d) Hold conferences to settle, simplify, or determine the issues in a hearing or to consider other matters that may expedite the hearing;

(e) Administer oaths and affirmations;

(f) Control the course of the hearing and the conduct of the participants;

(g) Examine witnesses and strike their testimony if they fail to respond fully to proper questions;

(h) Rule on, admit, exclude, or limit evidence;

(i) Set the time for filing pleadings;

(j) Rule on motions and other procedural matters;

(k) Rule on motions for summary decision under § 12.93;

(l) Conduct the hearing in stages if the number of parties is large or the issues are numerous and complex;

(m) Waive, suspend, or modify any rule in this subpart under § 10.19 if the presiding officer determines that no party will be prejudiced, the ends of justice will be served, and the action is in accordance with law;

(n) Strike the participation of any person under § 12.45(e) or exclude any person from the hearing under § 12.90, or take other reasonable disciplinary action; and

(o) Take any action for the fair, expeditious, and orderly conduct of the hearing.

§ 12.75 Disqualification of presiding officer.

(a) A participant may request the presiding officer to disqualify himself/herself and withdraw from the proceeding. The ruling on any such request may be appealed in accordance with § 12.97(b).

(b) A presiding officer who is aware of grounds for disqualification shall withdraw from the proceeding.

§ 12.78 Unavailability of presiding officer.

(a) If the presiding officer is unable to act for any reason, the Commissioner will assign the powers and duties to another presiding officer. The substitution will not affect the hearing, except as the new presiding officer may order.

(b) Any motion based on the substitution must be made within 10 days.

Subpart E—Hearing Procedures

§ 12.80 Filing and service of submissions.

(a) Submissions, including pleadings in a hearing, are to be filed with the Division of Dockets Management under § 10.20 except that only two copies need be filed. To determine compliance with filing deadlines in a hearing, a submission is considered submitted on the date it is actually received by the Division of Dockets Management. When this part allows a response to a submission and prescribes a period of time for the filing of the response, an additional 3 days are allowed for the filing of the response if the submission is served by mail.

(b) The person making a submission shall serve copies of it on the other participants. Submissions of documentary data and information are not required to be served on each participant, but any accompanying transmittal letter, pleading, summary, statement of position, certification under paragraph (d) of this section, or similar document must be served on each participant.

(c) Service is accomplished by mailing a submission to the address shown in the notice of participation or by personal delivery.

(d) All submissions are to be accompanied by a certificate of service, or a statement that service is not required.

(e) No written submission or other portion of the administrative record may be held in confidence, except as provided in § 12.105.

§ 12.82 Petition to participate in forma pauperis.

(a) A participant who believes that compliance with the filing and service

requirements of this section constitutes an unreasonable financial burden may submit to the Commissioner a petition to participate in forma pauperis.

(b) The petition will be in the form specified in § 10.30 except that the heading will be ''Request to Participate in Forma Pauperis, Docket No. ____.'' Filing and service requirements for the petition are described in paragraph (c) of this section, whether or not the petition is granted. The petition must demonstrate that either: (1) The person is indigent and a strong public interest justifies participation, or (2) the person's participation is in the public interest because it can be considered of primary benefit to the general public.

(c) The Commissioner may grant or deny the petition. If the petition is granted, the participant need file only one copy of each submission with the Division of Dockets Management. The Division of Dockets Management will make sufficient additional copies for the administrative record, and serve a copy on each other participant.

§ 12.83 Advisory opinions.

Before or during a hearing, a person may, under § 10.85, request the Commissioner for an advisory opinion on whether any regulation or order under consideration in the proceeding applies to a specific situation.

§ 12.85 Disclosure of data and information by the participants.

(a) Before the notice of hearing is published under § 12.35, the director of the center responsible for the matters involved in the hearing shall submit the following to the Division of Dockets Management:

(1) The relevant portions of the administrative record of the proceeding. Portions of the administrative record not relevant to the issues in the hearing are not part of the administrative record.

(2) All documents in the director's files containing factual information, whether favorable or unfavorable to the director's position, which relate to the issues involved in the hearing. *Files* means the principal files in the center in which documents relating to the issues in the hearing are ordinarily kept, e.g., the food additive master file and the food additive petition in the case of issues concerning a food additive, or the new drug application in the case of issues concerning a new drug. Internal memoranda reflecting the deliberative process, and attorney work product and material prepared specifically for use in connection with the hearing, are not required to be submitted.

(3) All other documentary data and information relied upon.

(4) A narrative position statement on the factual issues in the notice of hearing and the type of supporting evidence the director intends to introduce.

(5) A signed statement that, to the director's best knowledge and belief, the submission complies with this section.

(b) Within 60 days of the publication of the notice of hearing or, if no participant will be prejudiced, within another period of time set by the presiding officer, each participant shall submit to the Division of Dockets Management all data and information specified in paragraph (a)(2) through (5) of this section, and any objections that the administrative record filed under paragraph (a)(1) of this section is incomplete. With respect to the data and information specified in paragraph (a)(2) of this section, participants shall exercise reasonable diligence in identifying documents in files comparable to those described in that paragraph.

(c) Submissions required by paragraphs (a) and (b) of this section may be supplemented later in the proceeding, with the approval of the presiding officer, upon a showing that the material contained in the supplement was not reasonably known or available when the submission was made or that the relevance of the material contained in the supplement could not reasonably have been forseen.

(d) A participant's failure to comply substantially and in good faith with this section constitutes a waiver of the right to participate further in the hearing; failure of a party to comply constitutes a waiver of the right to a hearing.

(e) Participants may reference each other's submissions. To reduce duplicative submissions, participants are encouraged to exchange and consolidate lists of documentary evidence. If a particular document is bulky or in limited supply and cannot reasonably be reproduced, and it constitutes relevant evidence, the presiding officer may authorize submission of a reduced number of copies.

(f) The presiding officer will rule on questions relating to this section.

[44 FR 22339, Apr. 13, 1979, as amended at 54 FR 9035, Mar. 3, 1989]

§ 12.87 Purpose; oral and written testimony; burden of proof.

(a) The objective of a formal evidentiary hearing is the fair determination of relevant facts consistent with the right of all interested persons to participate and the public interest in promptly settling controversial matters affecting the public health and welfare.

(b) Accordingly, the evidence at a hearing is to be developed to the maximum extent through written submissions, including written direct testimony, which may be in narrative or in question-and-answer form.

(1) In a hearing, the issues may have general applicability and depend on general facts that do not concern particular action of a specific party, e.g., the safety or effectiveness of a class of drug products, the safety of a food or color additive, or a definition and standard of identity for a food; or the issues may have specific applicability to past action and depend upon particular facts concerning only that party, e.g., the applicability of a grandfather clause to a particular brand of a drug or the failure of a particular manufacturer to meet required manufacturing and processing specifications or other general standards.

(i) If the proceeding involves general issues, direct testimony will be submitted in writing, except on a showing that written direct testimony is insufficient for a full and true disclosure of relevant facts and that the participant will be prejudiced if unable to present oral direct testimony. If the proceeding involves particular issues, each party may determine whether, and the extent to which, each wishes to present direct testimony orally or in writing.

(ii) Oral cross-examination of witnesses will be permitted if it appears that alternative means of developing the evidence are insufficient for a full and true disclosure of the facts and that the party requesting oral cross-examination will be prejudiced by denial of the request or that oral cross-examination is the most effective and efficient means to clarify the matters at issue.

(2) Witnesses shall give testimony under oath.

(c) Except as provided in paragraph (d) of this section, in a hearing involving issuing, amending, or revoking a regulation or order, the originator of the proposal or petition or of any significant modification will be, within the meaning of 5 U.S.C. 556(d), the proponent of the regulation or order, and will have the burden of proof. A participant who proposes to substitute a new provision for a provision objected to has the burden of proof in relation to the new provision.

(d) At a hearing involving issuing, amending, or revoking a regulation or order relating to the safety or effectiveness of a drug, device, food additive, or color additive, the participant who is contending that the product is safe or effective or both and who is requesting approval or contesting withdrawal of approval has the burden of proof in establishing safety or effectiveness or both and thus the right to approval. The burden of proof remains on that participant in an amendment or revocation proceeding.

[44 FR 22339, Apr. 13, 1979, as amended at 64 FR 399, Jan. 5, 1999]

§ 12.89 Participation of nonparties.

(a) A nonparty participant may—

(1) Attend all conferences (including the prehearing conference), oral proceedings, and arguments;

(2) Submit written testimony and documentary evidence for inclusion in the record;

(3) File written objections, briefs, and other pleadings; and

(4) Present oral argument.

(b) A nonparty participant may not—

(1) Submit written interrogatories; and

(2) Conduct cross-examination.

(c) A person whose petition is the subject of the hearing has the same right as a party.

(d) A nonparty participant will be permitted additional rights if the presiding officer concludes that the participant's interests would not be adequately protected otherwise or that broader participation is required for a full and true disclosure of the facts, but the rights of a nonparty participant may not exceed the rights of a party.

[44 FR 22339, Apr. 13, 1979, as amended at 48 FR 51770, Nov. 14, 1983]

§ 12.90 Conduct at oral hearings or conferences.

All participants in a hearing will conduct themselves with dignity and observe judicial standards of practice and ethics. They may not indulge in personal attacks, unseemly wrangling, or intemperate accusations or characterizations. Representatives of parties shall, to the extent possible, restrain clients from improprieties in connection with any proceeding. Disrespectful, disorderly, or contumacious language or conduct, refusal to comply with directions, use of dilatory tactics, or refusal to adhere to reasonable standards of orderly and ethical conduct during any hearing, constitute grounds for immediate exclusion from the proceeding by the presiding officer.

§ 12.91 Time and place of prehearing conference.

A prehearing conference will commence at the date, time, and place announced in the notice of hearing, or in a later notice, or as specified by the presiding officer in a notice modifying a prior notice. At that conference the presiding officer will establish the methods and procedures to be used in developing the evidence, determine reasonable time periods for the conduct of the hearing, and designate the times and places for the production of witnesses for direct and cross-examination if leave to conduct oral examination is granted on any issue, as far as practicable at that time.

§ 12.92 Prehearing conference procedure.

(a) Participants in a hearing are to appear at the prehearing conference prepared to discuss and resolve all matters specified in paragraph (b) of this section.

(1) To expedite the hearing, participants are encouraged to prepare in advance for the prehearing conference. Participants should cooperate with each other, and request information and begin preparation of testimony at the earliest possible time. Failure of a participant to appear at the prehearing conference or to raise matters that could reasonably be anticipated and resolved at that time will not delay the progress of the hearing, and constitutes a waiver of the rights of the participant regarding such matters as objections to the agreements reached, actions taken, or rulings issued by the presiding officer and may be grounds for striking the participation under § 12.45.

(2) Participants shall bring to the prehearing conference the following specific information, which will be filed with the Division of Dockets Management under § 12.80:

(i) Any additional information to supplement the submission filed under § 12.85, which may be filed if approved under § 12.85(c).

(ii) A list of all witnesses whose testimony will be offered, orally or in writing, at the hearing, with a full curriculum vitae for each. Additional witnesses may later be identified, with the approval of the presiding officer, on a showing that the witness was not reasonably available at the time of the prehearing conference or the relevance of the witness' views could not reasonably have been foreseen at that time.

(iii) All prior written statements including articles and any written statement signed or adopted, or a recording or transcription of an oral statement made, by persons identified as witnesses if—

(*a*) The statement is available without making request of the witness or any other person;

(*b*) The statement relates to the subject matter of the witness' testimony; and

(*c*) The statement either was made before the time the person agreed to become a witness or has been made publicly available by the person.

(b) The presiding officer will conduct a prehearing conference for the following purposes:

(1) To determine the areas of factual disagreement to be considered at the hearing. The presiding officer may hold conferences off the record in an effort to reach agreement on disputed factual questions.

(2) To identify the most appropriate techniques for developing evidence on issues in controversy and the manner and sequence in which they will be used, including, where oral examination is to be conducted, the sequence in which witnesses will be produced for, and the time and place of, oral examination. The presiding officer may consider—

(i) Submission of narrative statements of position on factual issues in controversy;

(ii) Submission of evidence or identification of previously submitted evidence to support such statements, such as affidavits, verified statements of fact, data, studies, and reports;

(iii) Exchange of written interrogatories directed to particular witnesses;

(iv) Written requests for the production of additional documentation, data, or other relevant information;

(v) Submission of written questions to be asked by the presiding officer of a specific witness; and

(vi) Identification of facts for which oral examination and/or cross-examination is appropriate.

(3) To group participants with substantially like interests for presenting evidence, making motions and objections, including motions for summary decision, filing briefs, and presenting oral argument.

(4) To hear and rule on objections to admitting into evidence information submitted under § 12.85.

(5) To obtain stipulations and admissions of facts.

(6) To take other action that may expedite the hearing.

(c) The presiding officer shall issue, orally or in writing, a prehearing order reciting the actions taken at the prehearing conference and setting forth the schedule for the hearing. The order will control the subsequent course of the hearing unless modified by the presiding officer for good cause.

§ 12.93 Summary decisions.

(a) After the hearing commences, a participant may move, with or without supporting affidavits, for a summary decision on any issue in the hearing. Any other participant may, within 10 days after service of the motion, which time may be extended for an additional 10 days for good cause, serve opposing affidavits or countermove for summary decision. The presiding officer may set the matter for argument and call for the submission of briefs.

(b) The presiding officer will grant the motion if the objections, requests for hearing, other pleadings, affidavits, and other material filed in connection with the hearing, or matters officially noticed, show that there is no genuine issue as to any material fact and that a participant is entitled to summary decision.

(c) Affidavits should set forth facts that would be admissible in evidence and show affirmatively that the affiant is competent to testify to the matters stated. When a properly supported motion for summary decision is made, a participant opposing the motion may not rest upon mere allegations or denials or general descriptions of positions and contentions; affidavits or other responses must set forth specific facts showing that there is a genuine issue of fact for the hearing.

(d) Should it appear from the affidavits of a participant opposing the motion that for sound reasons stated, facts essential to justify the opposition cannot be presented by affidavit, the presiding officer may deny the motion for summary decision, order a continuance to permit affidavits or additional evidence to be obtained, or issue other just order.

(e) If on motion under this section a summary decision is not rendered upon the whole case or for all the relief asked. and evidentiary facts need to be developed, the presiding officer will issue an order specifying the facts that appear without substantial controversy

and directing further evidentiary proceedings. The facts so specified will be deemed established.

(f) A participant may obtain interlocutory review by the Commissioner of a summary decision of the presiding officer.

§ 12.94 Receipt of evidence.

(a) A hearing consists of the development of evidence and the resolution of factual issues as set forth in this subpart and in the prehearing order.

(b) All orders, transcripts, written statements of position, written direct testimony, written interrogatories and responses, and any other written material submitted in the proceeding is a part of the administrative record of the hearing, and will be promptly placed on public display in the office of the Division of Dockets Management, except as provided in § 12.105.

(c) Written evidence, identified as such, is admissible unless a participant objects and the presiding officer excludes it on objection of a participant or on the presiding officer's own initiative.

(1) The presiding officer may exclude written evidence as inadmissible only if—

(i) The evidence is irrelevant, immaterial, unreliable, or repetitive;

(ii) Exclusion of part or all of the written evidence of a participant is necessary to enforce the requirements of this subpart; or

(iii) The evidence was not submitted as required by § 12.85.

(2) Items of written evidence are to be submitted as separate documents, sequentially numbered, except that a voluminous document may be submitted in the form of a cross-reference to the documents filed under § 12.85.

(3) Written evidence excluded by the presiding officer as inadmissible remains a part of the administrative record, as an offer of proof, for judicial review.

(d) Testimony, whether on direct or on cross-examination, is admissible as evidence unless a participant objects and the presiding officer excludes it.

(1) The presiding officer may exclude oral evidence as inadmissible only if—

(i) The evidence is irrelevant, immaterial, unreliable, or repetitive; or

(ii) Exclusion of part or all of the evidence is necessary to enforce the requirements of this part.

(2) If oral evidence is excluded as inadmissible, the participant may take written exception to the ruling in a brief to the Commissioner, without taking oral exception at the hearing. Upon review, the Commissioner may reopen the hearing to permit the evidence to be admitted if the Commissioner determines that its exclusion was erroneous and prejudicial.

(e) The presiding officer may schedule conferences as needed to monitor the program of the hearing, narrow and simplify the issues, and consider and rule on motions, requests, and other matters concerning the development of the evidence.

(f) The presiding officer will conduct such proceedings as are necessary for the taking of oral testimony, for the oral examination of witnesses by the presiding officer on the basis of written questions previously submitted by the parties, and for the conduct of cross-examination of witnesses by the parties. The presiding officer shall exclude irrelevant or repetitious written questions and limit oral cross-examination to prevent irrelevant or repetitious examination.

(g) The presiding officer shall order the proceedings closed for the taking of oral testimony relating to matters specified in § 10.20(j)(2)(i) (*a*) and (*b*). Such closed proceedings will be conducted in accordance with § 10.20(j)(3). Participation in closed proceedings will be limited to the witness, the witness' counsel, and Federal Government executive branch employees and special government employees. Closed proceedings will be permitted only for, and will be limited to, oral testimony directly relating to matters specified in § 10.20(j)(3).

§ 12.95 Official notice.

(a) Official notice may be taken of such matters as might be judicially noticed by the courts of the United States or of any other matter peculiarly within the general knowledge of FDA as an expert agency.

(b) If official notice is taken of a material fact not appearing in the evidence of record, a participant, on timely request, will be afforded an opportunity to show the contrary.

§ 12.96 Briefs and arguments.

(a) Promptly after the taking of evidence is completed, the presiding officer will announce a schedule for the filing of briefs. Briefs are to be filed ordinarily within 45 days of the close of the hearing. Briefs must include a statement of position on each issue, with specific and complete citations to the evidence and points of law relied on. Briefs must contain proposed findings of fact and conclusions of law.

(b) The presiding officer may, as a matter of discretion, permit oral argument after the briefs are filed.

(c) Briefs and oral argument are to refrain from disclosing specific details of written and oral testimony and documents relating to matters specified in § 10.20(j)(2)(i)(*a*) and (*b*), except as specifically authorized in a protective order issued under § 10.20(j)(3).

§ 12.97 Interlocutory appeal from ruling of presiding officer.

(a) Except as provided in paragraph (b) of this section and in §§ 12.35(b), 12.45(e), 12.93(f), and 12.99(d), when an interlocutory appeal is specifically authorized by this subpart, rulings of the presiding officer may not be appealed to the Commissioner before the Commissioner's consideration of the entire record of the hearing.

(b) A ruling of the presiding officer is subject to interlocutory appeal to the Commissioner if the presiding officer certifies on the record or in writing that immediate review is necessary to prevent exceptional delay, expense, or prejudice to any participant, or substantial harm to the public interest.

(c) When an interlocutory appeal is made to the Commissioner, a participant may file a brief with the Commissioner only if specifically authorized by the presiding officer or the Commissioner, and if such authorization is granted, within the period the Commissioner directs. If a participant is authorized to file a brief, any other participant may file a brief in opposition, within the period the Commissioner directs. If no briefs are authorized, the appeal will be presented as an oral argument to the Commissioner. The oral argument will be transcribed. If briefs are authorized, oral argument will be heard only at the discretion of the Commissioner.

§ 12.98 Official transcript.

(a) The presiding officer will arrange for a verbatim stenographic transcript of oral testimony and for necessary copies of the transcript.

(b) One copy of the transcript will be placed on public display in the office of the Division of Dockets Management upon receipt.

(c) Except as provided in § 12.105, copies of the transcript may be obtained by application to the official reporter and payment of costs thereof or under part 20.

(d) Witnesses, participants, and counsel have 30 days from the time the transcript becomes available to propose corrections in the transcript of oral testimony. Corrections are permitted only for transcription errors. The presiding officer shall promptly order justified corrections.

§ 12.99 Motions.

(a) A motion on any matter relating to the proceeding is to be filed under § 12.80, and must include a draft order, except one made in the course of an oral hearing before the presiding officer.

(b) A response may be filed within 10 days of service of a motion. The time may be shortened or extended by the presiding officer for good cause shown.

(c) The moving party has no right to reply, except as permitted by the presiding officer.

(d) The presiding officer shall rule upon the motion and may certify that ruling to the Commissioner for interlocutory review.

Subpart F—Administrative Record

§ 12.100 Administrative record of a hearing.

(a) The record of a hearing consists of—

(1) The order or regulation or notice of opportunity for hearing that gave rise to the hearing;

(2) All objections and requests for hearing filed by the Division of Dockets Management under §§ 12.20 through 12.22;

(3) The notice of hearing published under § 12.35;

(4) All notices of participation filed under § 12.45;

(5) All FEDERAL REGISTER notices pertinent to the proceeding;

(6) All submissions filed under § 12.82, e.g., the submissions required by § 12.85, all other documentary evidence and written testimony, pleadings, statements of position, briefs, and other similar documents;

(7) The transcript, written order, and all other documents relating to the prehearing conference, prepared under § 12.92;

(8) All documents relating to any motion for summary decision under § 12.93;

(9) All documents of which official notice is taken under § 12.95;

(10) All pleadings filed under § 12.96;

(11) All documents relating to any interlocutory appeal under § 12.97;

(12) All transcripts prepared under § 12.98; and

(13) Any other document relating to the hearing and filed with the Division of Dockets Management by the presiding officer or any participant;

(b) The record of the administrative proceeding is closed—

(1) With respect to the taking of evidence, when specified by the presiding officer; and

(2) With respect to pleadings, at the time specified in § 12.96(a) for the filing of briefs.

(c) The presiding officer may reopen the record to receive further evidence at any time before the filing of the initial decision.

§ 12.105 Examination of record.

Documents in the record will be publicly available in accordance with § 10.20(j). Documents available for examination or copying will be placed on public display in the office of the Division of Dockets Management promptly upon receipt in that office.

Subpart G—Initial and Final Decisions

§ 12.120 Initial decision.

(a) The presiding officer shall prepare and file an initial decision as soon as possible after the filing of briefs and oral argument.

(b) The initial decision must contain—

(1) Findings of fact based issued upon relevant, material, and reliable evidence of record;

(2) Conclusions of law;

(3) A discussion of the reasons for the findings and conclusions, including a discussion of the significant contentions made by any participant;

(4) Citations to the record supporting the findings and conclusions;

(5) An appropriate regulation or order supported by substantial evidence of record and based upon the findings of fact and conclusions of law; and

(6) An effective date for the regulation or order.

(c) The initial decision must refrain from disclosing specific details of matters specified in § 10.20(j)(2)(i) (*a*) and (*b*), except as specifically authorized in a protective order issued pursuant to § 10.20(j)(3).

(d) The initial decision is to be filed with the Division of Dockets Management and served upon all participants. Once the initial decision is filed with the Division of Dockets Management, the presiding officer has no further jurisdiction over the matter, and any motions or requests filed with the Division of Dockets Management will be decided by the Commissioner.

(e) The initial decision becomes the final decision of the Commissioner by operation of law unless a participant files exceptions with the Division of Dockets Management under § 12.125(a) or the Commissioner files a notice of review under § 12.125(f).

(f) Notice that an initial decision has become the decision of the Commissioner without appeal to or review by the Commissioner will be published in the FEDERAL REGISTER, or the Commissioner may publish the decision when it is of widespread interest.

§ 12.125 Appeal from or review of initial decision.

(a) A participant may appeal an initial decision to the Commissioner by filing exceptions with the Division of Dockets Management, and serving them on the other participants, within 60 days of the date of the initial decision.

(b) Exceptions must specifically identify alleged errors in the findings of fact or conclusions of law in the initial decision, and provide supporting citations to the record. Oral argument before the Commissioner may be requested in the exceptions.

(c) Any reply to the exceptions is to be filed and served within 60 days of the end of the period for filing exceptions.

(d) The Commissioner may extend the time for filing exceptions under paragraph (a) of this section or replies to exceptions under paragraph (c) of this section only upon a showing by a participant of extraordinary circumstances. Such an extension shall be requested by filing a written request with the Commissioner's Executive Secretariat (HF–40) and serving copies of the request on the Division of Dockets Management (HFA–305), the Chief Counsel (GCF–1), and all hearing participants.

(e) If the Commissioner decides to hear oral argument, the participants will be informed of the date, time, and place, the amount of time allotted to each participant, and the issues to be addressed.

(f) Within 10 days following the expiration of the time for filing exceptions (including any extensions), the Commissioner may file with the Division of Dockets Management, and serve on the participants, a notice of the Commissioner's determination to review the initial decision. The Commissioner may invite the participants to file briefs or present oral argument on the matter. The time for filing briefs or presenting oral argument will be specified in that or a later notice.

[44 FR 22339, Apr. 13, 1979, as amended at 53 FR 29453, Aug. 5, 1988]

§ 12.130 Decision by Commissioner on appeal or review of initial decision.

(a) On appeal from or review of the initial decision, the Commissioner has all the powers given to make the initial decision. On the Commissioner's own initiative or on motion, the Commissioner may remand the matter to the presiding officer for any further action necessary for a proper decision.

(b) The scope of the issues on appeal is the same as the scope of the issues at the public hearing unless the Commissioner specifies otherwise.

(c) As soon as possible after the filing of briefs and any oral argument, the Commissioner will issue a final decision in the proceeding, which meets the requirements established in § 12.120 (b) and (c).

(d) The Commissioner may adopt the initial decision as the final decision.

(e) Notice of the Commissioner's decision will be published in the FEDERAL REGISTER, or the Commissioner may publish the decision when it is of widespread interest.

§ 12.139 Reconsideration and stay of action.

Following notice or publication of the final decisions, a participant may petition the Commissioner for reconsideration of any part or all of the decision under § 10.33 or may petition for a stay of the decision under § 10.35.

Subpart H—Judicial Review

§ 12.140 Review by the courts.

(a) The Commissioner's final decision constitutes final agency action from which a participant may petition for judicial review under the statutes governing the matter involved. Before requesting an order from a court for a stay of action pending review, a participant shall first submit a petition for a stay of action under § 10.35.

(b) Under 28 U.S.C. 2112(a), FDA will request consolidation of all petitions related to a particular matter.

§ 12.159 Copies of petitions for judicial review.

The Chief Counsel for FDA has been designated by the Secretary as the officer on whom copies of petitions of judicial review are to be served. This officer is responsible for filing the record on which the final decision is based. The record of the proceeding is certified by the Commissioner.

PART 13—PUBLIC HEARING BEFORE A PUBLIC BOARD OF INQUIRY

Subpart A—General Provisions

Sec.
13.1 Scope.
13.5 Notice of a hearing before a Board.
13.10 Members of a Board.
13.15 Separation of functions; ex parte communications; administrative support.

Subpart B—Hearing Procedures

13.20 Submissions to a Board.
13.25 Disclosure of data and information by the participants.
13.30 Proceedings of a Board.

Subpart C—Records of a Hearing Before a Board

13.40 Administrative record of a Board.
13.45 Examination of administrative record.
13.50 Record for administrative decision.

AUTHORITY: 5 U.S.C. 551–558, 701–721; 15 U.S.C. 1451–1461; 21 U.S.C. 141–149, 321–393, 467f, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201, 262, 263b–263n, 264.

SOURCE: 44 FR 22348, Apr. 13, 1979, unless otherwise noted.

Subpart A—General Provisions

§ 13.1 Scope.

The procedures in this part apply when—

(a) The Commissioner concludes, as a matter of discretion, that it is in the public interest to hold a public hearing before a Public Board of Inquiry (*Board*) with respect to any matter before FDA;

(b) Under specific sections of this chapter a matter before FDA is subject to a hearing before a Board; or

(c) Under § 12.32, a person who has a right to an opportunity for a formal evidentiary public hearing waives that opportunity and requests that a Board act as an administrative law tribunal concerning the matters involved, and the Commissioner decides to accept this request.

§ 13.5 Notice of a hearing before a Board.

If the Commissioner determines that a Board should be established to conduct a hearing on any matter, a notice of hearing will be published in the FEDERAL REGISTER setting forth the following information:

(a) If the hearing is under § 13.1 (a) or (b), all applicable information described in § 12.32(e).

(1) Any written document that is to be the subject matter of the hearing will be published as a part of the notice, or the notice will refer to it if the document has already been published in the FEDERAL REGISTER or state that the document is available from the Division of Dockets Management or an agency employee designated in the notice.

(2) For purposes of a hearing under § 13.1 (a) or (b), all participants who file a notice of participation under § 12.32(e)(6)(ii) are deemed to be parties and entitled to participate in selection of the Board under § 13.15(b).

(b) If the hearing is in lieu of a formal evidentiary hearing, as provided in § 13.1(c), all of the information described in § 12.32(e).

[44 FR 22348, Apr. 13, 1979, as amended at 47 FR 26375, June 18, 1982]

§ 13.10 Members of a Board.

(a) All members of a Board are to have medical, technical, scientific, or other qualifications relevant to the issues to be considered, are subject to the conflict of interest rules applicable to special Government employees, and are to be free from bias or prejudice concerning the issues involved. A member of a Board may be a full-time or part-time Federal Government employee or may serve on an FDA advisory committee but, except with the agreement of all parties, may not currently be a full-time or part-time employee of FDA or otherwise act as a special Government employee of FDA.

(b) Within 30 days of publication of the notice of hearing, the director of the center of FDA responsible for a

matter before a Board, the other parties to the proceeding, and any person whose petition was granted and is the subject of the hearing, shall each submit to the Division of Dockets Management the names and full curricula vitae of five nominees for members of the Board. Nominations are to state that the nominee is aware of the nomination, is interested in becoming a member of the Board, and appears to have no conflict of interest.

(1) Any two or more persons entitled to nominate members may agree upon a joint list of five qualified nominees.

(2) The lists of nominees must be submitted to the persons entitled to submit a list of nominees under this paragraph but not to all participants. Within 10 days of receipt of the lists of nominees, such persons may submit comments to the Division of Dockets Management on whether the nominees of the other persons meet the criteria established in paragraph (a) of this section. A person submitting comments to the Division of Dockets Management shall submit them to all persons entitled to submit a list of nominees.

(3) The lists of nominees and comments on them are to be held in confidence by the Division of Dockets Management as part of the administrative record of the proceeding and are not to be made available for public disclosure, and all persons who submit or receive them shall similarly hold them in confidence. This portion of the administrative record remains confidential but is available for judicial review in the event that it becomes relevant to any issue before a court.

(c) After reviewing the lists of nominees and any comments, the Commissioner will choose three qualified persons as members of a Board. One member will be from the lists of nominees submitted by the director of the center and by any person whose petition was granted and is the subject of the hearing. The second will be from the lists of nominees submitted by the other parties. The Commissioner may choose the third member from any source. That member is the Chairman of the Board.

(1) If the Commissioner is unable to find a qualified person with no conflict of interest from among a list of nominees or if additional information is needed, the Commissioner will request the submission of the required additional nominees or information.

(2) If a person fails to submit a list of nominees as required by paragraph (b) of this section, the Commissioner may choose a qualified member without further consultation with that person.

(3) The Commissioner will announce the members of a Board by filing a memorandum in the record of the proceeding and sending a copy to all participants.

(d) Instead of using the selection method in paragraphs (b) and (c) of this section, the director of the center, the other parties to the proceeding, and any person whose petition was granted and is the subject of the hearing, may, with the approval of the Commissioner, agree that a standing advisory committee listed in § 14.80 constitutes the Board for a particular proceeding, or that another procedure is to be used for selection of the members of the Board, or that the Board consists of a larger number of members.

(e) The members of a Board serve as consultants to the Commissioner and are special Government employees or Government employees. A Board functions as an administrative law tribunal in the proceeding and is not an advisory committee subject to the requirements of the Federal Advisory Committee Act or part 14.

(f) The Chairman of the Board has the authority of a presiding officer set out in § 12.70.

[44 FR 22348, Apr. 13, 1979, as amended at 50 FR 8994, Mar. 6, 1985]

§ 13.15 Separation of functions; ex parte communications; administrative support.

(a) The proceeding of a Board are subject to the provisions of § 10.55 relating to separation of functions and ex parte communications. Representatives of the participants in any proceeding before a Board, including any members of the office of the Chief Counsel of FDA assigned to advise the center responsible for the matter, may have no contact with the members of the Board, except as participants in the proceeding, and may not participate in the deliberations of the Board.

(b) Administrative support for a Board is to be provided only by the office of the Commissioner and the office of the Chief Counsel for FDA.

[44 FR 22348, Apr. 13, 1979, as amended at 54 FR 9035, Mar. 3, 1989]

Subpart B—Hearing Procedures

§ 13.20 Submissions to a Board.

(a) Submissions are to be filed with the Division of Dockets Management under § 10.20.

(b) The person making a submission shall serve copies of it on each participant in the proceeding, except as provided in §§ 13.10(b)(2) and 13.45. Submissions of documentary data and information need not be sent to each participant, but any accompanying transmittal letter, summary, statement of position, certification under paragraph (d) of this section, or similar document must be.

(c) A submission must be mailed to the address shown in the notice of appearance or personally delivered.

(d) All submissions are to be accompanied by a certificate of service, or a statement that service is not required.

(e) No written submission or other portion of the administrative record may be held in confidence, except as provided in §§ 13.10(b)(2) and 13.45.

(f) A participant who believes that compliance with the requirements of this section constitutes an unreasonable financial burden may submit to the Commissioner a petition to participate in forma pauperis in the form and manner specified in § 12.82.

§ 13.25 Disclosure of data and information by the participants.

(a) Before the notice of hearing is published under § 13.5, the director of the center responsible for the matters involved in the hearing must submit to the Division of Dockets Management—

(1) The relevant portions of the existing administrative record of the proceeding. Portions of the administrative record not relevant to the issues in the hearing are not part of the administrative record;

(2) A list of all persons whose views will be presented orally or in writing at the hearing;

(3) All documents in the director's files containing factual information, whether favorable or unfavorable to the director's position, which relate to the issues involved in the hearing. *Files* means the principal files in the center in which documents relating to the issues in the hearing are ordinarily kept, e.g., the food additive master file and the food additive petition in the case of issues concerning a food additive, or the new drug application in the case of issues concerning a new drug. Internal memoranda reflecting the deliberative process, and attorney work product and material prepared specifically for use in connection with the hearing, are not required to be submitted;

(4) All other documentary information relied on; and

(5) A signed statement that, to the best of the director's knowledge and belief, the submission complies with this section.

(b) Within the time prescribed in the notice of hearing published under § 13.5, each participant shall submit to the Division of Dockets Management all information specified in paragraph (a)(2) through (5) of this section and any objections that the administrative record filed under paragraph (a)(1) of this section is incomplete. With respect to the information specified in paragraph (a)(3) of this section, participants are to exercise reasonable diligence in identifying documents in files comparable to those described in that paragraph.

(c) The submissions required by paragraphs (a) and (b) of this section may be supplemented later in the proceeding, with the approval of the Board, on a showing that the views of the persons or the material contained in the supplement was not known or reasonably available when the initial submission was made or that the relevance of the views of the persons or the material contained in the supplement could not reasonably have been foreseen.

(d) The failure to comply substantially and in good faith with this section in the case of a participant constitutes a waiver of the right to participate further in the hearing and in

the case of a party constitutes a waiver of the right to a hearing.

(e) The Chairman rules on questions relating to this section. Any participant dissatisfied with a ruling may petition the Commissioner for interlocutory review.

[44 FR 22348, Apr. 13, 1979, as amended at 50 FR 8994, Mar. 6, 1985; 54 FR 9035, Mar. 3, 1989]

§ 13.30 Proceedings of a Board.

(a) The purpose of a Board is to review medical, scientific, and technical issues fairly and expeditiously. The proceedings of a Board are conducted as a scientific inquiry rather than a legal trial.

(b) A Board may not hold its first hearing until after all participants have submitted the information required by § 13.25.

(c) The Chairman calls the first hearing of the Board. Notice of the time and location of the first hearing is to be published at least 15 days in advance and the hearing will be open to the public. All participants will have an opportunity at the first hearing to make an oral presentation of the information and views which in their opinion are pertinent to the resolution of the issues being considered by a Board. A participant's presentation may be made by more than one person. The Chairman determines the order of the presentation. Participants may not interrupt a presentation, but members of the Board may ask questions. At the conclusion of a presentation, each of the other participants may briefly comment on the presentation and may request that the Board conduct further questioning on specified matters. Members of the Board may then ask further questions. Any other participant may be permitted to ask questions if the Chairman determines that it will help resolve the issues.

(d) The hearing is informal and the rules of evidence do not apply. No motions or objections relating to the admissibility of information and views may be made or considered, but other participants may comment upon or rebut all such information and views. No participant may interrupt the presentation of another participant for any reason.

(e) Within the time specified by the Board after its first hearing, participants may submit written rebuttal information and views in accordance with § 13.20. The Chariman will then schedule a second hearing, if requested and justified by a participant. A second hearing, and any subsequent hearing, will be called only if the Chairman concludes that it is needed to fully and fairly present information that cannot otherwise adequately be considered and to properly resolve the issues. Notice of the time and location of any hearing is to be published at least 15 days in advance. The hearing is open to the public.

(f) A Board may consult with any person who it concludes may have information or views relevant to the issues.

(1) The consultation may occur only at an announced hearing of a Board. Participants have the right to suggest or, with the permission of the Chairman, ask questions of the consultant and present rebuttal information and views, as provided in paragraphs (c) and (d) of this section except that written statements may be submitted to the Board with the consent of all participants.

(2) A participant may submit a request that the Board consult with a specific person who may have information or views relevant to the issues. The request will state why the person should be consulted and why the person's views cannot be furnished to the Board by means other than having FDA arrange for the person's appearance. The Board may, in its discretion, grant or deny the request.

(g) All hearings are to be transcribed. All hearings are open to the public, except that a hearing under § 10.20(j)(3) is closed to all persons except those persons making and participating in the presentation and Federal Government executive branch employees and special Government employees. At least a majority of Board members are to be present at every hearing. The executive sessions of a Board, during which a Board deliberates on the issues, are to be closed and are not transcribed. All members of the Board shall vote on the report of the Board.

(h) All legal questions are to be referred to the Chief counsel for FDA for resolution. The Chief Counsel's advice on any matter of procedure or legal authority is to be transmitted in writing and made a part of the record or presented in open session and transcribed.

(i) At the conclusion of all public hearings the Board will announce that the record is closed to receiving information. The Board will provide an opportunity for participants to submit written statements of their positions, with proposed findings and conclusions, and may in its discretion, provide an opportunity for participants to summarize their positions orally.

(j) The Board will prepare a decision on all issues. The decision is to include specific findings and references supporting and explaining the Board's conclusions, and a detailed statement of the reasoning on which the conclusions are based. Any member of the Board may file a separate report stating additional or dissenting views.

Subpart C—Records of a Hearing Before a Board

§ 13.40 Administrative record of a Board.

(a) The administrative record of a hearing before a Board consists of the following:

(1) All relevant FEDERAL REGISTER notices.

(2) All written submissions under § 13.20.

(3) The transcripts of all hearings of the Board.

(4) The initial decision of the Board.

(b) The record of the administrative proceeding is closed—

(1) Relevant to receiving information and data, at the time specified in § 13.30(i); and

(2) Relevant to pleadings, at the time specified in § 13.30(i) for filing a written statement of position with proposed findings and conclusions.

(c) The Board may, in its discretion, reopen the record to receive further evidence at any time before filing an initial decision.

§ 13.45 Examination of administrative record.

(a) The availability for public examination and copying of each document which is a part of the administrative record of the hearing is governed by § 10.20(j). Each document available for public examination or copying is placed on public display in the office of the Division of Dockets Management promptly upon receipt in that office.

(b) Lists of nominees and comments submitted on them under § 13.10(b)(3) are not subject to disclosure unless they become an issue in a court proceeding.

§ 13.50 Record for administrative decision.

The administrative record of the hearing specified in § 13.40(a) constitutes the exclusive record for decision.

PART 14—PUBLIC HEARING BEFORE A PUBLIC ADVISORY COMMITTEE

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AUTHORITY: 5 U.S.C. App. 2; 15 U.S.C. 1451–1461, 21 U.S.C. 41–50, 141–149, 321–394, 467f, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201, 262, 263b, 264; Pub. L. 107–109; Pub. L. 108–155; Pub. L. 113–54.

SOURCE: 44 FR 22351, Apr. 13, 1979, unless otherwise noted.

Subpart A—General Provisions

§ 14.1 Scope.

(a) This part governs the procedures when any of the following applies:

(1) The Commissioner concludes, as a matter of discretion, that it is in the public interest for a standing or ad hoc policy or technical public advisory committee (*advisory committee* or *committee*) to hold a public hearing and to review and make recommendations on any matter before FDA and for interested persons to present information and views at an oral public hearing before the advisory committee.

(2) Under specific provisions in the FD&C Act or other sections of this chapter, a matter is subject to a hearing before an advisory committee. The specific provisions are—

(i) Section 14.120 on review of a performance standard for an electronic product by the Technical Electronic Product Radiation Safety Standards Committee (TEPRSSC);

(ii) Section 14.140 on review of the safety of color additives;

(iii) Section 14.160 on review of the safety and effectiveness of human prescription drugs;

(iv) Section 330.10 on review of the safety and effectiveness of over-the-counter drugs;

(v) [Reserved]

(vi) Part 860, on classification of devices;

(vii) Section 514(b)(5) of the FD&C Act on establishment, amendment, or

revocation of a device performance standard;

(viii) Section 515 of the FD&C Act on review of device premarket approval applications and product development protocols; and

(ix) Section 520(f) of the FD&C Act on review of device good manufacturing practice regulations.

(3) A person who has a right to an opportunity for a formal evidentiary public hearing under part 12 waives that opportunity and instead under § 12.32 requests a hearing before an advisory committee, and the Commissioner, as a matter of discretion, accepts the request.

(b) In determining whether a group is a *public advisory committee* as defined in § 10.3(a) and thus subject to this part and to the Federal advisory Committee Act, the following guidelines will be used:

(1) An advisory committee may be a standing advisory committee or an ad hoc advisory committee. All standing advisory committees are listed in § 14.100.

(2) An advisory committee may be a policy advisory committee or a technical advisory committee. A policy advisory committee advises on broad and general matters. A technical advisory committee advises on specific technical or scientific issues, which may relate to regulatory decisions before FDA.

(3) An advisory committee includes any of its subgroups when the subgroup is working on behalf of the committee. Section 14.40(d) describes when a subgroup will be established as an advisory committee separate from the parent committee.

(4) A committee composed entirely of full-time Federal Government employees is not an advisory committee.

(5) An advisory committee ordinarily has a fixed membership, a defined purpose of providing advice to the agency on a particular subject, regular or periodic meetings, and an organizational structure, for example, a Chairperson and staff, and serves as a source of independent expertise and advice rather than as a representative of or advocate for any particular interest. The following groups are not advisory committees:

(i) A group of persons convened on an ad hoc basis to discuss a matter of current interest to FDA, but which has no continuing function or organization and does not involve substantial special preparation.

(ii) A group of two or more FDA consultants meeting with the agency on an ad hoc basis.

(iii) A group of experts who are employed by a private company or a trade association which has been requested by FDA to provide its views on a regulatory matter pending before FDA.

(iv) A consulting firm hired by FDA to provide advice regarding a matter.

(6) An advisory committee that is utilized by FDA is subject to this subpart even though it was not established by FDA. In general, a committee is *utilized* when FDA requests advice or recommendations from the committee on a specific matter in order to obtain an independent review and consideration of the matter, and not when FDA is merely seeking the comments of all interested persons or of persons who have a specific interest in the matter.

(i) A committee formed by an independent scientific or technical organization is utilized if FDA requests advice of that committee rather than of the parent organization, or if the circumstances show that the advice given is that of the committee and not of the parent organization. A committee formed by an independent scientific or technical organization is not utilized if FDA requests advice of the organization rather than of a committee and if the recommendations of any committee formed in response to the request are subject to substantial independent policy and factual review by the governing body of the parent organization.

(ii) A committee is not utilized by FDA if it provides only information, as contrasted with advice or opinions or recommendations.

(iii) FDA is charged with seeking out the views of all segments of the public on enforcement of the laws administered by the Commissioner. The fact that a group of individuals or a committee meets regularly with FDA, for example, a monthly meeting with consumer representatives, does not make that group or committee an advisory

committee. Thus, this subpart does not apply to routine meetings, discussions, and other dealings, including exchanges of views, between FDA and any committee representing or advocating the particular interests of consumers, industry, professional organizations, or others.

(7) The inclusion of one or two FDA consultants who are special Government employees on an internal FDA committee does not make that committee an advisory committee.

(8) A Public Board of Inquiry established under part 13, or other similar group convened by agreement between the parties to a regulatory proceeding pending before FDA to review and prepare an initial decision on the issues in lieu of a formal evidentiary public hearing, is acting as an administrative law tribunal and is not an advisory committee.

(9) An open public conference or meeting conducted under § 10.65(b) is not an advisory committee meeting.

(10) An FDA committee that primarily has operational responsibility rather than that of providing advice and recommendations is not an advisory committee, for example, the Research Involving Human Subjects Committee (RIHSC).

(c) This part applies only when a committee convenes to conduct committee business. Site visits, social gatherings, informal discussions by telephone or during meals or while traveling or at other professional functions, or other similar activities do not constitute a meeting.

(d) An advisory committee that is utilized but not established by FDA is subject to this part only to the extent of such utilization, and not concerning any other activities of such committee.

(e) Any conference or meeting between an employee of FDA and a committee or group which is not an advisory committee shall be subject to § 10.65 or other provisions specifically applicable to the committee or group, for example, part 13 for a Public Board of Inquiry.

(f) This part applies to all FDA advisory committees, except to the extent that specific statutes require otherwise for a particular committee, for example, TEPRSSC and advisory committees established under the Medical Device Amendments of 1976.

[44 FR 22351, Apr. 13, 1979, as amended at 54 FR 9035, Mar. 3, 1989; 78 FR 17087, Mar. 20, 2013; 81 FR 45409, July 14, 2016]

§ 14.5 Purpose of proceedings before an advisory committee.

(a) An advisory committee is utilized to conduct public hearings on matters of importance that come before FDA, to review the issues involved, and to provide advice and recommendations to the Commissioner.

(b) The Commissioner has sole discretion concerning action to be taken and policy to be expressed on any matter considered by an advisory committee.

§ 14.7 Administrative remedies.

A person who alleges noncompliance by the Commissioner or an advisory committee with any provision of this part or the Federal Advisory Committee Act may pursue the following administrative remedies:

(a) If the person objects to any action, including a failure to act, other than denial of access to an advisory committee document, the person shall submit a petition in the form and in accordance with the requirements of § 10.30. The provisions of § 10.45 relating to exhaustion of administrative remedies are applicable.

(1) If the person objects to past action, the person shall submit the petition within 30 days after the action objected to. If the Commissioner determines that there was noncompliance with any provision of this subpart or of the Federal Advisory Committee Act, the Commissioner will grant any appropriate relief and take appropriate steps to prevent its future recurrence.

(2) If the person objects to proposed future action, the Commissioner will expedite the review of the petition and make a reasonable effort to render a decision before the action concerned in the petition.

(3) If the person objects to action that is imminent or occurring and which could not reasonably have been anticipated, e.g., the closing of a portion of a meeting which is made known for the first time on the day of the meeting, the matter may be handled by

an oral petition in lieu of a written petition.

(b) If the person objects to a denial of access to an advisory committee document, administrative review is in accordance with the procedures established by the Department of Health and Human Services under 45 CFR 5.34.

[44 FR 22351, Apr. 13, 1979, as amended at 55 FR 1404, Jan. 16, 1990]

§ 14.10 Applicability to Congress.

This part applies to Congress, individual Members of Congress, and other employees or representatives of Congress in the same way that they apply to any other member of the public, except that disclosure of advisory committee records to Congress is governed by § 20.87.

§ 14.15 Committees working under a contract with FDA.

(a) FDA may enter into contracts with independent scientific or technical organizations to obtain advice and recommendations on particular matters, and these organizations may in turn undertake such work through existing or new committees. Whether a particular committee working under such a contract is an advisory committee subject to the Federal Advisory Committee Act and this subpart depends upon application of the criteria and principles in § 14.1(b).

(b) The following minimum standards apply to any committee of an independent scientific or technical organization which is working under a contract initially executed with FDA after July 1, 1975, but which is determined not to be an advisory committee:

(1) The committee shall give public notice of its meetings and agenda, and provide interested persons an opportunity to submit relevant information and views in writing at any time, and orally at specified times. The notice may be published in the FEDERAL REGISTER or disseminated by other reasonable means. It is in any event to be filed with the Division of Dockets Management not less than 15 days before the meeting. The time for oral presentations and the extent to which the committee meets in open session other than for such oral presentations is in the discretion of the committee.

(2) Minutes of open sessions are to be maintained, with all written submissions attached which were made to the committee in open session. After approval, the minutes are to be forwarded to the Division of Dockets Management and placed on public display. The extent to which the committee maintains minutes of closed sessions is in the discretion of the committee.

(3) In selecting the members of the committee, the organization involved is to apply the principles relating to conflicts of interest that FDA uses in establishing a public advisory committee. Those principles are set out or cross-referenced in this part and in part 19. Upon request, FDA will assist or provide guidance to any organization in meeting this requirement.

Subpart B—Meeting Procedures

§ 14.20 Notice of hearing before an advisory committee.

(a) Before the first of each month, and at least 15 days in advance of a meeting, the Commissioner will publish a notice in the FEDERAL REGISTER of all advisory committee meetings to be held during the month. Any advisory committee meetings for that month called after the publication of the general monthly notice are to be announced in the FEDERAL REGISTER on an individual basis at least 15 days in advance. The Commissioner may authorize an exception to these notice requirements in an emergency or for other reasons requiring an immediate meeting of an advisory committee, in which case public notice will be given at the earliest time and in the most accessible form feasible including, whenever possible, publication in the FEDERAL REGISTER.

(b) The FEDERAL REGISTER notice will include—

(1) The name of the committee;

(2) The date, time, and place of the meeting;

(3) The general function of the committee;

(4) A list of all agenda items, showing whether each will be discussed in an open or closed portion of the meeting;

(5) If any portion of the meeting is closed, a statement of the time of the open and closed portions;

(6) The nature of the subjects to be discussed during, and the reasons for closing, any closed portion of the meeting;

(7) The time set aside for oral statements and other public participation;

(8) The name, address, and telephone number of the advisory committee Designated Federal Officer and any other agency employee designated as responsible for the administrative support for the advisory committee;

(9) A statement that written submissions may be made to the advisory committee through the Designated Federal Officer at any time, unless a cutoff date has been established under § 14.35(d)(2);

(10) When a notice is published in the FEDERAL REGISTER less than 15 days before a meeting, an explanation for the lateness of the notice; and

(c) If a public hearing before an advisory committee is used in lieu of a formal evidentiary public hearing under § 14.1(a)(3), an initial notice of hearing is to be published separately in the FEDERAL REGISTER containing all the information described in § 12.32(e). This procedure may be used for any other hearing before an advisory committee when the Commissioner concludes, as a matter of discretion, that it would be informative to the public.

(d) A list of advisory committee meetings will be distributed to the press by the Associate Commissioner for Public Affairs.

[44 FR 22351, Apr. 13, 1979, as amended at 47 FR 26375, June 1, 1982; 54 FR 9035, Mar. 3, 1989; 66 FR 6469, Jan. 22, 2001; 66 FR 12850, Mar. 1, 2001]

§ 14.22 Meetings of an advisory committee.

(a) No advisory committee may conduct a meeting except at the call or with the advance approval of, and with an agenda approved by, the designated Federal employee or alternate. No meeting may be held in the absence of the designated Federal employee.

(1) If any matter is added to the agenda after its publication in the FEDERAL REGISTER under § 14.20(b)(4), an attempt is to be made to inform persons known to be interested in the matter, and the change is to be announced at the beginning of the open portion of the meeting.

(2) The advisory committee meeting is to be conducted in accordance with the approved final agenda insofar as practical.

(b) Advisory committee meetings will be held at places that are reasonably accessible to the public. All advisory committee meetings will be held in Washington, DC, or Rockville, MD, or the immediate vicinity, unless the Commissioner receives and approves a written request from the advisory committee for a different location. A different location may be approved when one or more of the following applies:

(1) The total cost of the meeting to the Government will be reduced.

(2) A substantial number of the committee members will be at the location at no expense to FDA for other reasons, e.g., for a meeting of a professional association.

(3) It is a central location more readily accessible to committee members.

(4) There is a need for increased participation available at that location.

(5) The committee wishes to review work or facilities in a specific location.

(6) The committee is concerned with matters that functionally or historically occur in some other location, e.g., the Science Advisory Board of the National Center for Toxicological Research will generally hold meetings in the Little Rock, AR, vicinity.

(c) Advisory committee members may, with the approval of FDA, conduct onsite visits relevant to their work.

(d) Unless the committee charter provides otherwise, a quorum for an advisory committee is a majority of the current voting members of the committee, except as provided in § 14.125(c) for TEPRSSC. Any matter before the advisory committee is to be decided by a majority vote of the voting members present at the time, except that the designated Federal official may require that any final report be voted upon by all current voting members of the committee. Any current voting member of the committee may file a separate report with additional or minority views.

(e) If space is available, any interested person may attend any portion of

any advisory committee meeting which is not closed.

(f) Whenever feasible, meetings are to be held in government facilities or other facilities involving the least expense to the public. The size of the meeting room is to be reasonable, considering such factors as the size of the committee, the number of persons expected to attend a meeting, and the resources and facilities available.

(g) The Commissioner may authorize a meeting to be held by conference telephone call. For these meetings, a speaker phone will be provided in a conference room located in Washington, DC, or Rockville, MD, or the immediate vicinity, to permit public participation in open portions of the meetings, as provided in §§ 14.25 and 14.29. These meetings generally will be brief, and authorized—

(1) For the purpose of taking final votes or otherwise confirming actions taken by the committee at other meetings; or

(2) Where time does not permit a meeting to be held at a central location.

(h) Any portion of a meeting will be closed by the committee Chairperson only when matters are to be discussed which the Commissioner has determined may be considered in closed session under § 14.27(b). If a portion of the meeting is closed, the closed portion will be held after the conclusion of the open portion whenever practicable.

(i) Any committee member may take notes during meetings and report and discuss committee deliberations after a meeting is completed and before official minutes or a report are available, within the rules and regulations adopted by FDA and by the advisory committee with the concurrence of FDA, including all of the following:

(1) There may be no attribution of individual views expressed in a closed session or revealing of numerical votes.

(2) There may be no reporting or discussion of any particular matter if the committee or FDA specifically so directs, e.g., where deliberations are incomplete or involve a sensitive regulatory decision that requires preparation or implementation.

(3) There may be no reporting or discussion of information prohibited from public disclosure under § 14.75.

(4) Notes or minutes kept or reports prepared by a committee member have no status or effect unless adopted into the official minutes or report by the committee.

[44 FR 22351, Apr. 13, 1979; 48 FR 40887, Sept. 12, 1983, as amended at 54 FR 9035, Mar. 3, 1989; 78 FR 17087, Mar. 20, 2013]

§ 14.25 Portions of advisory committee meetings.

An advisory committee meeting has the following portions:

(a) *The open public hearing*. Every committee meeting includes an open portion, which constitutes a public hearing during which interested persons may present relevant information or views orally or in writing. The hearing is conducted in accordance with § 14.29.

(b) *The open committee discussion*. A committee discusses any matter pending before it in an open portion of its meeting unless the meeting has been closed for that matter under § 14.27. To the maximum extent feasible, consistent with the policy expressed in § 14.27, a committee conducts its discussion of pending matters in an open portion. No public participation is permissible during this portion of the meeting except with the consent of the committee Chairperson.

(c) *The closed presentation of data*. Information prohibited from public disclosure under part 20 and the regulations referenced therein is presented to the committee in a closed portion of its meeting. However, if information is in the form of a summary that is not prohibited from public disclosure, the presentation is to be made in an open portion of a meeting.

(d) *The closed committee deliberations*. Deliberations about matters before an advisory committee may be held in a closed portion of a meeting only upon an appropriate determination by the Commissioner under § 14.27.

§ 14.27 Determination to close portions of advisory committee meetings.

(a) No committee meeting may be entirely closed. A portion of a meeting may be closed only in accordance with

a written determination by the Commissioner under this section.

(b) The Designated Federal Officer or other designated agency employee shall prepare the initial request for a determination to close a portion of a meeting, specifying the matter(s) to be discussed during the closed portion and the reasons why the portion should be closed. The Commissioner, based upon this request and with the concurrence of the Chief Counsel, will determine whether to close a portion of a meeting. The reasons for closing a portion of a meeting will be announced in the FEDERAL REGISTER notice of the meeting under § 14.20 in accordance with the following rules:

(1) Any determination to close a portion of a meeting restricts the closing to the shortest possible time consistent with the policy in this section.

(2) A portion of a meeting may be closed only if the Commissioner determines that the closing is permitted under 5 U.S.C. 552b(c), and that the closing is necessary.

(3) Portions of meetings may ordinarily be closed if they concern the review, discussion, and evaluation of drafts or regulations, guidance documents or similar preexisting internal agency documents, but only if their premature disclosure would significantly impede proposed agency action; review of trade secrets and confidential commercial or financial information; consideration of matters involving investigatory files compiled for law enforcement purposes; and review of matters, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

(4) Portions of meetings ordinarily may not be closed if they concern review, discussion, and evaluation of general preclinical and clinical test protocols and procedures for a class of drugs or devices; consideration of labeling requirements for a class of marketed drugs and devices; review of information on specific investigational or marketed drugs and devices that have previously been made public; presentation of any other information not exempt from public disclosure under 5 U.S.C. 552b(c); the formulation of advice and recommendations to FDA on matters that do not independently justify closing.

(5) No portion of a meeting devoted to matters other than those designated in paragraph (b) (1) through (3) of this section may be closed.

(6) A matter which is properly considered in an open portion of a meeting may instead be considered in a closed portion only if it is so inextricably intertwined with matters to be discussed in a closed portion that it is not feasible to separate them or discussion of the matter in an open portion would compromise the matters to be discussed in the closed portion.

(c) Attendance at a closed portion of a meeting is governed by the following rules:

(1) A portion of a meeting closed for the presentation or discussion of information that constitutes a trade secret or confidential commercial or financial information as defined in § 20.61 may be attended only by voting advisory committee members, nonvoting members representing consumer interests who are also special government employees as provided in § 14.80(b), the Designated Federal Officer of the advisory committee, a transcriber, consultants, and such other regular employees of FDA (including members of the Office of the Chief Counsel) as the Chairperson of the advisory committee may invite, and by those persons authorized to be present under § 14.25(c), for presentation of information prohibited from public disclosure. A person making a presentation described in § 14.25(c) may be accompanied by a reasonable number of employees, consultants, or other persons in a commercial arrangement within the meaning of § 20.81(a).

(2) A portion of a meeting that has been closed for consideration of existing internal agency documents falling within § 20.62 where premature disclosure is likely to significantly impede proposed agency action; personnel, medical, and similar files, disclosure of which would be a clearly unwarranted invasion of personal privacy within the meaning of § 20.63; or investigatory records compiled for law enforcement purposes as defined in § 20.64 may be attended only by committee members (voting and nonvoting), the Designated Federal Officer of the committee, a

transcriber, and other regular employees of FDA (including members of the Office of the Chief Counsel) whom the Chairperson of the committee may invite. Consultants, individuals performing personal service contracts, employees of other Federal agencies, and the general public may not attend such portions.

(3) If a person other than a person permitted to attend in accordance with paragraph (c) (1) and (2) of this section attempts to attend a closed portion of a meeting without the approval of the Designated Federal Officer and the Chairperson, and the matter is brought to their attention, the person will be required to leave the meeting immediately. This inadvertent and unauthorized attendance does not enable other unauthorized persons to attend, nor does it, of itself, constitute grounds for release of transcripts of closed portions or any other documents otherwise exempt from disclosure under § 14.75 and part 20.

(4) If a person other than a person permitted to attend in accordance with paragraphs (c) (1) and (2) of this section is allowed by the Designated Federal Officer and the Chairperson to attend a closed portion of a meeting, that portion is open to attendance by any interested person.

[44 FR 22351, Apr. 13, 1979, as amended at 65 FR 56479, Sept. 19, 2000]

§ 14.29 Conduct of a hearing before an advisory committee.

(a) For each meeting, the open portion for public participation, which constitutes a public hearing under § 14.25(a), will be at least 1 hour, unless public participation does not last that long, and may last for whatever longer time the committee Chairperson determines will facilitate the work of the committee. The FEDERAL REGISTER notice published under § 14.20 will designate the time specifically reserved for the hearing, which is ordinarily the first portion of the meeting. Further public participation in any open portion of the meeting under § 14.25(b) is solely at the discretion of the Chairperson.

(b) An interested person who wishes to be assured of the right to make an oral presentation at a meeting shall inform the Designated Federal Officer or other designated agency employee, orally or in writing, before the meeting.

(1) The person shall state the general nature of the presentation and the approximate time desired. Whenever possible, all written information to be discussed by that person at the meeting should be furnished in advance to the Designated Federal Officer or other designated agency employee. This material may be distributed or mailed by FDA to the committee members in advance of the meeting if time permits, and otherwise will be distributed to the members when they arrive for the meeting. The mailing or distribution may be undertaken only by FDA unless FDA grants permission to a person to mail or distribute the material

(2) Before the meeting, the Designated Federal Officer or other designated agency employee shall determine the amount of time allocated to each person for oral presentation and the time that the presentation is to begin. Each person will be so informed in writing, if time permits, or by telephone. FDA may require persons with common interests to make joint presentations.

(c) The Chairperson of the committee shall preside at the meeting in accordance with § 14.30 and be accompanied by other committee members, who serve as a panel in conducting the hearing portion of the meeting.

(d) Each person may use the allotted time as desired, consistent with an orderly hearing. A person may be accompanied by additional persons, and may present any written information or views for inclusion in the record of the hearing, subject to the requirements of § 14.35(c).

(e) If a person is absent at the time specified for that person's presentation, the persons following will appear in order. An attempt will be made to hear the person at the conclusion of the hearing. Interested persons attending the hearing who did not request an opportunity to make an oral presentation may be given an opportunity to do so at the discretion of the Chairperson.

(f) The Chairperson and other members may question a person concerning

that person's presentation. No other person, however, may question the person. The Chairperson may allot additional time when it is in the public interest, but may not reduce the time allotted without consent of the person.

(g) Participants may question a committee member only with that member's permission and only about matters before the committee.

(h) The hearing is informal, and the rules of evidence do not apply. No motions or objections relating to the admissibility of information and views may be made or considered, but other participants may comment upon or rebut matters presented. No participant may interrupt the presentation of another participant.

§ 14.30 Chairperson of an advisory committee.

(a) The advisory committee Chairperson has the authority to conduct hearings and meetings, including the authority to adjourn a hearing or meeting if the Chairperson determines that adjournment is in the public interest, to discontinue discussion of a matter, to conclude the open portion of a meeting, or to take any other action to further a fair and expeditious hearing or meeting.

(b) If the Chairperson is not a full-time employee of FDA, the Designated Federal Officer or other designated agency employee, or alternate, is to be the *designated Federal employee* who is assigned to the advisory committee. The designated Federal employee is also authorized to adjourn a hearing or meeting if the employee determines adjournment to be in the public interest.

§ 14.31 Consultation by an advisory committee with other persons.

(a) A committee may confer with any person who may have information or views relevant to any matter pending before the committee.

(b) An interested person may submit to the committee a written request that it confer with specific persons about any matter pending before the committee. The request is to contain adequate justification. The committee may, in its discretion, grant the request.

(c) A committee may confer with a person who is not a Federal Government executive branch employee only during the open portions of a meeting. The person may, however, submit views in writing to the committee as part of the administrative record under § 14.70. The person may participate at the closed portions of a meeting only if appointed as a special Government employee by the Commissioner as provided in paragraph (e) of this section. This paragraph (c) is not intended to bar the testimony of a person during a closed portion of a meeting about matters prohibited from public disclosure under §§ 14.25(c) and 14.27(c).

(d) To prevent inadvertent violation of Federal conflict of interest laws and laws prohibiting disclosure of trade secrets (18 U.S.C. 208, 21 U.S.C. 331(j), 18 U.S.C. 1905), Federal executive branch employees who are not employees of the Department may not confer, testify, or otherwise participate (other than as observers) at any portion of an advisory committee meeting unless they are appointed as special Government employees by the Commissioner under paragraph (e) of this section. this paragraph does not apply to Federal executive branch employees who are appointed as members of TEPRSSC, as provided in § 14.127.

(e) The Commissioner may appoint persons as special Government employees to be consultants to an advisory committee. Consultants may be appointed to provide expertise, generally concerning a highly technical matter, not readily available from the members of the committee. Consultants may be either from outside the Government or from agencies other than the Food and Drug Administration. Reports, data, information, and other written submissions made to a public advisory committee by a consultant are part of the administrative record itemized in § 14.70.

[44 FR 22351, Apr. 13, 1979, as amended at 55 FR 42703, Oct. 23, 1990]

§ 14.33 Compilation of materials for members of an advisory committee.

The Commissioner shall prepare and provide to all committee members a compilation of materials bearing upon

members' duties and responsibilities, including—

(a) All applicable conflict of interest laws and regulations and a summary of their principal provisions;

(b) All applicable laws and regulations relating to trade secrets and confidential commercial or financial information that may not be disclosed publicly and a summary of their principal provisions;

(c) All applicable laws, regulations, and guidance documents relating to the subject matter covered by the advisory committee and a summary of their principal provisions;

(d) All applicable laws, regulations, including the regulations in part 20 of this chapter, advisory committee charters, FEDERAL REGISTER notices, curricula vitae, rules adopted by the advisory committee, and other material relating to the formation, composition, and operation of the advisory committee, and a summary of their principal provisions;

(e) Instructions on whom to contact when questions arise; and

(f) Other material relating to FDA and the subject matter covered by the committee which may facilitate the work of the committee.

[44 FR 22351, Apr. 13, 1979, as amended at 65 FR 56479, Sept. 19, 2000]

§ 14.35 Written submissions to an advisory committee.

(a) Ten copies of written submissions to a committee are to be sent to the Designated Federal Officer unless an applicable FEDERAL REGISTER notice or other regulations in this chapter specify otherwise. Submissions are subject to the provisions of § 10.20, except that it is not necessary to send copies to the Division of Dockets Management.

(b) At the request of a committee, or on the Commissioner's own initiative, the Commissioner may issue in the FEDERAL REGISTER a notice requesting the submission to the committee of written information and views pertinent to a matter being reviewed by the committee. The notice may specify the manner in which the submission should be made.

(c) At the request of a committee, or on the Commissioner's own initiative, the Commissioner may at any time request the applicant or sponsor of an application or petition about a specific product on which action is pending before FDA, and is being reviewed by an advisory committee, to present or discuss safety, effectiveness, or other data concerning the product during a regularly scheduled meeting of the committee. The request may be for an oral presentation or for a concise, well-organized written summary of pertinent information for review by the committee members before the meeting, or both. Unless specified otherwise, one copy of the written summary along with a proposed agenda outlining the topics to be covered and identifying the participating industry staff members or consultants that will present each topic is to be submitted to the Designated Federal Officer or other designated agency employee at least 3 weeks before the meeting.

(d) An interested person may submit to a committee written information or views on any matter being reviewed. Voluminous data is to be accompanied by a summary. A submission is to be made to the Designated Federal Officer and not directly to a committee member.

(1) FDA will distribute submissions to each member, either by mail or at the next meeting. Submissions will be considered by the committee in its review of the matter.

(2) A committee may establish, and give public notice of, a cutoff date after which submissions about a matter will no longer be received or considered.

(e) The Commissioner will provide the committee all information the Commissioner deems relevant. A member will, upon request, also be provided any material available to FDA which the member believes appropriate for an independent judgment on the matter, e.g., raw data underlying a summary or report, or a briefing on the legal aspects of the matter.

§ 14.39 Additional rules for a particular advisory committee.

(a) In addition to these rules, an advisory committee may, with the concurrence of the designated Federal employee, adopt additional rules which

are not inconsistent with this subpart or with other legal requirements.

(b) Any additional rules will be included in the minutes of the meeting when adopted and in the materials compiled under § 14.33 and will be available for public disclosure under § 14.65(c).

Subpart C—Establishment of Advisory Committees

§ 14.40 Establishment and renewal of advisory committees.

(a) An advisory committee may be established or renewed whenever it is necessary or appropriate for the committee to hold a public hearing and to review and make recommendations on any matter pending before FDA. Except for committees established by statute, before a committee is established or renewed it must first be approved by the Department pursuant to 45 CFR part 11 and by the General Services Administration.

(b) When an advisory committee is established or renewed, the Commissioner will issue a FEDERAL REGISTER notice certifying that the establishment or renewal is in the public interest and stating the structure, function, and purposes of the committee and, if it is a standing advisory committee, shall amend § 14.100 to add it to the list of standing advisory committees. A notice of establishment will be published at least 15 days before the filing of the advisory committee charter under paragraph (c) of this section. A notice of renewal does not require the 15-day notice.

(c) No committee may meet or take action until its charter is prepared and filed as required by section 9(c) of the Federal Advisory Committee Act. This requirement is to be met by an advisory committee utilized by FDA, even though it is not established by the agency, prior to utilization.

(d) The regulations of the Department cited in paragraph (a) of this section provide that the charter of a parent committee may incorporate information concerning activities of a subgroup. In such instances, a subgroup will not be established as a committee distinct from the parent committee. However, a subgroup will be established as a separate committee when the charter of the parent committee does not incorporate the activities of the subgroup, or when the subgroup includes members who are not all drawn from the parent committee.

(e) An advisory committee not required to be established by law will be established or utilized only if it is in the public interest and only if its functions cannot reasonably be performed by other existing advisory committees or by FDA.

(f) An advisory committee must meet the following standards:

(1) Its purpose is clearly defined.

(2) Its membership is balanced fairly in terms of the points of view represented in light of the functions to be performed. Although proportional representation is not required, advisory committee members are selected without regard to race, color, national origin, religion, age, or sex.

(3) It is constituted and utilizes procedures designed to assure that its advice and recommendations are the result of the advisory committee's independent judgment.

(4) Its staff is adequate. The Commissioner designates an Designated Federal Officer and alternate for every advisory committee, who are employees of FDA. The Designated Federal Officer is responsible for all staff support unless other agency employees are designated for this function.

(5) Whenever feasible, or required by statute, it includes representatives of the public interest.

[44 FR 22351, Apr. 13, 1979, as amended at 55 FR 42703, Oct. 23, 1990]

§ 14.55 Termination of advisory committees.

(a) Except as provided in paragraph (c) of this section, a standing advisory committee is terminated when it is no longer needed, or not later than 2 years after its date of establishment unless it is renewed for an additional 2-year period. A committee may be renewed for as many 2-year periods as the public interest requires. The requirements for establishment of a committee under § 14.40 also apply to its renewal.

(b) FDA will issue a FEDERAL REGISTER notice announcing the reasons for terminating a committee and, if it

is a standing committee, amending § 14.100 to delete it from the list.

(c) TEPRSSC is a permanent statutory advisory committee established by section 358(f)(1)(A) of the Public Health Service Act, as added by the Radiation Control for Health and Safety Act of 1968, transferred to the FD&C Act (21 U.S.C. 360kk(f)(1)(A)), and is not subject to termination and renewal under paragraph (a) of this section, except that a new charter is prepared and filed at the end of each 2-year period as provided in § 14.40(c). Also, the statutory medical device classification panels established under section 513(b)(1) of the FD&C Act (21 U.S.C. 360c(b)(1)) and part 860, and the statutory medical device good manufacturing practice advisory committees established under section 520(f)(3) of the FD&C Act (21 U.S.C. 360j(f)(3)), are specifically exempted from the normal 2-year duration period.

(d) Color additive advisory committees are required to be established under the circumstances specified in sections 721(b)(5)(C) and (D) of the FD&C Act (21 U.S.C. 379e(b)(5)(C) and (D)). A color additive advisory committee is subject to the termination and renewal requirements of the Federal Advisory Committee Act and of this part.

(e) The Tobacco Products Scientific Advisory Committee is a permanent statutory advisory committee established by section 917 of the Family Smoking Prevention and Tobacco Control Act (21 U.S.C. 387q) (Pub. L. 111–31) and is not subject to termination and renewal under paragraph (a) of this section.

[44 FR 22351, Apr. 13, 1979, as amended at 75 FR 73953, Nov. 30, 2010; 78 FR 17087, Mar. 20, 2013]

Subpart D—Records of Meetings and Hearings Before Advisory Committees

§ 14.60 Minutes and reports of advisory committee meetings.

(a) The Designated Federal Officer or other designated agency employee prepares detailed minutes of all advisory committee meetings, except that less detailed minutes may be prepared for open portions of meetings which under § 14.61, must be transcribed or recorded by the agency. Their accuracy is approved by the committee and certified by the Chairperson. The approval and certification may be accomplished by mail or by telephone.

(b) The minutes include the following:

(1) The time and place of the meeting.

(2) The members, committee staff, and agency employees present, and the names and affiliations or interests of public participants.

(3) A copy of or reference to all written information made available for consideration by the committee at the proceedings.

(4) A complete and accurate description of matters discussed and conclusions reached. A description is to be kept separately for the following portions of the meeting to facilitate their public disclosure: The open portions specified in § 14.25 (a) and (b), any closed portion during which a presentation is made under § 14.25(c), and any closed deliberative portion under § 14.25(d). The minutes of a closed deliberative portion of a meeting may not refer to members by name, except upon their request, or to data or information described in § 14.75(b). Any inadvertent references that occur are to be deleted before public disclosure.

(5) A copy of or reference to all reports received, issued, or approved by the committee.

(6) The extent to which the meeting was open to the public.

(7) The extent of public participation, including a list of members of the public who presented oral or written statements.

(c) For a meeting that has a closed portion, either (1) the minutes of the closed portion are available for public disclosure under § 14.75(a)(6)(i), or (2) if under § 14.75(a)(6)(ii) they are not promptly available, the Designated Federal Officer or other designated agency employee shall prepare a brief summary of the matters considered in an informative manner to the public, consistent with 5 U.S.C. 552(b).

(d) Where a significant portion of the meeting of a committee is closed, the committee will issue a report at least annually setting forth a summary of

its activities and related matters informative to the public consistent with 5 U.S.C. 552(b). This report is to be a compilation of or be prepared from the individual reports on closed portions of meeting prepared under paragraph (c) of this section.

[44 FR 22351, Apr. 13, 1979, as amended at 45 FR 85725, Dec. 30, 1980]

§ 14.61 Transcripts of advisory committee meetings.

(a) The agency will arrange for a transcript or recording to be made for each portion of a meeting.

(b) A transcript or recording of an open portion of a meeting made by FDA is to be included in the record of the committee proceedings.

(c) A transcript or recording of any closed portion of a meeting made by FDA will not be included in the administrative record of the committee proceedings. The transcript or recording will be retained as confidential by FDA, and will not be discarded or erased.

(d) Any transcript or recording of a meeting or portion thereof which is publicly available under this section will be available at actual cost of duplication, which will be, where applicable, the fees established in § 20.45. FDA may furnish the requested transcript or recording for copying to a private contractor who shall charge directly for the cost of copying under § 20.53.

(e) A person attending any open portion of a meeting may, consistent with the orderly conduct of the meeting, record or otherwise take a transcript of the meeting. This transcription will not be part of the administrative record.

(f) Only FDA may make a transcript or recording of a closed portion of a meeting.

[44 FR 22351, Apr. 13, 1979, as amended at 68 FR 25285, May 12, 2003]

§ 14.65 Public inquiries and requests for advisory committee records.

(a) Public inquiries on general committee matters, except requests for records, are to be directed to the Committee Management Officer in the Advisory Committee Oversight and Management Staff, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5103, Silver Spring, MD 20993.

(b) Public inquiries on matters relating to a specific committee, except requests for records, are to be directed to the Designated Federal Officer or the designated agency employee listed in the FEDERAL REGISTER notices published under § 14.20.

(c) Requests for public advisory committee records, including minutes, are to be made, to FDA's Division of Freedom of Information (the Freedom of Information Staff's address is available on the agency's web site at *http://www.fda.gov*) under § 20.40 and the related provisions of part 20.

[44 FR 22351, Apr. 13, 1979, as amended at 46 FR 8456, Jan. 27, 1981; 76 FR 31469, June 1, 2011; 78 FR 17087, Mar. 20, 2013; 79 FR 68114, Nov. 14, 2014]

§ 14.70 Administrative record of a public hearing before an advisory committee.

(a) Advice or recommendations of an advisory committee may be given only on matters covered in the administrative record of the committee's proceedings. Except as specified in other FDA regulations, the administrative record consists of all the following items relating to the matter:

(1) Any transcript or recording of an open portion of a meeting.

(2) The minutes of all portions of all meetings, after any deletions under § 14.60(b)(4).

(3) All written submissions to and information considered by the committee.

(4) All reports made by the committee.

(5) Any reports prepared by a consultant under § 14.31(e).

(b) The record of the proceeding is closed at the time the advisory committee renders its advice or recommendations or at any earlier time specified by the committee or in other sections in this chapter.

§ 14.75 Examination of administrative record and other advisory committee records.

(a) The administrative record and other committee records are available

for public disclosure under part 20, except as provided in paragraph (b) of this section, at the following times:

(1) The written information for consideration by the committee at any meeting: at the same time it is made available to the committee.

(2) The transcript or recording of any open portion of a meeting: as soon as it is available.

(3) The minutes of any open portion of a meeting: after they have been approved by the committee and certified by the Chairperson.

(4) The brief summary of any closed portion of a meeting prepared under § 14.60(c): as soon as it is available.

(5) All written information or views submitted to the committee at an open portion of a meeting: as soon as they are submitted.

(6) The minutes or portions thereof of a closed portion of a meeting—

(i) For a matter not directed to be maintained as confidential under § 14.22(i)(2): After they have been approved by the committee and certified by the Chairperson; and

(ii) For a matter directed to be maintained as confidential under § 14.22(i)(2): After the advice or report of the committee relevant to those minutes or portions thereof is acted upon by the Commissioner, or upon a determination by the Commissioner that such minutes or portions thereof may be made available for public disclosure without undue interference with agency or advisory committee operations.

(7) Formal advice or a report of the committee: After it has been acted upon, i.e., approved, disapproved, or rejected as inadequate, by the Commissioner, or upon a determination by the Commissioner that such formal advice or report may be made available for public disclosure without undue interference with agency or committee operations. Such formal advice or report may be retained as confidential while it is under active advisement.

(8) Any other committee records relating to the matter, except transcripts and recordings of closed portions of meetings: After the advice or report of the committee relevant to those records is acted upon by the Commissioner, or upon a determination by the Commissioner that the records may be made available for public disclosure without undue interference with agency or committee operations.

(b) The following information contained in the administrative record is not available for public examination or copying except as provided in § 12.32(g):

(1) Material provided to the committee by FDA that is exempt from public disclosure under part 20 and the regulations referenced there.

(2) Material provided to the advisory committee by a person making a presentation described in § 14.25(c) and which is prohibited from public disclosure under part 20 and the regulations referenced there.

(c) The Division of Dockets Management (HFA–305) will maintain a file for each committee containing the following principal records for ready access by the public:

(1) The committee charter.

(2) A list of committee members and their curricula vitae.

(3) The minutes of committee meetings.

(4) Any formal advice or report of the committee.

[44 FR 22351, Apr. 13, 1979, as amended at 54 FR 9035, Mar. 3, 1989]

Subpart E—Members of Advisory Committees

§ 14.80 Qualifications for members of standing policy and technical advisory committees.

(a) Members of a policy advisory committee—

(1) Shall have diverse interests, education, training, and experience; specific technical expertise is not a requirement;

(2) Are subject to the conflict of interest laws and regulations either as special Government employees or as members of the uniformed services, including the Commissioned Corps of the Public Health Service (the Commissioner has determined that, because members representing particular interests, e.g., a representative of labor, industry, consumers, or agriculture, are included on advisory committees specifically for the purpose of representing these interests, any financial interest covered by 18 U.S.C. 208(a) in the class which the member represents

is irrelevant to the services which the Government expects from them and thus is hereby exempted under 18 U.S.C. 208(b) as too remote and inconsequential to affect the integrity of their services); and

(3) Shall be voting members.

(b) *Technical advisory committee.* (1) Voting members of technical advisory committees—

(i) Shall have expertise in the subject matter with which the committee is concerned and have diverse professional education, training, and experience so that the committee will reflect a balanced composition of sufficient scientific expertise to handle the problems that come before it; and

(ii) Except for members of the Technical Electronic Product Radiation Safety Standards Committee (TEPRSSC), are subject to the conflict of interest laws and regulations either as special Government employees or as members of the uniformed services, including the Commissioned Corps of the Public Health Service.

(2) The Commissioner shall, when required by statute, and may when not required by statute, provide for nonvoting members of a technical advisory committee to serve as representatives of and liaison with interested organizations. Nonvoting members—

(i) Shall be selected by the interested organizations, as provided in § 14.84; technical expertise in the subject matter with which the committee is involved is not a requirement; and

(ii) May be special Government employees subject to the conflict of interest laws and regulations, except as provided in § 14.84(e).

(c) A person may serve as a voting or nonvoting member on only one FDA advisory committee unless the Commissioner determines in writing that dual membership will aid the work of the committees involved and is in the public interest.

(d) Members of FDA advisory committees, and the Chairperson, are appointed from among those nominated under §§ 14.82 and 14.84 and from any other sources by the Secretary, or, by delegation of authority, by the Assistant Secretary for Health, or the Commissioner.

(e) Members appointed to an advisory committee serve for the duration of the committee, or until their terms of appointment expire, they resign, or they are removed from membership by the Commissioner.

(f) A committee member may be removed from membership for good cause. Good cause includes excessive absenteeism from committee meetings, a demonstrated bias that interferes with the ability to render objective advice, failure to abide by the procedures established in this subpart, or violation of other applicable rules and regulations, e.g., for nonvoting members, the provisions of § 14.86(c).

(g) Consultants appointed under § 14.31(e) are not members of advisory committees.

[44 FR 22351, Apr. 13, 1979, as amended at 53 FR 50949, Dec. 19, 1988; 54 FR 9035, Mar. 3, 1989]

§ 14.82 Nominations of voting members of standing advisory committees.

(a) The Commissioner will publish one or more notices in the FEDERAL REGISTER each year requesting nominations for voting members of all existing standing advisory committees. The notice will invite the submission of nominations for voting members from both individuals and organizations.

(b) The notice announcing the establishment of a new committee under § 14.40(b) will invite the submission of nominations for voting members.

(c) A person may nominate one or more qualified persons to an advisory committee. Nominations will specify the advisory committee for which the nominee is recommended and will include a complete curriculum vitae of the nominee. Nominations are to state that the nominee is aware of the nomination, is willing to serve as a member of the advisory committee, and appears to have no conflict of interest that would preclude membership.

(d) Voting members serve as individuals and not as representatives of any group or organization which nominated them or with which they may be affiliated.

§ 14.84 Nominations and selection of nonvoting members of standing technical advisory committees.

(a) This section applies when the Commissioner concludes that a technical advisory committee should include nonvoting members to represent and serve as a liaison with interested individuals and organizations.

(b) Except when the Commissioner concludes otherwise, nonvoting members of a technical advisory committee are selected in accordance with paragraphs (c) and (d) of this section and are normally limited to one person selected by consumer groups and organizations and one person selected by industry groups and organizations.

(c) To select a nonvoting member to represent consumer interests, except as provided in paragraph (c)(5) of this section, the Commissioner publishes a notice in the FEDERAL REGISTER requesting nominations for each specific committee, or subcommittee, for which nonvoting members are to be appointed.

(1) A period of 30 days will be permitted for submission of nominations for that committee or subcommittee. Interested persons may nominate one or more qualified persons to represent consumer interests. Although nominations from individuals will be accepted, individuals are encouraged to submit their nominations through consumer organizations as defined in paragraph (c)(3) of this section. Nominations of qualified persons for general consideration as nonvoting members of unspecified advisory committees or subcommittees may be made at any time. All nominations are to be submitted in writing to Advisory Committee Oversight and Management Staff, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 1503, Silver Spring, MD 20993.

(2) A complete curriculum vitae of any nominee is to be included. Nominations must state that the nominee is aware of the nomination, is willing to serve as a member of an advisory committee, and appears to have no conflict of interest. The nomination must state whether a nominee is interested only in a particular advisory committee or subcommittee, or whether the nominee is interested in becoming a member of any advisory committee or subcommittee. Nominations that do not comply with the requirements of this paragraph will not be considered.

(3) The Advisory Committee Oversight and Management Staff will compile a list of organizations whose objectives are to promote, encourage, and contribute to the advancement of consumer education and to the resolution of consumer problems. All organizations listed are entitled to vote upon the nominees. The list will include organizations representing the public interest, consumer advocacy groups, and consumer/health branches of Federal, State, and local governments. Any organization that meets the criteria may be included on such list on request.

(4) The executive secretary, or other designated agency employee, will review the list of nominees and select three to five qualified nominees to be placed on a ballot. Names not selected will remain on a list of eligible nominees and be reviewed periodically by the Advisory Committee Oversight and Management Staff to determine continued interest. Upon selection of the nominees to be placed on the ballot, the curriculum vitae for each of the nominees will be sent to each of the organizations on the list complied under paragraph (c)(3) of this section, together with a ballot to be filled out and returned within 30 days. After the time for return of the ballots has expired, the ballots will be counted and the nominee who has received the highest number of votes will be selected as the nonvoting member representing consumer interests for that particular advisory committee or subcommittee. In the event of a tie, the Commissioner will select the winner by lot from among those tied for the highest number of votes

(5) If a member representing consumer interests resigns or is removed before termination of the committee on which the member is serving, the following procedures will be used to appoint a replacement to serve out the term of the former member:

(i) The Commissioner will appoint the runner-up, in order of number of ballots received, on the original ballot submitted under paragraph (c)(4) of this section to fill the vacancy. If the

runner-up is no longer willing to serve as a member, then the next runner-up will be appointed.

(ii) If none of the nominees on the original ballot is willing to serve, or if there was only one nominee on the original ballot, the Advisory Committee Oversight and Management Staff will contact by telephone eligible individuals whose names have been submitted in the past as candidates for membership as representatives of consumer interests. A list of persons who are interested in serving on an advisory committee will then be prepared. The curricula vitae of these persons, together with a ballot, will be sent to a representative number of consumer organizations that have been determined to be eligible to vote for consumer representatives in accordance with paragraph (c)(3) of this section. After 4 days have elapsed, the Advisory Committee Oversight and Management Staff will contact the consumer organizations by telephone and elicit their votes. The candidate who has received the highest number of votes will be selected. In the event of a tie, the Commissioner will select the winner by lot from among those tied for the highest number of votes.

(d) To select a nonvoting member to represent industry interests, the Commissioner will publish, for each committee for which the Commissioner has determined to appoint a nonvoting member, a notice requesting that, within 30 days, any industry organization interested in participating in the selection of an appropriate nonvoting member to represent industry interests send a letter stating that interest to the FDA employee designated in the notice. After 30 days, a letter will be sent to each organization that has expressed an interest, attaching a complete list of all such organizations, and stating that it is their responsibility to consult with each other in selecting, within 60 days after receipt of the letter, a single nonvoting member to represent industry interests for that committee. If no individual is selected within 60 days, the Commissioner will select the nonvoting member representing industry interests.

(e) The Commissioner has determined that, because nonvoting members representing consumer and industry interests are included on advisory committees specifically for the purpose of representing such interests and have no vote, any financial interest covered by 18 U.S.C. 208(a) in the class which the member represents is irrelevant to the services the Government expects from them and thus is hereby exempted under 18 U.S.C. 208(b) as too remote and inconsequential to affect the integrity of their services.

[44 FR 22351, Apr. 13, 1979, as amended at 54 FR 9035, Mar. 3, 1989; 75 FR 15342, Mar. 29, 2010]

§ 14.86 Rights and responsibilities of nonvoting members of advisory committees.

(a) A nonvoting member of an advisory committee selected to represent and serve as a liaison with interested individuals, associations, and organizations has the same rights as any other committee member except that—

(1) A nonvoting member may vote only on procedural matters such as additional rules adopted under § 14.39(a), approval of minutes under § 14.60(a), decisions on transcripts under § 14.61(b), and future meeting dates;

(2) A nonvoting member who is a representative of industry interest may have access to data and information that constitute a trade secret or confidential commercial or financial information as defined in § 20.61 only if the person has been appointed as a special Government employee under § 14.80(b).

(b) A nonvoting member of an advisory committee is subject to, and shall abide by, all rules and regulations adopted by FDA and the committee.

(c) It is the responsibility of the nonvoting consumer and industry members of an advisory committee to represent the consumer and industry interests in all deliberations.

(1) A nonvoting member does not represent any particular organization or group, but rather represents all interested persons within the class which the member is selected to represent. Accordingly, an interested person within the class represented by that nonvoting member may, upon request, have access to all written statements or oral briefings concerning the committee prepared by the nonvoting

member for distribution to any person outside the committee. When documents are prepared with non-Government funds, persons desiring copies may be required to pay a reasonable fee to cover printing and similar costs.

(2) The nonvoting member reviews all official committee minutes to assure their completeness and accuracy.

(3) The nonvoting member acts as a liaison between the committee and the interested persons whom that member represents, and transmits requests for information from the committee and relevant information and views to the committee. The nonvoting member takes the initiative in contacting interested persons whom the member represents to seek out relevant information and views and to relate the progress of the advisory committee.

(4) A nonvoting industry member represents all members of the industry, and not any particular association, company, product, or ingredient. If a matter comes before the committee that directly or indirectly affects the company employing the nonvoting industry member, the member shall so inform the committee but need not be absent during the discussion or decline to participate in the discussion. a nonvoting industry member may not discuss the company's position as such, but may discuss any matter in general terms. All presentations and discussions of scientific data and their interpretation on behalf of a company will occur in open session, except as provided in § 14.25(c).

(5) A nonvoting member of an advisory committee may not make any presentation to that advisory committee during a hearing conducted by that committee.

(6) Although a nonvoting member serves in a representative capacity, the nonvoting member shall exercise restraint in performing such functions and may not engage in unseemly advocacy or attempt to exert undue influence over the other members of the committee.

(d) A nonvoting member of an advisory committee may be removed by the Commissioner for failure to comply with this section as well as § 14.80(f).

§ 14.90 Ad hoc advisory committee members.

In selecting members of an ad hoc advisory committee, the Commissioner may use the procedures in §§ 14.82 and 14.84 or any other procedure deemed appropriate.

§ 14.95 Compensation of advisory committee members.

(a)(1) Except as provided in paragraphs (a) (2) and (3) of this section, all voting advisory committee members shall, and nonvoting members may, be appointed as special Government employees and receive a consultant fee and be reimbursed for travel expenses, including per diem in lieu of subsistence, unless such compensation and reimbursement are waived.

(2) Members of the Technical Electronic Product Radiation Safety Standards Committee (TEPRSSC) are not appointed as special Government employees. Any member of TEPRSSC who is not a Federal employee or member of the uniformed services, including the Commissioned Corps of the Public Health Service, shall receive a consultant fee and be reimbursed for travel expenses, including per diem in lieu of subsistence, unless such compensation and reimbursement are waived.

(3) Voting and nonvoting advisory committee members who are members of the uniformed services, including the Commissioned Corps of the Public Health Service, provide service on Food and Drug Administration advisory committees as part of their assigned functions, are not appointed as special government employees, but are reimbursed by the Food and Drug Administration for travel expenses.

(b) Notwithstanding the member's primary residence, an advisory committee member, while attending meetings of the full committee or a subcommittee, will be paid whether the meetings are held in the Washington, DC, area or elsewhere.

(c) A committee member who participates in any agency-directed assignment will be paid at an hourly rate when doing assigned work at home, a place of business, or in an FDA facility located within the member's commuting area, and at a daily rate when

required to travel outside of that commuting area to perform the assignment. A committee member will not be paid for time spent on normal preparation for a committee meeting.

(1) An agency-directed assignment is an assignment that meets the following criteria:

(i) An activity that requires undertaking a definitive study. The activity must produce a tangible end product, usually a written report. Examples are:

(*a*) An analysis of the risks and benefits of the use of a class of drugs or a report on a specific problem generated by an IND or NDA;

(*b*) The performance of similar investigations or analysis of complex industry submissions to support advisory committee deliberations other than normal meeting preparation;

(*c*) The preparation of a statistical analysis leading to an estimate of toxicologically safe dose levels; and

(*d*) The design or analysis of animal studies of toxicity, mutagenicity, teratogenicity, or carcinogenicity.

(ii) The performance of an IND or NDA review or similar review.

(2) A committee member who undertakes a special assignment, the end product of which does not represent the end product of the advisory committee, but rather of the committee member's own assignment, can be compensated. Should this preparatory work by members collectively result in an end product of the committee, this is to be considered normal meeting preparation and committee members are not to be compensated for this work.

(d) Salary while in travel status is authorized when a committee member's ordinary pursuits are interrupted for the substantial portion of an additional day beyond the day or days spent in performing those services, and as a consequence the committee member loses some regular compensation. This applies on weekends and holidays if the special Government employee loses income that would otherwise be earned on that day. For travel purposes, a substantial portion of a day is defined as 50 percent of the working day, and the traveler will be paid at a daily rate.

[44 FR 22351, Apr. 13, 1979, as amended at 53 FR 50949, Dec. 19, 1988]

Subpart F—Standing Advisory Committees

§ 14.100 List of standing advisory committees.

Standing advisory committees and the dates of their establishment are as follows:

(a) *Office of the Commissioner*—

(1) *Board of Tea Experts*.

(i) Date established: March 2, 1897.

(ii) Function: Advises on establishment of uniform standards of purity, quality, and fitness for consumption of all tea imported into the United States under 21 U.S.C. 42.

(2) *Science Board to the Food and Drug Administration*.

(i) Date established: June 26, 1992.

(ii) Function: The board shall provide advice primarily to the agency's Senior Science Advisor and, as needed, to the Commissioner and other appropriate officials on specific complex and technical issues as well as emerging issues within the scientific community in industry and academia. Additionally, the board will provide advice to the agency on keeping pace with technical and scientific evolutions in the fields of regulatory science; on formulating an appropriate research agenda; and on upgrading its scientific and research facilities to keep pace with these changes. It will also provide the means for critical review of agency sponsored intramural and extramural scientific research programs.

(3) *Pediatric Advisory Committee*.

(i) Date established: June 18, 2004.

(ii) Function: Advises on pediatric therapeutics, pediatric research, and other matters involving pediatrics for which the Food and Drug Administration has regulatory responsibility.

(4) *Risk Communication Advisory Committee*.

(i) Date rechartered: July 9, 2009.

(ii) Function: The committee reviews and evaluates strategies and programs designed to communicate with the public about the risks and benefits of FDA-regulated products so as to facilitate optimal use of these products. The committee also reviews and evaluates research relevant to such communication to the public by both FDA and

other entities. It also facilitates interactively sharing risk and benefit information with the public to enable people to make informed independent judgments about use of FDA-regulated products.

(5) *Tobacco Products Scientific Advisory Committee.*

(i) Date Established: August 12, 2009.

(ii) Function: The committee reviews and evaluates safety, dependence, and health issues relating to tobacco products and provides appropriate advice, information, and recommendations to the Commissioner of Food and Drugs. Specifically, the committee will submit reports and recommendations on tobacco-related topics, including: The impact of the use of menthol in cigarettes on the public health, including such use among children, African Americans, Hispanics and other racial and ethnic minorities; the nature and impact of the use of dissolvable tobacco products on the public health, including such use on children; the effects of the alteration of nicotine yields from tobacco products and whether there is a threshold level below which nicotine yields do not produce dependence on the tobacco product involved; and any application submitted by a manufacturer for a modified risk tobacco product. The committee may provide recommendations to the Secretary of Health and Human Services regarding any regulations to be issued under the Federal Food, Drug, and Cosmetic Act and may review any applications for new tobacco products or petitions for exemption under section 906(e) of the Family Smoking Prevention and Tobacco Control Act. The committee may consider and provide recommendations on any other matter as provided in the Family Smoking Prevention and Tobacco Control Act.

(b) *Center for Biologics Evaluation and Research—*

(1) *Allergenic Products Advisory Committee.*

(i) Date established: July 9, 1984.

(ii) Function: Reviews and evaluates data on the safety and effectiveness of allergenic biological products intended for use in the diagnosis, prevention, or treatment of human disease.

(2) *Cellular, Tissue and Gene Therapies Advisory Committee.*

(i) Date established: October 28, 1988.

(ii) Function: Reviews and evaluates available data relating to the safety, effectiveness, and appropriate use of human cells, human tissues, gene transfer therapies and xenotransplantation products which are intended for transplantation, implantation, infusion, and transfer in the prevention and treatment of a broad spectrum of human diseases and in the reconstruction, repair or replacement of tissues for various conditions. The Committee also considers the quality and relevance of FDA's research program which provides scientific support for the regulation of these products, and makes appropriate recommendations to the Commissioner of Food and Drugs.

(3) *Blood Products Advisory Committee.*

(i) Date established: May 13, 1980.

(ii) Function: Reviews and evaluates data on the safety and effectiveness, and appropriate use of blood products intended for use in the diagnosis, prevention, or treatment of human diseases.

(4) *Vaccines and Related Biological Products Advisory Committee—*

(i) Date established: December 31, 1979.

(ii) Function: Reviews and evaluates data on the safety and effectiveness of vaccines intended for use in the diagnosis, prevention, or treatment of human diseases.

(c) *Center for Drug Evaluation and Research—*

(1) *Anesthetic and Analgesic Drug Products Advisory Committee.*

(i) Date established: May 1, 1978.

(ii) *Function:* Reviews and evaluates data concerning the safety and effectiveness of marketed and investigational human drug products including analgesics, *e.g.*, abuse-deterrent opioids, novel analgesics, and issues related to opioid abuse, and those for use in anesthesiology.

(2) *Antimicrobial Drugs Advisory Committee.*

(i) Date established: October 7, 1980.

(ii) Function: Reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for

use in the treatment of infectious diseases and disorders.

(3) *Arthritis Advisory Committee.*

(i) Date established: April 5, 1974.

(ii) Function: Reviews and evaluates data on the safety and effectiveness of marketed and investigational human drugs for use in arthritic conditions.

(4) *Cardiovascular and Renal Drugs Advisory Committee.*

(i) Date established: August 27, 1970.

(ii) Function: Reviews and evaluates data on the safety and effectiveness of marketed and investigational human drugs for use in cardiovascular and renal disorders.

(5) *Dermatologic and Ophthalmic Drugs Advisory Committee.*

(i) Date established: October 7, 1980.

(ii) Function: Reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of dermatologic and ophthalmic disorders.

(6) *Drug Safety and Risk Management Advisory Committee.*

(i) Date established: May 31, 1978.

(ii) Function: Reviews and evaluates data on risk management plans, provides active surveillance methodologies, trademark studies, methodologies for risk management communication, and related issues.

(7) *Endocrinologic and Metabolic Drugs Advisory Committee.*

(i) Date established: August 27, 1970.

(ii) Function: Reviews and evaluates data on the safety and effectiveness of marketed and investigational human drugs for use in endocrine and metabolic disorders.

(8) *Bone, Reproductive and Urologic Drugs Advisory Committee.*

(i) Date established: March 23, 1978.

(ii) Function: Advises the Commissioner or designee in discharging responsibilities as they relate to helping to ensure safe and effective drugs for human use and, as required, any other product for which the Food and Drug Administration has regulatory responsibility.

(9) *Gastrointestinal Drugs Advisory Committee.*

(i) Date established: March 3, 1978.

(ii) Function: Reviews and evaluates data on the safety and effectiveness of marketed and investigational human drugs for use in gastrointestinal diseases.

(10) *Oncologic Drugs Advisory Committee.*

(i) Date established: September 1, 1978.

(ii) Function: Reviews and evaluates data on the safety and effectiveness of marketed and investigational human drugs for use in treatment of cancer.

(11) *Peripheral and Central Nervous System Drugs Advisory Committee.*

(i) Date established: June 4, 1974.

(ii) Function: Reviews and evaluates data on the safety and effectiveness of marketed and investigational human drugs for use in neurological disease.

(12) *Psychopharmacologic Drugs Advisory Committee.*

(i) Date established: June 4, 1974.

(ii) Function: Reviews and evaluates data on the safety and effectiveness of marketed and investigational human drugs for use in the practice of psychiatry and related fields.

(13) *Pulmonary-Allergy Drugs Advisory Committee.*

(i) Date established: February 17, 1972.

(ii) Function: Reviews and evaluates data on the safety and effectiveness of marketed and investigational human drugs for use in the treatment of pulmonary disease and diseases with allergic and/or immunologic mechanisms.

(14) *Medical Imaging Drugs Advisory Committee.*

(i) Date established: May 18, 2011.

(ii) Function: Reviews and evaluates data concerning the safety and effectiveness of marketed and investigational human drug products for use in diagnostic and therapeutic procedures using radioactive pharmaceuticals and contrast media used in diagnostic radiology.

(15) *Pharmaceutical Science and Clinical Pharmacology Advisory Committee.*

(i) Date established: January 22, 1990.

(ii) Function: The committee shall provide advice on scientific, clinical and technical issues related to safety and effectiveness of drug products for use in the treatment of a broad spectrum of human diseases, the quality characteristics which such drugs purport or are represented to have and as required, any other product for which the Food and Drug Administration has

regulatory responsibility, and make appropriate recommendations to the Commissioner of Food and Drugs. The Committee may also review agency sponsored intramural and extramural biomedical research programs in support of FDA's drug regulatory responsibilities and its critical path initiatives related to improving the efficacy and safety of drugs and improving the efficiency of drug development.

(16) *Nonprescription Drugs Advisory Committee.*

(i) Date established: August 27, 1991.

(ii) Functions: The committee reviews and evaluates available data concerning the safety and effectiveness of over-the-counter (nonprescription) human drug products for use in the treatment of a broad spectrum of human symptoms and diseases.

(17) *Pharmacy Compounding Advisory Committee.*

(i) Date re-established: April 25, 2012.

(ii) Function: Provides advice on scientific, technical, and medical issues concerning drug compounding under sections 503A and 503B of the Federal Food, Drug, and Cosmetic Act and, as required, any other product for which the Food and Drug Administration has regulatory responsibility, and makes appropriate recommendations to the Commissioner of Food and Drugs.

(d) *Center for Devices and Radiological Health—*

(1) *Medical Devices Advisory Committee.*

(i) *Date established:* October 27, 1990.

(ii) *Function:* Reviews and evaluates data on the safety and effectiveness of marketed and investigational devices and makes recommendations for their regulation.

(2) *Device Good Manufacturing Practice Advisory Committee.*

(i) Date established: May 17, 1987.

(ii) Function: Reviews proposed regulations for good manufacturing practices governing the methods used in, and the facilities and controls used for, the manufacture, packing, storage, and installation of devices, and makes recommendations on the feasibility and reasonableness of the proposed regulations.

(3) *Technical Electronic Product Radiation Safety Standards Committee.*

(i) Date established: October 18, 1968.

(ii) Function: Advises on technical feasibility, reasonableness, and practicability of performance standards for electronic products to control the emission of radiation under 42 U.S.C. 263f(f)(1)(A).

(4) *National Mammography Quality Assurance Advisory Committee.*

(i) Date established: July 6, 1993.

(ii) Function: Advises on developing appropriate quality standards and regulations for the use of mammography facilities.

(5) *Patient Engagement Advisory Committee.*

(i) Date Established: October 6, 2015.

(ii) Function: Provides advice to the Commissioner on complex issues relating to medical devices, the regulation of devices, and their use by patients. Agency guidance and policies, clinical trial or registry design, patient preference study design, benefit-risk determinations, device labeling, unmet clinical needs, available alternatives, patient reported outcomes, and device-related quality of life or health status issues are among the topics that may be considered by the Committee. The Committee provides relevant skills and perspectives in order to improve communication of benefits, risks, and clinical outcomes, and increase integration of patient perspectives into the regulatory process for medical devices. It performs its duties by identifying new approaches, promoting innovation, recognizing unforeseen risks or barriers, and identifying unintended consequences that could result from FDA policy.

(e) *National Center for Toxicological Research—Science Advisory Board.*

(1) Date established: June 2, 1973.

(2) Function: Advises on establishment and implementation of a research program that will assist the Commissioner of Food and Drugs to fulfill regulatory responsibilities.

[54 FR 9036, Mar. 3, 1989]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting §14.100, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at *www.govinfo.gov.*

Subpart G—Technical Electronic Products Radiation Safety Standards Committee

§ 14.120 Establishment of the Technical Electronic Product Radiation Safety Standards Committee (TEPRSSC).

The Technical Electronic Product Radiation Safety Standards Committee (TEPRSSC), consisting of 15 members, is established in accordance with the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360kk(f)(1)(A)) to provide consultation before the Commissioner prescribes any performance standard for an electronic product.

[44 FR 22351, Apr. 13, 1979, as amended at 78 FR 17087, Mar. 20, 2013]

§ 14.122 Functions of TEPRSSC.

(a) In performing its function of advising the Commissioner, TEPRSSC—

(1) May propose electronic product radiation safety standards to the Commissioner for consideration;

(2) Provides consultation to the Commissioner on all performance standards proposed for consideration under 21 U.S.C. 360kk; and

(3) May make recommendations to the Commissioner on any other matters it deems necessary or appropriate in fulfilling the purposes of the act.

(b) Responsibility for action on performance standards under 21 U.S.C. 360kk rests with the Commissioner, after receiving the advice of TEPRSSC.

[44 FR 22351, Apr. 13, 1979, as amended at 78 FR 17087, Mar. 20, 2013]

§ 14.125 Procedures of TEPRSSC.

(a) When the Commissioner is considering promulgation of a performance standard for an electronic product, or an amendment of an existing standard, before issuing a proposed regulation in the FEDERAL REGISTER the Commissioner will submit to TEPRSSC the proposed standard or amendment under consideration, together with other relevant information to aid TEPRSSC in its deliberations.

(b) The agenda and other material to be considered at any meeting will be sent to members whenever possible at least 2 weeks before the meeting.

(c) Ten members constitute a quorum, provided at least three members are present from each group specified in 21 U.S.C. 360kk(f)(1)(A) and in § 14.127(a), i.e., Government, industry, and the public.

(d) The Chairperson of TEPRSSC will ordinarily submit a report to the Commissioner of the committee's consideration of any proposed performance standard for an electronic product within 60 days after consideration. If the Chairperson believes that more time is needed, the Chairperson will inform the Director of the Center for Devices and Radiological Health in writing, in which case an additional 30 days will be allowed to make the report.

(e) Sections 14.1 through 14.7 apply to TEPRSSC, except where other provisions are specifically included in §§ 14.120 through 14.130.

[44 FR 22351, Apr. 13, 1979, as amended at 54 FR 9037, Mar. 3, 1989; 78 FR 17087, Mar. 20, 2013]

§ 14.127 Membership of TEPRSSC.

(a) The Commissioner will appoint the members after consultation with public and private organizations concerned with the technical aspect of electronic product radiation safety. TEPRSSC consists of 15 members, each of whom is technically qualified by training and experienced in one or more fields of science or engineering applicable to electronic product radiation safety, as follows:

(1) Five members selected from government agencies, including State and Federal Governments.

(2) Five members selected from the affected industries after consultation with industry representatives.

(3) Five members selected from the general public, of whom at least one shall be a representative of organized labor.

(b) The Commissioner will appoint a committee member as Chairperson of TEPRSSC.

(c) Appointments of members are for a term of 3 years or as specified by the Commissioner.

(1) The Chairperson is appointed for a term concurrent with the Chairperson's term as a member of TEPRSSC. If the Chairpersonship becomes vacant without adequate notice,

the Designated Federal Officer may appoint a committee member as temporary Chairperson pending appointment of a new Chairperson by the Commissioner.

(2) Members may not be reappointed for a second consecutive full term.

(d) A person otherwise qualified for membership is not eligible for selection as a member of TEPRSSC from Government agencies or the general public if the Commissioner determines that the person does not meet the requirements of the conflict of interest laws and regulations.

(e) Retention of membership is conditioned upon the following:

(1) Continued status as a member of the group from which the member was selected as specified in paragraph (a) of this section.

(2) Absence of any conflict of interest during the term of membership as specified in paragraph (d) of this section.

(3) Active participation in TEPRSSC activities.

(f) Appointment as a member of TEPRSSC is conditioned on certification that the prospective member:

(1) Agrees to the procedures and criteria specified in this subpart.

(2) Has no conflict of interest as specified in paragraph (d) of this section.

(3) Will notify the Designated Federal Officer of TEPRSSC before any change in representative status on TEPRSSC which may be contrary to the conditions of the appointment.

(g) Members of TEPRSSC who are not full-time officers or employees of the United States receive compensation under § 14.95, in accordance with 42 U.S.C. 210(c).

§ 14.130 Conduct of TEPRSSC meeting; availability of TEPRSSC records.

(a) In accordance with 21 U.S.C. 360kk(f)(1)(B), all proceedings of TEPRSSC are recorded, and the record of each proceeding is available for public inspection.

(b) All proceedings of TEPRSSC are open except when the Commissioner has determined, under § 14.27, that a portion of a meeting may be closed.

[44 FR 22351, Apr. 13, 1979, as amended at 78 FR 17087, Mar. 20, 2013]

Subpart H—Color Additive Advisory Committees

§ 14.140 Establishment of a color additive advisory committee.

The Commissioner will establish a color additive advisory committee under the following circumstances:

(a) The Commissioner concludes, as a matter of discretion, that it would be in the public interest for a color additive advisory committee to review and make recommendations about the safety of a color additive on which important issues are pending before FDA and for interested persons to present information and views at an oral public hearing before a color additive advisory committee.

(b) There is an issue arising under section 721(b)(5)(B) of the FD&C Act concerning the safety of a color additive, including its potential or actual carcinogenicity, that requires the exercise of scientific judgment and a person who would be adversely affected by the issuance, amendment, or repeal of a regulation listing a color additive requests that the matter, or the Commissioner as a matter of discretion determines that the matter should, be referred to a color additive advisory committee.

(1) Paragraph (b) does not apply to any issue arising under the transitional provisions in section 203 of the Color Additive Amendments of 1960 relating to provisional listing of commercially established colors. A color additive advisory committee to consider any such matter will be established under paragraph (a) of this section.

(2) A request for establishment of a color additive advisory committee is to be made in accordance with § 10.30. The Commissioner may deny any petition if inadequate grounds are stated for establishing a color additive advisory committee. A request for establishment of a color additive advisory committee may not rest on mere allegations or denials, but must set forth specific facts showing that there is a genuine and substantial issue of fact that requires scientific judgment and justifies a hearing before a color additive advisory committee. When it conclusively appears from the request for a

color additive advisory committee that the matter is premature or that it does not involve an issue arising under section 721(b)(5)(B) of the FD&C Act or that there is no genuine and substantial issue of fact requiring scientific judgment, or for any other reason a color additive advisory committee is not justified, the Commissioner may deny the establishment of a color additive advisory committee.

(3) Establishment of a color additive advisory committee on the request of an interested person is conditioned upon receipt of the application fee specified in § 14.155.

(4) Any person adversely affected may request referral of the matter to a color additive advisory committee at any time before, or within 30 days after, publication of an order of the Commissioner acting upon a color additive petition or proposal.

§ 14.142 Functions of a color additive advisory committee.

(a) A color additive advisory committee reviews all available information relating to the matter referred to it, including all information contained in any pertinent color additive petition and in FDA files. All information reviewed is placed on public display and is available for review at the office of the Division of Dockets Management.

(b) The Commissioner specifies to the color additive advisory committee, in writing, the issues on which review and recommendations are requested.

(c) The date of the first meeting of a color additive advisory committee, following receipt of the administrative record by each of the committee members, is designated as the beginning of the period allowed for consideration of the matter by the committee. Within 60 days after the first meeting, unless the time is extended as provided in paragraph (d) of this section, the Chairperson of the committee shall certify to the Commissioner the report containing the recommendations of the committee, including any minority report. The report states the recommendations of the committee and the reasons or basis for them. The report includes copies of all material considered by the committee in addition to the administrative record furnished to it.

(d) If the Chairperson concludes that the color additive advisory committee needs additional time, the Chairperson shall so inform the Commissioner in writing and may certify the report of the committee to the Commissioner within 90 days instead of 60 days.

(e) More than one matter may be handled concurrently by a color additive advisory committee.

§ 14.145 Procedures of a color additive advisory committee.

(a) A color additive advisory committee is subject to all the requirements of the Federal Advisory Committee Act and this part.

(b) All interested persons have a right to consult with the color additive advisory committee reviewing a matter and to submit information and views to a color additive advisory committee, in accordance with the procedures in this part.

§ 14.147 Membership of a color additive advisory committee.

(a) The members of a color additive advisory committee are selected in the following manner:

(1) If a color additive advisory committee is established for purposes that do not include review of an issue arising under section 721(b)(5)(B) of the act, or is established on the initiative of the Commissioner, the Commissioner may use the procedure in paragraph (a)(2) of this section to select the members or may use an existing standing advisory committee listed in § 14.100, or may establish a new advisory committee under this subpart. Once the Commissioner has established a color additive advisory committee under this paragraph and has referred to it a matter relating to a color additive, no interested person may subsequently request that an additional or different color additive advisory committee be established to review and make recommendations about that color additive.

(2) If the Commissioner established a color additive advisory committee to review an issue arising under section 721(b)(5)(B) of the FD&C Act on the request of an interested person, it shall

be established under the following requirements:

(i) Except as provided in paragraph (a)(2) (ii) and (iii) of this section, the Commissioner will request the National Academy of Sciences to select the members of a color additive advisory committee from among experts qualified in the subject matter to be reviewed by the committee, and of adequately diversified professional backgrounds. The Commissioner will appoint one of the members as the Chairperson.

(ii) If the National Academy of Sciences is unable or refuses to select the members of a color additive advisory committee, the Commissioner will select the members.

(iii) If the Commissioner and the requesting party agree, section 721(b)(5)(D) of the FD&C Act may be waived and the matter may be referred to any standing advisory committee listed in § 14.100 or to any advisory committee established under any other procedure that is mutually agreeable. Once the Commissioner has established a color additive advisory committee and has referred to it a matter relating to a color additive, no interested person may subsequently request that an additional or different color additive advisory committee be established to review and make recommendations about that color additive.

(b) Members of a color additive advisory committee are subject to the requirements of the Federal Advisory Committee Act and this subpart, except that no member of a color additive advisory committee may by reason of such membership alone be a special government employee or be subject to the conflict of interest laws and regulations.

§ 14.155 Fees and compensation pertaining to a color additive advisory committee.

(a) When a matter is referred to a color additive advisory committee, all related costs, including personal compensation of committee members, travel, materials, and other costs, are borne by the person requesting the referral, such costs to be assessed on the basis of actual cost to the government. The compensation of such costs includes personal compensation of committee members at a rate not to exceed $128.80 per member per day.

(b) In the case of a request for referral to a color additive advisory committee, a special advance deposit is to be made in the amount of $2,500. Where required, further advances in increments of $2,500 each are to be made upon request of the Commissioner. All deposits for referrals to a color additive advisory committee in excess of actual expenses will be refunded to the depositor.

(c) All deposits and fees required by this section are to be paid by money order, bank draft, or certified check drawn to the order of the Food and Drug Administration, collectible at par in Washington, DC. All deposits and fees are to be forwarded to the Associate Commissioner for Management and Operations, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, and after appropriate record of them is made, they will be transmitted to the Treasurer of the United States for deposit in the special account ''Salaries and Expenses, Certification, Inspection, and Other Services, Food and Drug Administration.''

(d) The Commissioner may waive or refund such fees in whole or in part when, in the Commissioner's judgment, such action will promote the public interest. Any person who believes that payment of these fees will be a hardship may petition the Commissioner under § 10.30 to waive or refund the fees.

Subpart I—Advisory Committees for Human Prescription Drugs

§ 14.160 Establishment of standing technical advisory committees for human prescription drugs.

The standing technical advisory committees for human prescription drugs are established to advise the Commissioner:

(a) Generally on the safety and effectiveness, including the labeling and advertising, and regulatory control of the human prescription drugs falling within the pharmacologic class covered by

the advisory committee and on the scientific standards appropriate for a determination of safety and effectiveness in that class of drugs.

(b) Specifically on any particular matter involving a human prescription drug pending before FDA, including whether the available information is adequate to support a determination that—

(1) A particular IND study may properly be conducted;

(2) A particular drug meets the statutory standard for proof of safety and effectiveness necessary for approval or continued approval for marketing; or

(3) A particular drug is properly classified as a new drug, an old drug, or a banned drug.

§ 14.171 Utilization of an advisory committee on the initiative of FDA.

(a) Any matter involving a human prescription drug under review within the agency may, in the discretion of the Commissioner, be the subject of a public hearing and continuing or periodic review by the appropriate standing technical advisory committee for human prescription drugs. The Commissioner's determinations on the agenda of the committee are based upon the priorities of the various matters pending before the agency which fall within the pharmacologic class covered by that committee.

(b) High priority for such hearing and review by the appropriate standing technical advisory committee for human prescription drugs are given to the following types of human prescription drugs:

(1) Investigational drugs which are potential therapeutic advances over currently marketed products from the standpoint of safety or effectiveness, or which pose significant safety hazards, or which present narrow benefit-risk considerations requiring a close judgmental decision on approval for marketing, or which have a novel delivery system or formulation, or which are the subject of major scientific or public controversy, or which may be subject to special regulatory requirements such as a limitation on clinical trials, a patient followup requirement, postmarketing Phase IV studies, distributional controls, or boxed warnings.

(2) Marketed drugs for which an important new use has been discovered or which pose newly discovered safety hazards, or which are the subject of major scientific or public controversy, or which may be subject to important regulatory actions such as withdrawal of approval for marketing, boxed warnings, distributional controls, or newly required scientific studies.

(c) The committee may request the Commissioner for an opportunity to hold a public hearing and to review any matter involving a human prescription drug which falls within the pharmacologic class covered by the committee. The Commissioner may, after consulting with the committee on such request, grant or deny the request in light of the priorities of the other matters pending before the committee. Whenever feasible, consistent with the other work of the committee, the request will be granted.

(d) For a drug that meets any of the criteria established in paragraph (b) of this section, one or more members of or consultants to the appropriate advisory committee may be selected for more detailed monitoring of the matter and consultation with FDA on behalf of the committee. The member or consultant may be invited to attend appropriate meetings and shall assist the center in any briefing of the committee on that matter.

(e) An advisory committee may obtain advice and recommendations from other agency advisory committees, consultants, and experts which the advisory committee and the center conclude would facilitate the work of the advisory committee.

(f) Presentation of all relevant information about the matter will be made in open session unless it relates to an IND the existence of which has not previously been disclosed to the public as defined in § 20.81 or is otherwise prohibited from public disclosure under part 20 and the regulations referenced therein. Sections 314.430 and 601.51 determine whether, and the extent to which, relevant information may be made available for public disclosure, summarized and discussed in open session but not otherwise made available for public

disclosure, or not in any way discussed or disclosed in open session or otherwise disclosed to the public.

[44 FR 22351, Apr. 13, 1979, as amended at 54 FR 9037, Mar. 3, 1989]

§ 14.172 Utilization of an advisory committee at the request of an interested person.

Any interested person may request, under § 10.30, that a specific matter relating to a particular human prescription drug be submitted to an appropriate advisory committee for a hearing and review and recommendations. The request must demonstrate the importance of the matter and the reasons why it should be submitted for a hearing at that time. The Commissioner may grant or deny the request.

§ 14.174 Advice and recommendations in writing.

Advice and recommendations given by a committee on a specific drug or a class of drugs are ordinarily in the form of a written report. The report may consist of the approved minutes of the meeting or a separate written report. The report responds to the specific issues or questions which the Commissioner has addressed to the advisory committee, and states the basis of the advice and recommendations of the committee.

PART 15—PUBLIC HEARING BEFORE THE COMMISSIONER

Subpart A—General Provisions

Sec.
15.1 Scope.

Subpart B—Procedures for Public Hearing Before the Commissioner

15.20 Notice of a public hearing before the Commissioner.
15.21 Notice of participation; schedule for hearing.
15.25 Written submissions.
15.30 Conduct of a public hearing before the Commissioner.

Subpart C—Records of a Public Hearing Before the Commissioner

15.40 Administrative record.
15.45 Examination of administrative record.

AUTHORITY: 5 U.S.C. 553; 15 U.S.C. 1451–1461; 21 U.S.C. 141–149, 321–393, 467f, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201, 262, 263b–263n, 264.

SOURCE: 44 FR 22366, Apr. 13, 1979, unless otherwise noted.

Subpart A—General Provisions

§ 15.1 Scope.

The procedures in this part apply when:

(a) The Commissioner concludes, as a matter of discretion, that it is in the public interest to permit persons to present information and views at a public hearing on any matter pending before the Food and Drug Administation.

(b) The act or regulation specifically provides for a public hearing before the Commissioner on a matter, e.g., § 330.10(a)(8) relating to over-the-counter drugs and sections 520 (b) and (f)(1)(B), and 521 of the act relating to proposals to allow persons to order custom devices, to proposed device good manufacturing practice regulations, and to proposed exemptions from preemption of State and local device requirements under § 808.25(e).

(c) A person who has right to an opportunity for a formal evidentiary public hearing under part 12 waives that opportunity and instead requests under § 12.32 a public hearing before the Commissioner, and the Commissioner, as a matter of discretion, accepts the request.

Subpart B—Procedures for Public Hearing Before the Commissioner

§ 15.20 Notice of a public hearing before the Commissioner.

(a) If the Commissioner determines that a public hearing should be held on a matter, the Commissioner will publish a notice of hearing in the FEDERAL REGISTER setting forth the following information:

(1) If the hearing is under § 15.1 (a) or (b), the notice will state the following:

(i) The purpose of the hearing and the subject matter to be considered. If a written document is to be the subject matter of the hearing, it will be published as part of the notice, or reference made to it if it has already been published in the FEDERAL REGISTER, or

the notice will state that the document is available from an agency office identified in the notice.

(ii) The time, date, and place of the hearing, or a statement that the information will be contained in a subsequent notice.

(2) If the hearing is in lieu of a formal evidentiary public hearing under § 15.1(c), all of the information described in § 12.32(e).

(b) The scope of the hearing is determined by the notice of hearing and any regulation under which the hearing is held. If a regulation, e.g., § 330.10(a)(10), limits a hearing to review of an existing administrative record, information not already in the record may not be considered at the hearing.

(c) The notice of hearing may require participants to submit the text of their presentations in advance of the hearing if the Commissioner determines that advance submissions are necessary for the panel to formulate useful questions to be posed at the hearing under § 15.30(e). The notice may provide for the submission of a comprehensive outline as an alternative to the submission of the text if the Commissioner determines that submission of an outline will be sufficient.

[44 FR 22366, Apr. 13, 1979, as amended at 47 FR 26375, June 18, 1982]

§ 15.21 Notice of participation; schedule for hearing.

(a) The notice of hearing will provide persons an opportunity to file a written notice of participation with the Division of Dockets Management within a specified period of time containing the information specified in the notice, e.g., name of participant, address, phone number, affiliation, if any, topic of presentation and approximate amount of time requested for the presentation. If the public interest requires, e.g., a hearing is to be conducted within a short period of time or is to be primarily attended by individuals without an organizational affiliation, the notice may name a specific FDA employee and telephone number to whom an oral notice of participation may be given or provide for submitting notices of participation at the time of the hearing. A written or oral notice of participation must be received by the designated person by the close of business of the day specified in the notice.

(b) Promptly after expiration of the time for filing a notice, the Commissioner will determine the amount of time allotted to each person and the approximate time that oral presentation is scheduled to begin. If more than one hearing is held on the same subject, a person will ordinarily be allotted time for a presentation at only one hearing.

(c) Individuals and organizations with common interests are urged to consolidate or coordinate their presentations and to request time for a joint presentation. The Commissioner may require joint presentations by persons with common interests.

(d) The Commissioner will prepare a hearing schedule showing the persons making oral presentations and the time alloted to each person, which will be filed with the Division of Dockets Management and mailed or telephoned before the hearing to each participant.

(e) The hearing schedule will state whether participants must be present by a specified time to be sure to be heard in case the absence of participants advances the schedule.

§ 15.25 Written submissions.

A person may submit information or views on the subject of the hearing in writing to the Division of Dockets Management, under § 10.20. The record of the hearing will remain open for 15 days after the hearing is held for any additional written submissions, unless the notice of the hearing specifies otherwise or the presiding officer rules otherwise.

§ 15.30 Conduct of a public hearing before the Commissioner.

(a) The Commissioner or a designee may preside at the hearing, except where a regulation provides that the Commissioner will preside personally. The presiding officer may be accompanied by other FDA employees or other Federal Government employees designated by the Commissioner, who may serve as a panel in conducting the hearing.

(b) The hearing will be transcribed.

(c) Persons may use their alloted time in whatever way they wish, consistent with a reasonable and orderly hearing. A person may be accompanied by any number of additional persons, and may present any written information or views for inclusion in the record of the hearing, subject to the requirements of § 15.25. The presiding officer may allot additional time to any person when the officer concludes that it is in the public interest, but may not reduce the time allotted for any person without the consent of the person.

(d) If a person is not present at the time specified for the presentation, the persons following will appear in order, with adjustments for those appearing at their scheduled time. An attempt will be made to hear any person who is late at the conclusion of the hearing. Other interested persons attending the hearing who did not request an opportunity to make an oral presentation will be given an opportunity to make an oral presentation at the conclusion of the hearing, in the discretion of the presiding officer, to the extent that time permits.

(e) The presiding officer and any other persons serving on a panel may question any person during or at the conclusion of the presentation. No other person attending the hearing may question a person making a presentation. The presiding officer may, as a matter of discretion, permit questions to be submitted to the presiding officer or panel for response by them or by persons attending the hearing.

(f) The hearing is informal in nature, and the rules of evidence do not apply. No motions or objections relating to the admissibility of information and views may be made or considered, but other participants may comment upon or rebut all such information and views. No participant may interrupt the presentation of another participant at any hearing for any reason.

(g) The hearing may end early only if all persons scheduled for a later presentation have already appeared or it is past the time specified in the hearing schedule, under § 15.21(e), by which participants must be present.

(h) The Commissioner or the presiding officer may, under § 10.19, suspend, modify, or waive any provision of this part.

Subpart C—Records of a Public Hearing Before the Commissioner

§ 15.40 Administrative record.

(a) The administrative record of a public hearing before the Commissioner consists of the following:

(1) All relevant FEDERAL REGISTER notices, including any documents to which they refer.

(2) All written submissions under § 15.25.

(3) The transcript of the oral hearing.

(b) The record of the administrative proceeding will be closed at the time specified in § 15.25.

§ 15.45 Examination of administrative record.

Section 10.20(j) governs the availability for public examination and copying of each document in the administrative record of the hearing

PART 16—REGULATORY HEARING BEFORE THE FOOD AND DRUG ADMINISTRATION

Subpart A—General Provisions

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16.120 Judicial review.

AUTHORITY: 15 U.S.C. 1451–1461; 21 U.S.C. 141–149, 321–394, 467f, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201–262, 263b, 364.

SOURCE: 44 FR 22367, Apr. 13, 1979, unless otherwise noted.

Subpart A—General Provisions

§ 16.1 Scope.

The procedures in this part apply when:

(a) The Commissioner is considering any regulatory action, including a refusal to act, and concludes, as a matter of discretion, on the Commissioner's initiative or at the suggestion of any person, to offer an opportunity for a regulatory hearing to obtain additional information before making a decision or taking action.

(b) The act or a regulation provides a person with an opportunity for a hearing on a regulatory action, including proposed action, and the act or a regulation either specifically provides an opportunity for a regulatory hearing under this part or provides an opportunity for a hearing for which no procedures are specified by regulation. Listed below are the statutory and regulatory provisions under which regulatory hearings are available:

(1) Statutory provisions:

Section 304(g) of the act relating to the administrative detention of devices and drugs (see §§ 800.55(g) and 1.980(g) of this chapter).

Section 304(h) of the act relating to the administrative detention of food for human or animal consumption (see part 1, subpart k of this chapter).

Section 419(c)(2)(D) of the Federal Food, Drug, and Cosmetic Act relating to the modification or revocation of a variance from the requirements of section 419 (see part 112, subpart P of this chapter).

Section 515(e)(1) of the act relating to the proposed withdrawal of approval of a device premarket approval application.

Section 515(e)(3) of the act relating to the temporary suspension of approval of a premarket approval application.

Section 515(f)(6) of the act relating to a proposed order revoking a device product development protocol or declaring a protocol not completed.

Section 515(f)(7) of the act relating to revocation of a notice of completion of a product development protocol.

Section 516(b) of the act regarding a proposed regulation to ban a medical device with a special effective date.

Section 518(b) of the act relating to a determination that a device is subject to a repair, replacement, or refund order or that a correction plan, or revised correction plan, submitted by a manufacturer, importer, or distributor is inadequate.

Section 518(e) of the act relating to a cease distribution and notification order or mandatory recall order concerning a medical device for human use.

Section 520(f)(2)(D) of the act relating to exemptions or variances from device current good manufacturing practice requirements (see § 820.1(d)).

Section 520(g)(4) and (g)(5) of the act relating to disapproval and withdrawal of approval of an application from an investigational device exemption (see §§ 812.19(c), 812.30(c), 813.30(d), and 813.35(c) of this chapter).

Section 903(a)(8)(B)(ii) of the Federal Food, Drug, and Cosmetic Act relating to the misbranding of tobacco products.

Section 906(e)(1)(B) of the Federal Food, Drug, and Cosmetic Act relating to the establishment of good manufacturing practice requirements for tobacco products.

Section 910(d)(1) of the Federal Food, Drug, and Cosmetic Act relating to the withdrawal of an order allowing a new tobacco product to be introduced or delivered for introduction into interstate commerce.

Section 911(j) of the Federal Food, Drug, and Cosmetic Act relating to the withdrawal of an order allowing a modified risk tobacco product to be introduced or delivered for introduction into interstate commerce.

(2) Regulatory provisions:

§§ 1.634 and 1.664, relating to revocation of recognition of an accreditation body and withdrawal of accreditation of third-party certification bodies that conduct food safety audits of eligible entities in the food import supply chain and issue food and facility certifications.

§ 56.121(a), relating to disqualifying an institutional review board or an institution.

§ 58.204(b), relating to disqualifying a testing facility.

§ 71.37(a), relating to use of food containing a color additive.

§ 80.31(b), relating to refusal to certify a batch of a color additive.
§ 80.34(b), relating to suspension of certification service for a color additive.
§ 99.401(c), relating to a due diligence determination concerning the conduct of studies necessary for a supplemental application for a new use of a drug or device.
§§ 112.201 through 112.213, (see part 112, subpart R of this chapter), relating to withdrawal of a qualified exemption.
§§ 117.251 through 117.287 (part 117, subpart E of this chapter), relating to withdrawal of a qualified facility exemption.
§ 130.17(1), relating to a temporary permit to vary from a food standard.
§ 170.17(b), relating to use of food containing an investigational food additive.
§ 202.1(j)(5), relating to approval of prescription drug advertisements.
§ 312.70, relating to whether an investigator is eligible to receive test articles under part 312 of this chapter and eligible to conduct any clinical investigation that supports an application for a research or marketing permit for products regulated by FDA, including drugs, biologics, devices, new animal drugs, foods, including dietary supplements, that bear a nutrient content claim or a health claim, infant formulas, food and color additives, and tobacco products.
§ 312.70(d) and 312.44, relating to termination of an IND for a sponsor.
§ 312.160(b), relating to termination of an IND for tests in vitro and in laboratory research animals for a sponsor.
§§ 507.60 through 507.85 (part 507, subpart D of this chapter) relating to withdrawal of a qualified facility exemption.
§ 511.1(b)(5), relating to use of food containing an investigational new animal drug.
§ 511.1 (c)(1), relating to whether an investigator is eligible to receive test articles under part 511 of this chapter and eligible to conduct any clinical investigation that supports an application for a research or marketing permit for products regulated by FDA including drugs, biologics, devices, new animal drugs, foods, including dietary supplements, that bear a nutrient content claim or a health claim, infant formulas, food and color additives, and tobacco products; and any nonclinical laboratory study intended to support an application for a research or marketing permit for a new animal drug.
§ 511.1(c) (4) and (d), relating to termination of an INAD for a sponsor.
§ 812.119, relating to whether an investigator is eligible to receive test articles under part 812 of this chapter and eligible to conduct any clinical investigation that supports an application for a research or marketing permit for products regulated by FDA including drugs, biologics, devices, new animal drugs, foods, including dietary supplements, that bear a nutrient content claim or a health claim, infant formulas, food and color additives, and tobacco products.
§ 814.46(c) relating to withdrawal of approval of a device premarket approval application.
§ 822.7(a)(3), relating to an order to conduct postmarket surveillance of a medical device under section 522 of the act.
§ 830.130, relating to suspension or revocation of the accreditation of an issuing agency.
§ 895.30(c), regarding a proposed regulation to ban a medical device with a special effective date.
§ 900.7, relating to approval, reapproval, or withdrawal of approval of mammography accreditation bodies or rejection of a proposed fee for accreditation.
§ 900.14, relating to suspension or revocation of a mammography certificate.
§ 900.25, relating to approval or withdrawal of approval of certification agencies.
§ 1003.11(a)(3), relating to the failure of an electronic product to comply with an applicable standard or to a defect in an electronic product.
§ 1003.31(d), relating to denial of an exemption from notification requirements for an electronic product which fails to comply with an applicable standard or has a defect.
§ 1004.6, relating to plan for repurchase, repair, or replacement of an electronic product.
§ 1107.1(d), relating to rescission of an exemption from the requirement of demonstrating substantial equivalence for a tobacco product.
§ 1210.30, relating to denial, suspension, or revocation of a permit under the Federal Import Milk Act.
§ 1270.43(e), relating to the retention, recall, and destruction of human tissue.
§ 1271.440(e) relating to the retention, recall, and destruction of human cells, tissues, and cellular and tissue-based products (HCT/Ps), and/or the cessation of manufacturing HCT/Ps.

[44 FR 22367, Apr. 13, 1979]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 16.1, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at *www.govinfo.gov*.

§ 16.5 Inapplicability and limited applicability.

(a) This part does not apply to the following:

(1) Informal presentation of views before reporting a criminal violation under section 305 of the act and section 5 of the Federal Import Milk Act and § 1210.31.

(2) A hearing on a refusal of admission of a food, drug, device, or cosmetic under section 801(a) of the act and §1.94, or of an electronic product under section 360(a) of the Public Health Service Act and §1005.20.

(3) Factory inspections, recalls (except mandatory recalls of medical devices intended for human use), regulatory letters, and similar compliance activities related to law enforcement.

(4) A hearing on an order for relabeling, diversion, or destruction of shell eggs under section 361 of the Public Health Service Act (42 U.S.C. 264) and §§101.17(h) and 115.50 of this chapter.

(5) A hearing on an order for diversion or destruction of shell eggs under section 361 of the Public Health Service Act (42 U.S.C. 264), and §118.12 of this chapter.

(b) If a regulation provides a person with an opportunity for hearing and specifies some procedures for the hearing but not a comprehensive set of procedures, the procedures in this part apply to the extent that they are supplementary and not in conflict with the other procedures specified for the hearing. Thus, the procedures in subpart A of part 108 relating to emergency permit control are supplemented by the nonconflicting procedures in this part, e.g., the right to counsel, public notice of the hearing, reconsideration and stay, and judicial review.

[44 FR 22367, Apr. 13, 1979, as amended at 57 FR 58403, Dec. 10, 1992; 65 FR 76110, Dec. 5, 2000; 74 FR 33095, July 9, 2009]

Subpart B—Initiation of Proceedings

§ 16.22 Initiation of regulatory hearing.

(a) A regulatory hearing is initiated by a notice of opportunity for hearing from FDA. The notice will—

(1) Be sent by mail, telegram, telex, personal delivery, or any other mode of written communication;

(2) Specify the facts and the action that are the subject of the opportunity for a hearing;

(3) State that the notice of opportunity for hearing and the hearing are governed by this part; and

(4) State the time within which a hearing may be requested, and state the name, address, and telephone number of the FDA employee to whom any request for hearing is to be addressed.

(5) Refer to FDA's guideline on electronic media coverage of its administrative proceedings (21 CFR part 10, subpart C).

(b) A person offered an opportunity for a hearing has the amount of time specified in the notice, which may not be less than 3 working days after receipt of the notice, within which to request a hearing. The request may be filed by mail, telegram, telex, personal delivery, or any other mode of written communication, addressed to the designated FDA employee. If no response is filed within that time, the offer is deemed to have been refused and no hearing will be held.

(c) If a hearing is requested, the Commissioner will designate a presiding officer, and the hearing will take place at a time and location agreed upon by the party requesting the hearing, the FDA, and the presiding officer or, if agreement cannot be reached, at a reasonable time and location designated by the presiding officer.

(d) A notice of opportunity for hearing under this section will not operate to delay or stay any administrative action, including enforcement action by the agency unless the Commissioner, as a matter of discretion, determines that delay or a stay is in the public interest.

[44 FR 22367, Apr. 13, 1979, as amended at 49 FR 32173, Aug. 13, 1984]

§ 16.24 Regulatory hearing required by the act or a regulation.

(a) A regulatory hearing required by the act or a regulation under §16.1(b) will be initiated in the same manner as other regulatory hearings subject to the additional procedures in this section.

(b) [Reserved]

(c) The notice will state whether any action concerning the matter that is the subject of the opportunity for hearing is or is not being taken pending the hearing under paragraph (d) of this section.

(d) The Commissioner may take such action pending a hearing under this

section as the Commissioner concludes is necessary to protect the public health, except where expressly prohibited by statute or regulation. A hearing to consider action already taken, and not stayed by the Commissioner, will be conducted on an expedited basis.

(e) The hearing may not be required to be held at a time less than 2 working days after receipt of the request for hearing.

(f) Before the hearing, FDA will give to the party requesting the hearing reasonable notice of the matters to be considered at the hearing, including a comprehensive statement of the basis for the decision or action taken or proposed that is the subject of the hearing and a general summary of the information that will be presented by FDA at the hearing in support of the decision or action. This information may be given orally or in writing, in the discretion of FDA.

(g) FDA and the party requesting the hearing will, if feasible, at least 1 day before the hearing provide to each other written notice of any published articles or written information to be presented at or relied on at the hearing. A copy will also be provided in advance if the other participant could not reasonably be expected to have or be able to obtain a copy. If written notice or a copy is not provided, the presiding officer may, if time permits, allow the party who did not receive the notice or copy additional time after the close of the hearing to make a submission concerning the article or information.

[44 FR 22367, Apr. 13, 1979, as amended at 47 FR 26375, June 18, 1982; 54 FR 9037, Mar. 3, 1989]

§ 16.26 Denial of hearing and summary decision.

(a) A request for a hearing may be denied, in whole or in part, if the Commissioner or the FDA official to whom authority is delegated to make the final decision on the matter determines that no genuine and substantial issue of fact has been raised by the material submitted. If the Commissioner or his or her delegate determines that a hearing is not justified, written notice of the determination will be given to the parties explaining the reason for denial.

(b) After a hearing commences, the presiding officer may issue a summary decision on any issue in the hearing if the presiding officer determines from the material submitted in connection with the hearing, or from matters officially noticed, that there is no genuine and substantial issue of fact respecting that issue. For the purpose of this paragraph, a hearing commences upon the receipt by FDA of a request for hearing submitted under § 16.22(b).

(c) The Commissioner or his or her delegate may review any summary decision of the presiding officer issued under paragraph (b) of this section at the request of a party or on the Commissioner's or his or her delegate's own initiative.

[53 FR 4615, Feb. 17, 1988, as amended at 69 FR 17290, Apr. 2, 2004]

Subpart C—Commissioner and Presiding Officer

§ 16.40 Commissioner.

Whenever the Commissioner has delegated authority on a matter for which a regulatory hearing is available under this part, the functions of the Commissioner under this part may be performed by any of the officials to whom the authority has been delegated, e.g., a center director.

[69 FR 17290, Apr. 2, 2004]

§ 16.42 Presiding officer.

(a) An FDA employee to whom the Commissioner delegates such authority, or any other agency employee designated by an employee to whom such authority is delegated, or, consistent with 5 CFR 930.209(b) or (c), an administrative law judge to whom such authority is delegated, may serve as the presiding officer and conduct a regulatory hearing under this part.

(b) In a regulatory hearing required by the act or a regulation, the presiding officer is to be free from bias or prejudice and may not have participated in the investigation or action that is the subject of the hearing or be subordinate to a person, other than the Commissioner, who has participated in such investigation or action.

(c)(1) The Commissioner or the delegate under § 16.40 is not precluded by this section from prior participation in the investigation or action that is the subject of the hearing. If there has been prior participation, the Commissioner or the delegate should, if feasible, designate a presiding officer for the hearing who is not a subordinate. Thus, if the Commissioner's authority to make a final decision has been delegated to a center director, the presiding officer may be an official in another center or the office of the Commissioner. The exercise of general supervisory responsibility, or the designation of the presiding officer, does not constitute prior participation in the investigation or action that is the subject of the hearing so as to preclude the Commissioner or delegate from designating a subordinate as the presiding officer.

(2) The party requesting a hearing may make a written request to have the Commissioner or the delegate under § 16.40 be the presiding officer, notwithstanding paragraph (c)(1) of this section. If accepted, as a matter of discretion, by the Commissioner or the delegate, the request is binding upon the party making the request.

(3) A different presiding officer may be substituted for the one originally designated under § 16.22 without notice to the parties.

[44 FR 22367, Apr. 13, 1979, as amended at 54 FR 9037, Mar. 3, 1989; 67 FR 53306, Aug. 15, 2002]

§ 16.44 Communication to presiding officer and Commissioner.

(a) Regulatory hearings are not subject to the separation of functions rules in § 10.55.

(b) Those persons who are directly involved in the investigation or presentation of the position of FDA or any party at a regulatory hearing that is required by the act or a regulation should avoid any off-the-record communication on the matter to the presiding officer or the Commissioner or their advisors if the communication is inconsistent with the requirement of § 16.95(b)(1) that the administrative record be the exclusive record for decision. If any communication of this type occurs, it is to be reduced to writing and made part of the record, and the other party provided an opportunity to respond.

(c) A copy of any letter or memorandum of meeting between a participant in the hearing and the presiding officer or the Commissioner, e.g., a response by the presiding officer to a request for a change in the time of the hearing, is to be sent to all participants by the person writing the letter or the memorandum.

Subpart D—Procedures for Regulatory Hearing

§ 16.60 Hearing procedure.

(a) A regulatory hearing is public, except when the Commissioner determines that all or part of a hearing should be closed to prevent a clearly unwarranted invasion of personal privacy; to prevent the disclosure of a trade secret or confidential commercial or financial information that is not available for public disclosure under § 20.61; or to protect investigatory records complied for law enforcement purposes that are not available for public disclosure under § 20.64.

(1) The Commissioner may determine that a regulatory hearing is closed either on the Commissioner's initiative or on a request by the party asking for a regulatory hearing, in the request for the hearing.

(2) If the hearing is a private hearing, no persons other than the party requesting the hearing, counsel and witnesses, and an employee or consultant or other person subject to a commercial arrangement as defined in § 20.81(a) and FDA representatives with a direct professional interest in the subject matter of the proceeding are entitled to attend.

(b) A regulatory hearing will be conducted by a presiding officer. Employees of FDA will first give a full and complete statement of the action which is the subject of the hearing, together with the information and reasons supporting it, and may present any oral or written information relevant to the hearing. The party requesting the hearing may then present any oral or written information relevant to the hearing. All parties may confront and conduct reasonable cross-

examination of any person (except for the presiding officer and counsel for the parties) who makes any statement on the matter at the hearing.

(c) The hearing is informal in nature, and the rules of evidence do not apply. No motions or objections relating to the admissibility of information and views will be made or considered, but any other party may comment upon or rebut all such data, information, and views.

(d) The presiding officer may order the hearing to be transcribed. The party requesting the hearing may have the hearing transcribed, at the party's expense, in which case a copy of the transcript is to be furnished to FDA. Any transcript of the hearing will be included with the presiding officer's report of the hearing.

(e) The presiding officer shall prepare a written report of the hearing. All written material presented at the hearing will be attached to the report. Whenever time permits, the parties to the hearing will be given the opportunity to review and comment on the presiding officer's report of the hearing.

(f) The presiding officer shall include as part of the report of the hearing a finding on the credibility of witnesses (other than expert witnesses) whenever credibility is a material issue, and shall include a recommended decision, with a statement of reasons, unless the Commissioner directs otherwise.

(g) The presiding officer has the power to take such actions and make such rulings as are necessary or appropriate to maintain order and to conduct a fair, expeditious, and impartial hearing, and to enforce the requirements of this part concerning the conduct of hearings. The presiding officer may direct that the hearing be conducted in any suitable manner permitted by law and these regulations.

(h) The Commissioner or the presiding officer has the power under § 10.19 to suspend, modify, or waive any provision of this part.

[44 FR 22367, Apr. 13, 1979, as amended at 66 FR 6469, Jan. 22, 2001; 66 FR 12850, Mar. 1, 2001]

§ 16.62 Right to counsel.

Any party to a hearing under this part has the right at all times to be advised and accompanied by counsel.

Subpart E—Administrative Record and Decision

§ 16.80 Administrative record of a regulatory hearing.

(a) The administrative record of the regulatory hearing consists of the following:

(1) The notice of opportunity for hearing and the response.

(2) All written information and views submitted to the presiding officer at the hearing or after if specifically permitted by the presiding officer.

(3) Any transcript of the hearing.

(4) The presiding officer's report of the hearing and comments on the report under § 16.60(e).

(5) All letters and memoranda of meetings or communications between participants and the presiding officer or the Commissioner referred to in § 16.44(c).

(b) The record of the regulatory hearing is closed to the submission of information and views, at the close of the hearing, unless the presiding officer specifically permits additional time for a further submission.

§ 16.85 Examination of administrative record.

Part 20 governs the availability for public disclosure of each document that is a part of the administrative record of a regulatory hearing.

§ 16.95 Administrative decision and record for decision.

(a) With respect to a regulatory hearing at the Commissioner's initiative under § 16.1(a), the Commissioner shall consider the administrative record of the hearing specified in § 16.80(a) together with all other relevant information and views available to FDA in determining whether regulatory action should be taken and, if so, in what form.

(b) With respect to a regulatory hearing required by the act or a regulation under § 16.1(b)—

(1) The administrative record of the hearing specified in § 16.80(a) constitutes the exclusive record for decision;

(2) On the basis of the administrative record of the hearing, the Commissioner shall issue a written decision stating the reasons for the Commissioner's administrative action and the basis in the record; and

(3) For purposes of judicial review under § 10.45, the record of the administrative proceeding consists of the record of the hearing and the Commissioner's decision.

Subpart F—Reconsideration and Stay

§ 16.119 Reconsideration and stay of action.

After any final administrative action that is the subject of a hearing under this part, any party may petition the Commissioner for reconsideration of any part or all of the decision or action under § 10.33 or may petition for a stay of the decision or action under § 10.35.

[44 FR 22367, Apr. 13, 1979, as amended at 54 FR 9037, Mar. 3, 1989]

Subpart G—Judicial Review

§ 16.120 Judicial review.

Section 10.45 governs the availability of judicial review concerning any regulatory action which is the subject of a hearing under this part

PART 17—CIVIL MONEY PENALTIES HEARINGS

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AUTHORITY: 21 U.S.C. 331, 333, 337, 351, 352, 355, 360, 360c, 360f, 360i, 360j, 371; 42 U.S.C. 262, 263b, 300aa–28; 5 U.S.C. 554, 555, 556, 557.

SOURCE: 60 FR 38626, July 27, 1995, unless otherwise noted.

EDITORIAL NOTE: Nomenclature changes to part 17 appear at 68 FR 24879, May 9, 2003.

§ 17.1 Scope.

This part sets forth practices and procedures for hearings concerning the administrative imposition of civil money penalties by FDA. Listed below are the statutory provisions that authorize civil money penalties that are governed by these procedures.

(a) Section 303(b)(2) and (b)(3) of the Federal Food, Drug, and Cosmetic Act (the act) authorizing civil money penalties for certain violations of the act that relate to prescription drug marketing practices.

(b) Section 303(f)(1) of the act authorizing civil money penalties for certain violations of the act that relate to medical devices and section 303(f)(2) of the act authorizing civil money penalties for certain violations of the act that relate to pesticide residues.

(c) Section 303(f)(3) of the act authorizing civil money penalties for certain violations relating to the submission of certifications and/or clinical trial information to the clinical trial data bank and section 303(f)(4) of the act authorizing civil money penalties for certain violations of the act relating to

postmarket studies, clinical trial requirements, and risk evaluation and mitigation strategies for drugs.

(d) Section 303(g)(1) of the act authorizing civil money penalties for certain violations of the act that relate to dissemination of direct-to-consumer advertisements for approved drugs or biological products.

(e) Section 307 of the act authorizing civil money penalties for certain actions in connection with an abbreviated new drug application or certain actions in connection with a person or individual debarred under section 306 of the act.

(f) Section 539(b)(1) of the act authorizing civil money penalties for certain violations of the act that relate to electronic products.

(g) Section 351(d)(2) of the Public Health Service Act (the PHS Act) authorizing civil money penalties for violations of biologic recall orders.

(h) Section 354(h)(3) of the PHS Act, as amended by the Mammography Quality Standards Act of 1992 and the Mammography Quality Standards Act of 1998, authorizing civil money penalties for failure to obtain a certificate and failure to comply with established standards, among other things.

(i) Section 2128(b)(1) of the PHS Act authorizing civil money penalties for intentionally destroying, altering, falsifying, or concealing any record or report required to be prepared, maintained, or submitted by vaccine manufacturers under section 2128 of the PHS Act.

(j) Section 303(f) of the act authorizing civil money penalties for any person who violates a requirement of the Family Smoking Prevention and Tobacco Control Act which relates to tobacco products.

[60 FR 38626, July 27, 1995, as amended at 69 FR 43301, July 20, 2004; 73 FR 66752, Nov. 12, 2008; 75 FR 73953, Nov. 30, 2010]

§ 17.2 Maximum penalty amounts.

The maximum civil money penalties associated with the statutory provisions authorizing civil money penalties under the Federal Food, Drug, and Cosmetic Act or the Public Health Service Act can be found at 45 CFR part 102. The table of these maximum civil money penalties can be found at 45 CFR 102.3.

[81 FR 62358, Sept. 9, 2016]

§ 17.3 Definitions.

The following definitions are applicable in this part:

(a) For specific acts giving rise to civil money penalty actions brought under 21 U.S.C. 333(f)(1):

(1) *Significant departure,* for the purpose of interpreting 21 U.S.C. 333(f)(1)(B)(i), means a departure from requirements that is either a single major incident or a series of incidents that collectively are consequential.

(2) *Knowing departure,* for the purposes of interpreting 21 U.S.C. 333(f)(1)(B)(i), means a departure from a requirement taken:

(i) With actual knowledge that the action is such a departure; or

(ii) In deliberate ignorance of a requirement; or

(ii) In reckless disregard of a requirement.

(3) *Minor violations,* for the purposes of interpreting 21 U.S.C. 333(f)(1)(B)(ii), means departures from requirements that do not rise to a level of a single major incident or a series of incidents that are collectively consequential.

(4) *Defective,* for the purposes of interpreting 21 U.S.C. 333(f)(1)(B)(iii), includes any defect in performance, manufacture, construction, components, materials, specifications, design, installation, maintenance, or service of a device, or any defect in mechanical, physical, or chemical properties of a device.

(b) *Person* or *respondent* includes an individual, partnership, corporation, association, scientific or academic establishment, government agency or organizational unit thereof, or other legal entity, or as may be defined in the act or regulation pertinent to the civil penalty action being brought.

(c) *Presiding officer* means an administrative law judge qualified under 5 U.S.C. 3105.

(d) Any term that is defined in the act has the same definition for civil money penalty actions that may be brought under that act.

(e) Any term that is defined in Title 21 of the Code of Federal Regulations has the same definition for civil money

penalty actions that may arise from the application of the regulation(s).

(f) Any term that is defined in the PHS Act has the same definition for civil money penalty actions that may be brought under that act.

(g) *Departmental Appeals Board (DAB)* means the Departmental Appeals Board of the Department of Health and Human Services.

[60 FR 38626, July 27, 1995, as amended at 82 FR 34402, July 25, 2017]

§ 17.5 Complaint.

(a) The Center with principal jurisdiction over the matter involved shall begin all administrative civil money penalty actions by serving on the respondent(s) a complaint signed by the Office of the Chief Counsel attorney for the Center and by filing a copy of the complaint with the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. For a civil money penalty action against retailers of tobacco products, the complaint may be signed by any Agency employee designated by the Chief Counsel.

(b) The complaint shall state:

(1) The allegations of liability against the respondent, including the statutory basis for liability, the identification of violations that are the basis for the alleged liability, and the reasons that the respondent is responsible for the violations;

(2) The amount of penalties and assessments that the Center is seeking;

(3) Instructions for filing an answer to request a hearing, including a specific statement of the respondent's right to request a hearing by filing an answer and to retain counsel to represent the respondent; and

(4) That failure to file an answer within 30 days of service of the complaint will result in the imposition of the proposed amount of penalties and assessments, as provided in § 17.11.

(c) The Center may, on motion, subsequently amend its complaint to conform with the evidence adduced during the administrative process, as justice may require.

(d) The presiding officer will be assigned to the case upon the filing of the complaint under this part.

[60 FR 38626, July 27, 1995, as amended at 79 FR 6091, Feb. 3, 2014]

§ 17.7 Service of complaint.

(a) Service of a complaint may be made by:

(1) Certified or registered mail or similar mail delivery service with a return receipt record reflecting receipt; or

(2) Delivery in person to:

(i) An individual respondent; or

(ii) An officer or managing or general agent in the case of a corporation or unincorporated business.

(b) Proof of service, stating the name and address of the person on whom the complaint was served, and the manner and date of service, may be made by:

(1) Affidavit or declaration under penalty of perjury of the individual serving the complaint by personal delivery;

(2) A United States Postal Service or similar mail delivery service return receipt record reflecting receipt; or

(3) Written acknowledgment of receipt by the respondent or by the respondent's counsel or authorized representative or agent.

§ 17.9 Answer.

(a) The respondent may request a hearing by filing an answer with the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, within 30 days of service of the complaint. Unless stated otherwise, an answer shall be deemed to be a request for hearing.

(b) In the answer, the respondent:

(1) Shall admit or deny each of the allegations of liability made in the complaint; allegations not specifically denied in an answer are deemed admitted;

(2) Shall state all defenses on which the respondent intends to rely;

(3) Shall state all reasons why the respondent contends that the penalties and assessments should be less than the requested amount; and

(4) Shall state the name, address, and telephone number of the respondent's counsel, if any.

(c) If the respondent is unable to file an answer meeting the requirements of paragraph (b) of this section within the time provided, the respondent shall, before the expiration of 30 days from service of the complaint, file a request for an extension of time within which to file an answer that meets the requirements of paragraph (b) of this section. The presiding officer may, for good cause shown, grant the respondent up to 30 additional days within which to file an answer that meets the requirements of paragraph (b) of this section.

(d) The respondent may, on motion, amend its answer to conform with the evidence as justice may require.

§ 17.11 Default upon failure to file an answer.

(a) If the respondent does not file an answer within the time prescribed in § 17.9 and if service has been effected as provided in § 17.7, the presiding officer shall assume the facts alleged in the complaint to be true, and, if such facts establish liability under the relevant statute, the presiding officer shall issue an initial decision within 30 days of the time the answer was due, imposing:

(1) The maximum amount of penalties provided for by law for the violations alleged; or

(2) The amount asked for in the complaint, whichever amount is smaller.

(b) Except as otherwise provided in this section, by failing to file a timely answer, the respondent waives any right to a hearing and to contest the amount of the penalties and assessments imposed under paragraph (a) of this section, and the initial decision shall become final and binding upon the parties 30 days after it is issued.

(c) If, before such a decision becomes final, the respondent files a motion seeking to reopen on the grounds that extraordinary circumstances prevented the respondent from filing an answer, the initial decision shall be stayed pending a decision on the motion.

(d) If, on such motion, the respondent can demonstrate extraordinary circumstances excusing the failure to file an answer in a timely manner, the presiding officer may withdraw the decision under paragraph (a) of this section, if such a decision has been issued, and shall grant the respondent an opportunity to answer the complaint as provided in § 17.9(a).

(e) If the presiding officer decides that the respondent's failure to file an answer in a timely manner is not excused, he or she shall affirm the decision under paragraph (a) of this section, and the decision shall become final and binding upon the parties 30 days after the presiding officer issues the decision on the respondent's motion filed under paragraph (c) of this section.

§ 17.13 Notice of hearing.

After an answer has been filed, the Center shall serve a notice of hearing on the respondent. Such notice shall include:

(a) The date, time, and place of a prehearing conference, if any, or the date, time, and place of the hearing if there is not to be a prehearing conference;

(b) The nature of the hearing and the legal authority and jurisdiction under which the hearing is to be held;

(c) A description of the procedures for the conduct of the hearing;

(d) The names, addresses, and telephone numbers of the representatives of the government and of the respondent, if any; and

(e) Such other matters as the Center or the presiding officer deems appropriate.

§ 17.15 Parties to the hearing.

(a) The parties to the hearing shall be the respondent and the Center(s) with jurisdiction over the matter at issue. No other person may participate.

(b) The parties may at any time prior to a final decision by the entity deciding any appeal agree to a settlement of all or a part of the matter. The settlement agreement shall be filed in the docket and shall constitute complete or partial resolution of the administrative case as so designated by the settlement agreement. The settlement document shall be effective upon filing in the docket and need not be ratified by the presiding officer or the Commissioner of Food and Drugs.

(c) The parties may be represented by counsel, who may be present at the hearing.

§ 17.17 Summary decisions.

(a) At any time after the filing of a complaint, a party may move, with or without supporting affidavits (which, for purposes of this part, shall include declarations under penalty of perjury), for a summary decision on any issue in the hearing. The other party may, within 30 days after service of the motion, which may be extended for an additional 10 days for good cause, serve opposing affidavits or countermove for summary decision.

The presiding officer may set the matter for argument and call for the submission of briefs.

(b) The presiding officer shall grant the motion if the pleadings, affidavits, and other material filed in the record, or matters officially noticed, show that there is no genuine issue as to any material fact and that the party is entitled to summary decision as a matter of law.

(c) Affidavits shall set forth only such facts as would be admissible in evidence and shall show affirmatively that the affiant is competent to testify to the matters stated. When a motion for summary decision is made and supported as provided in this regulation, a party opposing the motion may not rest on mere allegations or denials or general descriptions of positions and contentions; affidavits or other responses must set forth specific facts showing that there is a genuine issue of material fact for the hearing.

(d) If, on motion under this section, a summary decision is not rendered on all issues or for all the relief asked, and if additional facts need to be developed, the presiding officer will issue an order specifying the facts that appear without substantial controversy and directing further evidentiary proceedings on facts still at issue. The facts specified not to be at issue shall be deemed established.

(e) Except as provided in § 17.18, a party may not obtain interlocutory review by the entity deciding the appeal (currently the DAB) of a partial summary decision of the presiding officer. A review of final summary decisions on all issues may be had through the procedure set forth in § 17.47.

§ 17.18 Interlocutory appeal from ruling of presiding officer.

(a) Except as provided in paragraph (b) of this section, rulings of the presiding officer may not be appealed before consideration on appeal of the entire record of the hearing.

(b) A ruling of the presiding officer is subject to interlocutory appeal to the entity deciding the appeal (currently the DAB) if the presiding officer certifies on the record or in writing that immediate review is necessary to prevent exceptional delay, expense, or prejudice to any participant, or substantial harm to the public interest.

(c) When an interlocutory appeal is made, a participant may file a brief on the appeal only if specifically authorized by the presiding officer or the entity deciding the appeal (currently the DAB), and if such authorization is granted, only within the period allowed by the presiding officer or the entity deciding the appeal. If a participant is authorized to file a brief, any other participant may file a brief in opposition, within the period allowed by the entity deciding the appeal (currently the DAB). The deadline for filing an interlocutory appeal is subject to the discretion of the presiding officer.

§ 17.19 Authority of the presiding officer.

(a) The presiding officer shall conduct a fair and impartial hearing, avoid delay, maintain order, and assure that a record of the proceeding is made.

(b) The presiding officer has the authority to:

(1) Set and change the date, time, and place of the hearing on reasonable notice to the parties;

(2) Continue or recess the hearing in whole or in part for a reasonable time;

(3) Require parties to attend conferences for settlement, to identify or simplify the issues, or to consider other matters that may aid in the expeditious disposition of the proceeding;

(4) Administer oaths and affirmations;

(5) Issue subpoenas requiring the attendance and testimony of witnesses and the production of evidence that relates to the matter under investigation;

(6) Rule on motions and other procedural matters;

(7) Regulate the scope and timing of discovery consistent with § 17.23;

(8) Regulate the course of the hearing and the conduct of the parties;

(9) Examine witnesses;

(10) Upon motion of a party for good cause shown, the presiding officer may allow a witness to be recalled for additional testimony;

(11) Receive, rule on, exclude, or limit evidence;

(12) Upon motion of a party or on the presiding officer's own motion, take official notice of facts;

(13) Upon motion of a party, decide cases, in whole or in part, by summary decision when there is no genuine issue of material fact;

(14) Conduct any conference, argument, or hearing on motions in person or by telephone;

(15) Consolidate related or similar proceedings or sever unrelated matters;

(16) Limit the length of pleadings;

(17) Waive, suspend, or modify any rule in this part if the presiding officer determines that no party will be prejudiced, the ends of justice will be served, and the action is in accordance with law;

(18) Issue protective orders pursuant to § 17.28; and

(19) Exercise such other authority as is necessary to carry out the responsibilities of the presiding officer under this part.

(c) The presiding officer does not have the authority to find Federal statutes or regulations invalid.

§ 17.20 Ex parte contacts.

No party or person (except employees of the presiding officer's office) shall communicate in any way with the presiding officer on any matter at issue in a case, unless on notice and opportunity for all parties to participate. This provision does not prohibit a person or party from inquiring about the status of a case or asking routine questions concerning administrative functions or procedures.

§ 17.21 Prehearing conferences.

(a) The presiding officer may schedule prehearing conferences as appropriate.

(b) Upon the motion of any party, the presiding officer shall schedule at least one prehearing conference at a reasonable time in advance of the hearing.

(c) The presiding officer may use a prehearing conference to discuss the following:

(1) Simplification of the issues;

(2) The necessity or desirability of amendments to the pleadings, including the need for a more definite statement;

(3) Stipulations and admissions of fact as to the contents and authenticity of documents;

(4) Whether the parties can agree to submission of the case on a stipulated record;

(5) Whether a party chooses to waive appearance at an oral hearing and to submit only documentary evidence (subject to the objection of the other party) and written argument;

(6) Limitation of the number of witnesses;

(7) Scheduling dates for the exchange of witness lists and of proposed exhibits;

(8) Discovery and scheduling dates for completion of discovery;

(9) The date, time, and place for the hearing; and

(10) Such other matters as may tend to expedite the fair and just disposition of the proceedings.

(d) The presiding officer shall issue an order containing all matters agreed upon by the parties or ordered by the presiding officer at a prehearing conference.

§ 17.23 Discovery.

(a) No later than 60 days prior to the hearing, unless otherwise ordered by the presiding officer, a party may make a request to another party for production, inspection, and copying of documents that are relevant to the issues before the presiding officer. Documents must be provided no later than 30 days after the request has been made.

(b) For the purpose of this part, the term *documents* includes information, reports, answers, records, accounts, papers and other data and documentary evidence. Nothing contained in this section may be interpreted to require the creation of a document, except that

requested data stored in an electronic data storage system must be produced in a form readily accessible to the requesting party.

(c) Requests for documents, requests for admissions, written interrogatories, depositions, and any forms of discovery, other than those permitted under paragraphs (a) and (e) of this section, are not authorized.

(d)(1) Within 10 days of service of a request for production of documents, a party may file a motion for a protective order.

(2) The presiding officer may grant a motion for a protective order, in whole or in part, if he or she finds that the discovery sought:

(i) Is unduly costly or burdensome,

(ii) Will unduly delay the proceeding, or

(iii) Seeks privileged information.

(3) The burden of showing that a protective order is necessary shall be on the party seeking the order.

(4) The burden of showing that documents should be produced is on the party seeking their production.

(e) The presiding officer shall order depositions upon oral questions only upon a showing that:

(1) The information sought cannot be obtained by alternative methods, and

(2) There is a substantial reason to believe that relevant and probative evidence may otherwise not be preserved for presentation by a witness at the hearing.

§ 17.25 Exchange of witness lists, witness statements, and exhibits.

(a) At least 30 days before the hearing, or by such other time as is specified by the presiding officer, the parties shall exchange witness lists, copies of prior written statements of proposed witnesses, and copies of proposed hearing exhibits, including written testimony.

(b)(1) If a party objects to the proposed admission of evidence not exchanged in accordance with paragraph (a) of this section, the presiding officer will exclude such evidence if he or she determines that the failure to comply with paragraph (a) of this section should result in its exclusion.

(2) Unless the presiding officer finds that extraordinary circumstances justified the failure to make a timely exchange of witness lists under paragraph (a) of this section, he or she must exclude from the party's hearing evidence the testimony of any witness whose name does not appear on the witness list.

(3) If the presiding officer finds that extraordinary circumstances existed, the presiding officer must then determine whether the admission of the testimony of any witness whose name does not appear on the witness lists exchanged under paragraph (a) of this section would cause substantial prejudice to the objecting party. If the presiding officer finds that there is not substantial prejudice, the evidence may be admitted. If the presiding officer finds that there is substantial prejudice, the presiding officer may exclude the evidence, or at his or her discretion, may postpone the hearing for such time as is necessary for the objecting party to prepare and respond to the evidence.

(c) Unless a party objects within 5 days prior to the hearing, documents exchanged in accordance with paragraph (a) of this section will be deemed to be authentic for the purpose of admissibility at the hearing.

§ 17.27 Hearing subpoenas.

(a) A party wishing to procure the appearance and testimony of any individual at the hearing may, when authorized by law, request that the presiding officer issue a subpoena.

(b) A subpoena requiring the attendance and testimony of an individual may also require the individual to produce documents at the hearing.

(c) A party seeking a subpoena shall file a written request therefor not less than 20 days before the date fixed for the hearing unless otherwise allowed by the presiding officer, upon a showing by the party of good cause. Such request shall specify any documents to be produced and shall designate the witnesses and describe the address and location thereof with sufficient particularity to permit such witnesses to be found.

(d) The subpoena shall specify the time and place at which the witness is to appear and any documents the witness is to produce.

(e) The party seeking the subpoena shall serve it in the manner prescribed for service of a complaint in § 17.7.

(f) If a party or the individual to whom the subpoena is directed believes a subpoena to be unreasonable, oppressive, excessive in scope, or unduly burdensome, or if it wishes to raise any other objection or privilege recognized by law, the party or individual may file a motion to quash the subpoena within 10 days after service or on or before the time specified in the subpoena for compliance if it is less than 10 days after service. Such a filing will state the basis for the motion to quash. The presiding officer may quash or modify the subpoena or order it implemented, as justice may require.

§ 17.28 Protective order.

(a) A party or a prospective witness may file a motion for a protective order with respect to discovery sought by a party or with respect to the hearing, seeking to limit the availability or disclosure of evidence.

(b) When issuing a protective order, the presiding officer may make any order which justice requires to protect a party or person from oppression or undue burden or expense, or to protect trade secrets or confidential commercial information, as defined in § 20.61 of this chapter, information the disclosure of which would constitute a clearly unwarranted invasion of personal privacy, or other information that would be withheld from public disclosure under 21 CFR part 20. Such orders may include, but are not limited to, one or more of the following:

(1) That the discovery not be had;

(2) That the discovery may be had only on specified terms and conditions, including a designation of the time or place;

(3) That the discovery may be had only through a method of discovery provided for by this part other than that requested;

(4) That certain matters not be inquired into, or that the scope of discovery be limited to certain matters;

(5) That the contents of discovery or evidence be sealed;

(6) That the information not be disclosed to the public or be disclosed only in a designated way; or

(7) That the parties simultaneously file specified documents or information enclosed in sealed envelopes to be opened as directed by the presiding officer.

§ 17.29 Fees.

The party requesting a subpoena shall pay the cost of the fees and mileage of any witness subpoenaed in the amounts that would be payable to a witness in a proceeding in a United States District Court. A check for witness fees and mileage shall accompany the subpoena when served.

§ 17.30 Computation of time.

(a) In computing any period of time under this part or in an order issued thereunder, the time begins with the day following the act or event, and includes the last day of the period, unless either such day is a Saturday, Sunday, or Federal holiday, in which event the time includes the next business day.

(b) When the period of time allowed is less than 7 days, intermediate Saturdays, Sundays, and Federal holidays shall be excluded from the computation.

(c) When a document has been served or issued by placing it in the mail, an additional 5 days will be added to the time permitted for any response.

§ 17.31 Form, filing, and service of papers.

(a) *Form.* (1) Documents filed with the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, shall include an original and two copies.

(2) The first page of every pleading and paper filed in the proceeding shall contain a caption setting forth the title of the action, the case number assigned by the Office of the Chief Counsel, and designation of the pleading or paper (e.g., ''motion to quash subpoena'').

(3) Every pleading shall be signed by, and shall contain the address and telephone number of, the party or the person on whose behalf the pleading was filed, or his or her counsel.

(4) Pleadings or papers are considered filed when they are received by the Division of Dockets Management.

(b) *Service.* A party filing a document with the Division of Dockets Management under this part shall, no later than the time of filing, serve a copy of such document on every other party. Service upon any party of any document, other than service of a complaint, shall be made by delivering a copy personally or by placing a copy of the document in the United States mail or express delivery service, postage prepaid and addressed, to the party's last known address. When a party is represented by counsel, service shall be made on such counsel in lieu of the actual party.

(c) *Proof of service.* A certificate of the individual serving the document by personal delivery or by mail, setting forth the time and manner of service, shall be proof of service.

§ 17.32 Motions.

(a) Any application to the presiding officer for an order or ruling shall be by motion. Motions shall state the relief sought, the authority relied upon, and the facts alleged, and shall be filed with the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, delivered to the presiding officer, and served on all other parties.

(b) Except for motions made during a prehearing conference or at the hearing, all motions shall be in writing. The presiding officer may require that oral motions be reduced to writing.

(c) Within 15 days after a written motion is served, or such other time as may be fixed by the presiding officer, any party may file a response to such motion.

(d) The presiding officer may not grant a written motion before the time for filing responses thereto has expired, except upon consent of the parties or following a hearing on the motion, but may overrule or deny such motion without awaiting a response.

§ 17.33 The hearing and burden of proof.

(a) The presiding officer shall conduct a hearing on the record to determine whether the respondent is liable for a civil money penalty and, if so, the appropriate amount of any such civil money penalty considering any aggravating or mitigating factors.

(b) In order to prevail, the Center must prove respondent's liability and the appropriateness of the penalty under the applicable statute by a preponderance of the evidence.

(c) The respondent must prove any affirmative defenses and any mitigating factors by a preponderance of the evidence.

(d) The hearing shall be open to the public unless otherwise ordered by the presiding officer, who may order closure only to protect trade secrets or confidential commercial information, as defined in § 20.61 of this chapter, information the disclosure of which would constitute a clearly unwarranted invasion of personal privacy, or other information that would be withheld from public disclosure under part 20 of this chapter.

§ 17.34 Determining the amount of penalties and assessments.

(a) When determining an appropriate amount of civil money penalties and assessments, the presiding officer and the Commissioner of Food and Drugs or entity designated by the Commissioner to decide the appeal (currently the DAB) shall evaluate any circumstances that mitigate or aggravate the violation and shall articulate in their opinions the reasons that support the penalties and assessments imposed.

(b) The presiding officer and the entity deciding the appeal shall refer to the factors identified in the statute under which the penalty is assessed for purposes of determining the amount of penalty.

(c) Nothing in this section shall be construed to limit the presiding officer or the entity deciding the appeal from considering any other factors that in any given case may mitigate or aggravate the offense for which penalties and assessments are imposed.

§ 17.35 Sanctions.

(a) The presiding officer may sanction a person, including any party or counsel for:

(1) Failing to comply with an order, subpoena, rule, or procedure governing the proceeding;

(2) Failing to prosecute or defend an action; or

(3) Engaging in other misconduct that interferes with the speedy, orderly, or fair conduct of the hearing.

(b) Any such sanction, including, but not limited to, those listed in paragraphs (c), (d), and (e) of this section, shall reasonably relate to the severity and nature of the failure or misconduct.

(c) When a party fails to comply with a discovery order, including discovery and subpoena provisions of this part, the presiding officer may:

(1) Draw an inference in favor of the requesting party with regard to the information sought;

(2) Prohibit the party failing to comply with such order from introducing evidence concerning, or otherwise relying upon, testimony relating to the information sought; and

(3) Strike any part of the pleadings or other submissions of the party failing to comply with such request.

(d) The presiding officer may exclude from participation in the hearing any legal counsel, party, or witness who refuses to obey an order of the presiding officer. In the case of repeated refusal, the presiding officer may grant judgment to the opposing party.

(e) If a party fails to prosecute or defend an action under this part after service of a notice of hearing, the presiding officer may dismiss the action or may issue an initial decision imposing penalties and assessments.

(f) The presiding officer may refuse to consider any motion, request, response, brief, or other document that is not filed in a timely fashion or in compliance with the rules of this part.

(g) Sanctions imposed under this section may be the subject of an interlocutory appeal as allowed in § 17.18(b), provided that no such appeal will stay or delay a proceeding.

§ 17.37 Witnesses.

(a) Except as provided in paragraph (b) of this section, testimony at the hearing shall be given orally by witnesses under oath or affirmation.

(b) Direct testimony shall be admitted in the form of a written declaration submitted under penalty of perjury. Any such written declaration must be provided to all other parties along with the last known address of the witness. Any prior written statements of witnesses proposed to testify at the hearing shall be exchanged as provided in § 17.25(a).

(c) The presiding officer shall exercise reasonable control over the manner and order of questioning witnesses and presenting evidence so as to:

(1) Make the examination and presentation effective for the ascertainment of the truth;

(2) Avoid undue consumption of time; and

(3) Protect witnesses from harassment or undue embarrassment.

(d) The presiding officer shall permit the parties to conduct such cross-examination as may be required for a full disclosure of the facts.

(e) At the discretion of the presiding officer, a witness may be cross-examined on relevant matters without regard to the scope of his or her direct examination. To the extent permitted by the presiding officer, a witness may be cross-examined on relevant matters with regard to the scope of his or her direct examination. To the extent permitted by the presiding officer, cross-examination on matters outside the scope of direct examination shall be conducted in the manner of direct examination and may proceed by leading questions only if the witness is a hostile witness, an adverse party, or a witness identified with an adverse party.

(f) Upon motion of any party, the presiding officer may order witnesses excluded so that they cannot hear the testimony of the other witnesses. This rule does not authorize exclusion of:

(1) A party who is an individual;

(2) In the case of a party that is not an individual, an officer or employee of the party designated to be the party's sole representative for purposes of the hearing; or

(3) An individual whose presence is shown by a party to be essential to the presentation of its case, including an individual employed by a party engaged in assisting counsel for the party.

(g) If a witness' testimony is submitted in writing prior to cross-examination, the cross-examining party need not subpoena the witness or pay

for his or her travel to the hearing. The sponsoring party is responsible for producing the witness at its own expense, and failure to do so shall result in the striking of the witness' testimony.

§ 17.39 Evidence.

(a) The presiding officer shall determine the admissibility of evidence.

(b) Except as provided in this part, the presiding officer shall not be bound by the ''Federal Rules of Evidence.'' However, the presiding officer may apply the ''Federal Rules of Evidence'' when appropriate, e.g., to exclude unreliable evidence.

(c) The presiding officer shall exclude evidence that is not relevant or material.

(d) Relevant evidence may be excluded if its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or by considerations of undue delay or needless presentation of cumulative evidence.

(e) Relevant evidence may be excluded if it is privileged under Federal law.

(f) Evidence of furnishing or offering or promising to furnish, or accepting or offering or promising to accept, a valuable consideration in settling or attempting to settle a civil money penalty assessment which was disputed as to either validity or amount, is not admissible to prove liability for or invalidity of the civil money penalty or its amount. Evidence of conduct or statements made in settlement negotiations is likewise not admissible. This rule does not require the exclusion of any evidence otherwise discoverable merely because it is presented in the course of settlement negotiations. This rule also does not require exclusion when the evidence is offered for another purpose, such as proving bias or prejudice of a witness or opposing a contention of undue delay.

(g) The presiding officer may in his or her discretion permit the parties to introduce rebuttal witnesses and evidence.

(h) All documents and other evidence offered or taken for the record shall be open to examination by all parties, unless otherwise ordered by the presiding officer pursuant to § 17.28.

§ 17.41 The administrative record.

(a) The hearing will be recorded and transcribed. Witnesses, participants, and counsel have 30 days from the time the transcript becomes available to propose corrections in the transcript of oral testimony. Corrections are permitted only for transcription errors. The presiding officer shall promptly order justified corrections. Transcripts may be obtained following the hearing from the Division of Dockets Management at a cost not to exceed the actual cost of duplication.

(b) The transcript of testimony, exhibits, and other evidence admitted at the hearing and all papers and requests filed in the proceeding constitute the administrative record for the decision by the presiding officer and the entity designated by the Commissioner of Food and Drugs to decide the appeal, currently the DAB.

(c) The administrative record may be inspected and copied (upon payment of a reasonable fee) by anyone unless otherwise ordered by the presiding officer, who shall upon motion of any party order otherwise when necessary to protect trade secrets or confidential commercial information, as defined in § 20.61 of this chapter, information the disclosure of which would constitute a clearly unwarranted invasion of personal privacy, or other information that would be withheld from public disclosure under part 20.

§ 17.43 Posthearing briefs.

Any party may file a posthearing brief. The presiding officer shall fix the time for filing such briefs (which shall be filed simultaneously), which shall not exceed 60 days from the date the parties received the transcript of the hearing or, if applicable, the stipulated record. Such briefs may be accompanied by proposed findings of fact and conclusions of law. The presiding officer may permit the parties to file responsive briefs. No brief may exceed 30 pages (exclusive of proposed findings and conclusions) unless the presiding officer has previously found that the issues in the proceeding are so complex, or the administrative record is so voluminous, as to justify longer briefs, in which case the presiding officer may

set a longer page limit. Proposed findings of fact and conclusions of law shall not exceed 30 pages unless the presiding officer has previously found that the issues in the proceeding are so complex, or the administrative record is so voluminous, as to justify longer proposed findings and conclusions, in which case the presiding officer may set a longer page limit.

§ 17.45 Initial decision.

(a) The presiding officer shall issue an initial decision based only on the administrative record. The decision shall contain findings of fact, conclusions of law, and the amount of any penalties and assessments imposed.

(b) The findings of fact shall include a finding on each of the following issues:

(1) Whether the allegations in the complaint are true, and, if so, whether respondent's actions identified in the complaint violated the law;

(2) Whether any affirmative defenses are meritorious; and

(3) If the respondent is liable for penalties or assessments, the appropriate amount of any such penalties or assessments, considering any mitigating or aggravating factors that he or she finds in the case.

(c) The presiding officer shall serve the initial decision or the decision granting summary decision on all parties within 90 days after the time for submission of posthearing briefs and responsive briefs (if permitted) has expired. If the presiding officer believes that he or she cannot meet the 90-day deadline, he or she shall notify the Commissioner of Food and Drugs or other entity designated by the Commissioner to decide the appeal of the reason(s) therefor, and the Commissioner or that entity may then set a new deadline.

(d) Unless the initial decision or the decision granting summary decision of the presiding officer is timely appealed, the initial decision or the decision granting summary decision shall constitute the final decision of FDA and shall be final and binding on the parties 30 days after it is issued by the presiding officer.

§ 17.47 Appeals.

(a) Either the Center or any respondent may appeal an initial decision, including a decision not to withdraw a default judgment, or a decision granting summary decision to the Commissioner of Food and Drugs or other entity the Commissioner designates to decide the appeal. The Commissioner has currently designated the Departmental Appeals Board (DAB) to decide appeals under this part. Parties may appeal to the DAB by filing a notice of appeal with the DAB, Appellate Division MS6127, Departmental Appeals Board, United States Department of Health and Human Services, 330 Independence Ave. SW., Cohen Bldg., rm. G–644, Washington, DC 20201, and the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, in accordance with this section.

(b)(1) A notice of appeal may be filed at any time within 30 days after the presiding officer issues an initial decision or decision granting summary decision.

(2) The Commissioner or the entity designated by the Commissioner to hear appeals may, within his or her discretion, extend the initial 30-day period for an additional period of time if the Center or any respondent files a request for an extension within the initial 30-day period and shows good cause.

(c) A notice of appeal shall be accompanied by a written brief of no greater length than that allowed for the posthearing brief. The notice must identify specific exceptions to the initial decision, must support each exception with citations to the record, and must explain the basis for each exception.

(d) The opposing party may file a brief of no greater length than that allowed for the posthearing brief in opposition to exceptions within 30 days of receiving the notice of appeal and accompanying brief, unless such time period is extended by the Commissioner or the entity designated by the Commissioner to hear appeals on request of the opposing party for good cause

shown. Any brief in opposition to exceptions shall be filed with the Division of Dockets Management and the DAB (addresses above).

(e) The appellant may file a reply brief not more than 10 pages in length within 10 days of being served with appellee's brief.

(f) There is no right to appear personally before the Commissioner of Food and Drugs or other entity deciding the appeal (currently the DAB).

(g) The entity deciding the appeal will consider only those issues raised before the presiding officer, except that the appellee may make any argument based on the record in support of the initial decision or decision granting summary decision.

(h) If on appeal the entity deciding the appeal considers issues not adequately briefed by the parties, the entity may ask for additional briefing. However, no such additional briefs will be considered unless so requested.

(i) If any party demonstrates to the satisfaction of the entity deciding the appeal (currently the DAB) that additional evidence not presented at the hearing is relevant and material and that there were reasonable grounds for the failure to adduce such evidence at the hearing, the entity deciding the appeal may remand the matter to the presiding officer for consideration of the additional evidence.

(j) The Commissioner of Food and Drugs or other entity deciding the appeal (currently the DAB) will issue a decision on the appeal within 60 days, if practicable, of the due date for submission of the appellee's brief. In the decision, the entity deciding the appeal may decline to review the case, affirm the initial decision or decision granting summary decision (with or without an opinion), or reverse the initial decision or decision granting summary decision, or increase, reduce, reverse, or remand any civil money penalty determined by the presiding officer in the initial decision. If the entity deciding the appeal declines to review the case, the initial decision or the decision granting summary decision shall constitute the final decision of FDA and shall be final and binding on the parties 30 days after the declination by the entity deciding the appeal.

(k) The standard of review on a disputed issue of fact is whether the initial decision is supported by substantial evidence on the whole record. The standard of review on a disputed issue of law is whether the initial decision is erroneous.

[60 FR 38626, July 27, 1995, as amended at 71 FR 5979, Feb. 6, 2006]

§ 17.48 Harmless error.

No error in either the admission or the exclusion of evidence, and no error or defect in any ruling or order or in any act done or omitted by the presiding officer or by any of the parties is grounds for vacating, modifying, or otherwise disturbing an otherwise appropriate ruling or order or act, unless refusal to take such action appears to the presiding officer or the Commissioner of Food and Drugs or other entity deciding the appeal (currently the DAB) to be inconsistent with substantial justice. The presiding officer and the entity deciding the appeal at every stage of the proceeding will disregard any error or defect in the proceeding that does not affect the substantial rights of the parties.

§ 17.51 Judicial review.

(a) The final decision of the Commissioner of Food and Drugs or other entity deciding the appeal (currently the DAB) constitutes final agency action from which a respondent may petition for judicial review under the statutes governing the matter involved. Although the filing of a petition for judicial review does not stay a decision under this part, a respondent may file a petition for stay of such decision under § 10.35 of this chapter.

(b) The Chief Counsel of FDA has been designated by the Secretary of Health and Human Services as the officer on whom copies of petitions for judicial review are to be served. This officer is responsible for filing the record on which the final decision is based. The record of the proceeding is certified by the entity deciding the appeal (currently the DAB).

(c) Exhaustion of an appeal to the entity deciding the appeal (currently the DAB) is a jurisdictional prerequisite to judicial review.

§ 17.54 Deposit in the Treasury of the United States.

All amounts assessed pursuant to this part shall be delivered to the Director, Division of Financial Management (HFA–100), Food and Drug Administration, rm. 11–61, 5600 Fishers Lane, Rockville, MD 20857, and shall be deposited as miscellaneous receipts in the Treasury of the United States.

PART 19—STANDARDS OF CONDUCT AND CONFLICTS OF INTEREST

Subpart A—General Provisions

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19.1 Scope.
19.5 Reference to Department regulations.
19.6 Code of ethics for government service.
19.10 Food and Drug Administration Conflict of Interest Review Board.

Subpart B—Reporting of Violations

19.21 Duty to report violations.

Subpart C—Disqualification Conditions

19.45 Temporary disqualification of former employees.
19.55 Permanent disqualification of former employees.

AUTHORITY: 21 U.S.C. 371.

SOURCE: 42 FR 15615, Mar. 22, 1977, unless otherwise noted.

Subpart A—General Provisions

§ 19.1 Scope.

This part governs the standards of conduct for, and establishes regulations to prevent conflicts of interest by, all Food and Drug Administration employees.

§ 19.5 Reference to Department regulations.

(a) The provisions of 45 CFR part 73, establishing standards of conduct for all Department employees, are fully applicable to all Food and Drug Administration employees, except that such regulations shall be applicable to special government employees, i.e., consultants to the Food and Drug Administration, only to the extent stated in subpart L of 45 CFR part 73.

(b) The provisions of 45 CFR part 73a supplement the Department standards of conduct and apply only to Food and Drug Administration employees except special government employees.

§ 19.6 Code of ethics for government service.

The following code of ethics, adopted by Congress on July 11, 1958, shall apply to all Food and Drug Administration employees:

CODE OF ETHICS FOR GOVERNMENT SERVICE

Any person in Government service should:

1. Put loyalty to the highest moral principles and to country above loyalty to persons, party, or Government department.
2. Uphold the Constitution, laws, and legal regulations of the United States and of all governments therein and never be a party to their evasion.
3. Give a full day's labor for a full day's pay; giving to the performance of his duties his earnest effort and best thought.
4. Seek to find and employ more efficient and economical ways of getting tasks accomplished.
5. Never discriminate unfairly by the dispensing of special favors or privileges to anyone, whether for remuneration or not; and never accept, for himself or his family, favors or benefits under circumstances which might be construed by reasonable persons as influencing the performance of his governmental duties.
6. Make no private promises of any kind binding upon the duties of office, since a Government employee has no private word which can be binding on public duty.
7. Engage in no business with the Government, either directly or indirectly, which is inconsistent with the conscientious performance of his governmental duties.
8. Never use any information coming to him confidentially in the performance of governmental duties as a means for making private profit.
9. Expose corruption wherever discovered.
10. Uphold these principles, ever conscious that public office is a public trust.

§ 19.10 Food and Drug Administration Conflict of Interest Review Board.

(a) The Commissioner shall establish a permanent five-member Conflict of Interest Review Board, which shall review and make recommendations to the Commissioner on all specific or policy matters relating to conflicts of interest arising within the Food and

Drug Administration that are forwarded to it by: (1) The Associate Commissioner for Management and Operations or (2) anyone who is the subject of an adverse determination by the Associate Commissioner for Management and Operations on any matter arising under the conflict of interest laws, except a determination of an apparent violation of law. The Director, Division of Ethics and Program Integrity, Office of Management and Operations, shall serve as executive secretary of the Review Board.

(b) It shall be the responsibility of every Food and Drug Administration employee with whom any specific or policy issue relating to conflicts of interest is raised, or who otherwise wishes to have any such matter resolved, to forward the matter to the Associate Commissioner for Management and Operations for resolution, except that reporting of apparent violations of law are governed by § 19.21.

(c) All general policy relating to conflicts of interest shall be established in guidance documents pursuant to the provisions of § 10.90(b) of this chapter and whenever feasible shall be incorporated in regulations in this subpart.

(d) All decisions relating to specific individuals shall be placed in a public file established for this purpose by the Division of Freedom of Information, e.g., a determination that a consultant may serve on an advisory committee with specific limitations or with public disclosure of stock holdings, except that such determination shall be written in a way that does not identify the individual in the following situations:

(1) A determination that an employee must dispose of prohibited financial interests or refrain from incompatible outside activities in accordance with established Department or agency regulations.

(2) A determination that a proposed consultant is not eligible for employment by the agency.

(3) A determination that public disclosure of any information would constitute an unwarranted invasion of personal privacy in violation of § 20.63 of this chapter.

[42 FR 15615, Mar. 22, 1977, as amended at 46 FR 8456, Jan. 27, 1981; 50 FR 52278, Dec. 23, 1985; 55 FR 1404, Jan. 16, 1990; 65 FR 56479, Sept. 19, 2000; 76 FR 31469, June 1, 2011]

Subpart B—Reporting of Violations

§ 19.21 Duty to report violations.

(a) The Office of Internal Affairs, Office of the Commissioner, is responsible for obtaining factual information for the Food and Drug Administration on any matter relating to allegations of misconduct, impropriety, conflict of interest, or other violations of Federal statutes by agency personnel.

(b) Any Food and Drug Administration employee who has factual information showing or who otherwise believes that any present or former Food and Drug Administration employee has violated or is violating any provision of this subpart or of 45 CFR parts 73 or 73a or of any statute listed in appendix A to 45 CFR part 73 should report such information directly to the Office of Internal Affairs. Any such reports shall be in writing or shall with the assistance of the Office of Internal Affairs, be reduced to writing, and shall be promptly investigated.

(c) Any report pursuant to paragraph (b) of this section and any records relating to an investigation of such reports shall be maintained in strict confidence in the files of the Office of Internal Affairs, shall be exempt from public disclosure, and may be reviewed only by authorized Food and Drug Administration employees who are required to do so in the performance of their duties.

[42 FR 15615, Mar. 22, 1977, as amended at 46 FR 8456, Jan. 27, 1981; 50 FR 52278, Dec. 23, 1985; 60 FR 47478, Sept. 13, 1995]

Subpart C—Disqualification Conditions

§ 19.45 Temporary disqualification of former employees.

Within 1 year after termination of employment with the Food and Drug Administration, no former Food and Drug Administration employee, including a special government employee,

shall appear personally before the Food and Drug Administration or other federal agency or court as agent or attorney for any person other than the United States in connection with any proceeding or matter in which the United States is a party or has a direct and substantial interest and which was under his official responsibility at any time within one year preceding termination of such responsibility. The term *official responsibility* means the direct administrative or operating authority, whether intermediate or final, and either exercisable alone or with others, and either personally or through subordinates, to approve, disapprove, or otherwise direct government action.

§ 19.55 Permanent disqualification of former employees.

No former Food and Drug Administration employee, including a special government employee, shall knowingly act as agent or attorney for anyone other than United States in connection with any judicial or other proceeding, application, request for a ruling or other determination, contract, claim, controversy, charge, accusation, or other particular matter involving a specific party or parties in which the United States is a party or has a direct and substantial interest and in which he participated personally and substantially through decision, approval, disapproval, recommendation, rendering of advice, investigation, or otherwise as a Food and Drug Administration employee.

PART 20—PUBLIC INFORMATION

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20.120 Records available in Food and Drug Administration Public Reading Rooms.

AUTHORITY: 5 U.S.C. 552; 18 U.S.C. 1905; 19 U.S.C. 2531–2582; 21 U.S.C. 321–393, 1401–1403; 42 U.S.C. 241, 242, 242a, 242l, 242n, 243, 262, 263, 263b–263n, 264, 265, 300u–300u–5, 300aa–1.

SOURCE: 42 FR 15616, Mar. 22, 1977, unless otherwise noted.

Subpart A—Official Testimony and Information

§ 20.1 Testimony by Food and Drug Administration employees.

(a) No officer or employee of the Food and Drug Administration or of any other office or establishment in the Department of Health and Human Services, except as authorized by the Commissioner of Food and Drugs pursuant to this section or in the discharge of his official duties under the laws administered by the Food and Drug Administration, shall give any testimony before any tribunal pertaining to any function of the Food and Drug Administration or with respect to any information acquired in the discharge of his official duties.

(b) Whenever a subpoena, in appropriate form, has been lawfully served upon an officer or employee of the Food and Drug Administration commanding the giving of any testimony, such officer or employee shall, unless otherwise authorized by the Commissioner, appear in response thereto and respectfully decline to testify on the grounds that it is prohibited by this section.

(c) A person who desires testimony from any employee may make written request therefor, verified by oath, directed to the Commissioner setting forth his interest in the matter sought to be disclosed and designating the use to which such testimony will be put in the event of compliance with such request: *Provided,* That a written request therefor made by a health, food, or drug officer, prosecuting attorney, or member of the judiciary of any State, Territory, or political subdivision thereof, acting in his official capacity, need not be verified by oath. If it is determined by the Commissioner, or any other officer or employee of the Food and Drug Administration whom he may designate to act on his behalf for the purpose, that such testimony will be in the public interest and will promote the objectives of the act and the agency, the request may be granted. Where a request for testimony is granted, one or more employees of the Food

and Drug Administration may be designated to appear, in response to a subpoena, and testify with respect thereto.

§ 20.2 Production of records by Food and Drug Administration employees.

(a) Any request for records of the Food and Drug Administration, whether it be by letter or by a subpena duces tecum or by any other writing, shall be handled pursuant to the procedures established in subpart B of this part, and shall comply with the rules governing public disclosure established in subparts C, D, E, and F of this part and in other regulations cross-referenced in § 20.100(c).

(b) Whenever a subpoena duces tecum, in appropriate form, has been lawfully served upon an officer or employee of the Food and Drug Administration commanding the production of any record, such officer or employee shall appear in response thereto, respectfully decline to produce the record on the ground that it is prohibited by this section, and state that the production of the record(s) involved will be handled by the procedures established in this part.

§ 20.3 Certification and authentication of Food and Drug Administration records.

(a) Upon request, the Food and Drug administration will certify the authenticity of copies of records that are requested to be disclosed pursuant to this part or will authenticate copies of records previously disclosed.

(b) A request for certified copies of records or for authentication of records shall be sent in writing to the Division of Freedom of Information at the address located on the agency's web site at *http://www.fda.gov*.

[42 FR 15616, Mar. 22, 1977, as amended at 46 FR 8456, Jan. 27, 1981; 76 FR 31469, June 1, 2011; 79 FR 68114, Nov. 14, 2014]

Subpart B—General Policy

§ 20.20 Policy on disclosure of Food and Drug Administration records.

(a) The Food and Drug Administration will make the fullest possible disclosure of records to the public, consistent with the rights of individuals to privacy, the property rights of persons in trade secrets and confidential commercial or financial information, and the need for the agency to promote frank internal policy deliberations and to pursue its regulatory activities without disruption.

(b) Except where specifically exempt pursuant to the provisions of this part, all Food and Drug Administration records shall be made available for public disclosure.

(c) Except as provided in paragraph (d) of this section, all nonexempt records shall be made available for public disclosure upon request regardless whether any justification or need for such records have been shown.

(d) Under § 21.71 of this chapter, a statement of the purposes to which the record requested is to be put, and a certification that the record will be so used, may be requested when:

(1) The requested record is contained in a Privacy Act Record System as defined in § 21.3(c) of this chapter;

(2) The requester is a person other than the individual who is the subject of the record that is so retrieved or a person acting on his behalf; and

(3) The disclosure is one that is discretionary, i.e., not required under this part.

(e) ''Record'' and any other term used in this section in reference to information includes any information that would be an agency record subject to the requirements of this part when maintained by the agency in any format, including an electronic format.

[42 FR 15616, Mar. 22, 1977, as amended at 68 FR 25285, May 12, 2003]

§ 20.21 Uniform access to records.

Any record of the Food and Drug Administration that is disclosed in an authorized manner to any member of the public is available for disclosure to all members of the public, except that:

(a) Data and information subject to the exemptions established in § 20.61 for trade secrets and confidential commercial or financial information, and in § 20.63 for personal privacy, shall be disclosed only to the persons for the protection of whom these exemptions exist.

(b) The limited disclosure of records permitted in § 7.87(c) of this chapter for

section 305 hearing records, in § 20.80(b) regarding certain limitations on exemptions, in § 20.103(b) for certain correspondence, and in § 20.104(b) for certain summaries of oral discussions, shall be subject to the special rules stated therein.

(c) Disclosure of a record about an individual, as defined in § 21.3(a) of this chapter, that is retrieved by the individual's name or other personal identifier and is contained in a Privacy Act Record System, as defined in § 21.3(c) of this chapter, shall be subject to the special requirements of part 21 of this chapter. Disclosure of such a record to an individual who is the subject of the record does not invoke the rule established in this section that such records shall be made available for disclosure to all members of the public.

[42 FR 15616, Mar. 22, 1977, as amended at 54 FR 9037, Mar. 3, 1989]

§ 20.22 Partial disclosure of records.

(a) If a record contains both disclosable and nondisclosable information, the nondisclosable information will be deleted and the remaining record will be disclosed unless the two are so inextricably intertwined that it is not feasible to separate them or release of the disclosable information would compromise or impinge upon the nondisclosable portion of the record.

(b)(1) Whenever information is deleted from a record that contains both disclosable and nondisclosable information, the amount of information deleted shall be indicated on the portion of the record that is made available, unless including that indication would harm an interest protected by an exemption under the Freedom of Information Act.

(2) When technically feasible, the amount of information deleted shall be indicated at the place in the record where the deletion is made.

[42 FR 15616, Mar. 22, 1977, as amended at 68 FR 25285, May 12, 2003]

§ 20.23 Request for existing records.

(a) Any written request to the Food and Drug Administration for existing records not prepared for routine distribution to the public shall be deemed to be a request for records pursuant to the Freedom of Information Act, whether or not the Freedom of Information Act is mentioned in the request, and shall be governed by the provisions of this part.

(b) Records or documents prepared by the Food and Drug Administration for routine public distribution, e.g., pamphlets, speeches, and educational materials, shall be furnished free of charge upon request as long as the supply lasts. The provisions of this part shall not be applicable to such requests except when the supply of such material is exhausted and it is necessary to reproduce individual copies upon specific request.

(c) All existing Food and Drug Administration records are subject to routine destruction according to standard record retention schedules.

§ 20.24 Preparation of new records.

(a) The Freedom of Information Act and the provisions of this part apply only to existing records that are reasonably described in a request filed with the Food and Drug Administration pursuant to the procedures established in subpart C of this part.

(b) The Commissioner may, in his discretion, prepare new records in order to respond adequately to a request for information when he concludes that it is in the public interest and promotes the objectives of the act and the agency.

§ 20.25 Retroactive application of regulations.

The provisions of this part apply to all records in Food and Drug Administration files.

§ 20.26 Indexes of certain records.

(a) Indexes shall be maintained, and revised at least quarterly, for the following Food and Drug Administration records:

(1) Final orders published in the FEDERAL REGISTER with respect to every denial or withdrawal of approval of a new drug application or a new animal drug application for which a public hearing has been requested.

(2) Statements of policy and interpretation adopted by the agency and still in force and not published in the FEDERAL REGISTER.

(3) Administrative staff manuals and instructions to staff that affect a member of the public.

(4) Records that have been released to any person in response to a Freedom of Information request and that the agency has determined have become, or are likely to become, the subject of subsequent requests for substantially the same records.

(b) Each such index will be made available by accessing the agency's web site at *http://www.fda.gov*. A printed copy of each index is available by writing or visiting the Freedom of Information Staff's address on the agency's web site at *http://www.fda.gov*.

[42 FR 15616, Mar. 22, 1977, as amended at 46 FR 8456, Jan. 27, 1981; 68 FR 25285, May 12, 2003; 76 FR 31469, June 1, 2011; 79 FR 68114, Nov. 14, 2014]

§ 20.27 Submission of records marked as confidential.

Marking records submitted to the Food and Drug Administration as confidential, or with any other similar term, raises no obligation by the Food and Drug Administration to regard such records as confidential, to return them to the person who has submitted them, to withhold them from disclosure to the public, or to advise the person submitting them when a request for their public disclosure is received or when they are in fact disclosed.

[42 FR 15616, Mar. 22, 1977, as amended at 68 FR 25285, May 12, 2003]

§ 20.28 Food and Drug Administration determinations of confidentiality.

A determination that data or information submitted to the Food and Drug Administration will be held in confidence and will not be available for public disclosure shall be made only in the form of a regulation published or cross-referenced in this part.

[42 FR 15616, Mar. 22, 1977, as amended at 68 FR 25285, May 12, 2003]

§ 20.29 Prohibition on withdrawal of records from Food and Drug Administration files.

No person may withdraw records submitted to the Food and Drug Administration. All Food and Drug Administration records shall be retained by the agency until disposed of pursuant to routine record disposal procedures.

[42 FR 15616, Mar. 22, 1977, as amended at 68 FR 25285, May 12, 2003]

§ 20.30 Food and Drug Administration Division of Freedom of Information.

(a) The office responsible for Agency compliance with the Freedom of Information Act and this part is the Division of Freedom of Informationat the address located on the agency's web site at *http://www.fda.gov*.

(b) All requests for Agency records shall be sent in writing to this office.

[76 FR 31469, June 1, 2011, as amended at 79 FR 68114, Nov. 14, 2014]

§ 20.31 Retention schedule of requests for Food and Drug Administration records.

(a) Unless unusual circumstances dictate otherwise, the Food and Drug Administration shall maintain and dispose of files of requests and reponses furnished thereto within the time limits authorized by GSA General Records Schedule 14, FPMR 101–11–4, January 10, 1977, as follows:

(1) Files created by the receipt of and response to freedom of information requests, except denials and/or appeals, may be destroyed 2 years from date of final response.

(2) Files created by a freedom of information request which was wholly or partially denied may be destroyed 5 years after the denial letter was issued.

(3) Files created by a freedom of information request which was wholly or partially denied and which denial was subsequently appealed to the Department of Health and Human Services may be destroyed 4 years after final determination by FDA or 3 years after final adjudication by courts, whichever is later.

(b) This destruction schedule will automatically be revised whenever the time limits pertaining to these records are revised by the GSA General Records Schedule.

[47 FR 24277, June 4, 1982]

§ 20.32 Disclosure of Food and Drug Administration employee names.

The names of Food and Drug Administration employees will not be deleted

from disclosable records except where such deletion is necessary to prevent disclosure of an informant or danger to the life or physical safety of the employee or under other extraordinary circumstances.

§ 20.33 Form or format of response.

(a) The Food and Drug Administration shall make reasonable efforts to provide a record in any requested form or format if the record is readily reproducible by the agency in that form or format.

(b) If the agency determines that a record is not readily reproducible in the requested form or format, the agency may notify the requester of alternative forms and formats that are available. If the requester does not express a preference for an alternative in response to such notification, the agency may provide its response in the form and format of the agency's choice.

[68 FR 25285, May 12, 2003]

§ 20.34 Search for records.

(a) In responding to a request for records, the Food and Drug Administration shall make reasonable efforts to search for records kept in electronic form or format, except when such efforts would significantly interfere with the operation of the agency's automated information systems.

(b) The term ''search'' means to review, manually or by automated means, agency records for the purpose of locating those records that are responsive to the request.

[68 FR 25285, May 12, 2003]

Subpart C—Procedures and Fees

§ 20.40 Filing a request for records.

(a) All requests for Food and Drug Administration records shall be made in writing by mailing or delivering the request to the Freedom of Information Staff at the address on the agency's web site at *http://www.fda.gov* or by faxing it to the fax number listed on the agency's web site at *http://www.fda.gov*. All requests must contain the postal address and telephone number of the requester and the name of the person responsible for payment of any fees that may be charged.

(b) A request for Food and Drug Administration records shall reasonably describe the records being sought, in a way that they can be identified and located. A request should include all pertinent details that will help identify the records sought.

(1) If the description is insufficient to locate the records requested, the Food and Drug Administration will so notify the person making the request and indicate the additional information needed to identify the records requested.

(2) Every reasonable effort shall be made by the Food and Drug Administration to assist in the identification and location of the records sought.

(c) Upon receipt of a request for records, the Division of Freedom of Information shall enter it in a public log. The log shall state the date received, the name of the person making the request, the nature of the record requested, the action taken on the request, the date of determination letter sent pursuant to § 20.41(b), and the date(s) any records are subsequently furnished.

(d) A request by an individual, as defined in § 21.3(a) of this chapter, for a record about himself shall be subject to:

(1) The special requirements of part 21 of this chapter (the privacy regulations), and not to the provisions of this subpart, if the record requested is retrieved by the individual's name or other personal identifier and is contained in a Privacy Act Record System, as defined in § 21.3(c) of this chapter.

(2) The provisions of this subpart if the record requested is not retrieved by the individual's name or other personal identifier, whether or not the record is contained in a Privacy Act Record System.

[42 FR 15616, Mar. 22, 1977, as amended at 46 FR 8456, Jan. 27, 1981; 68 FR 25285, May 12, 2003; 76 FR 31469, June 1, 2011; 79 FR 68114, Nov. 14, 2014]

§ 20.41 Time limitations.

(a) All time limitations prescribed pursuant to this section shall begin as of the time at which a request for records is logged in by the Division of Freedom of Information pursuant to § 20.40(c). An oral request for records

shall not begin any time requirement. A written request for records sent elsewhere within the agency shall not begin any time requirement until it is redirected to the Division of Freedom of Information and is logged in there in accordance with § 20.40(c).

(b) Within 20 working days (excluding Saturdays, Sundays, and legal public holidays) after a request for records is logged in at the Division of Freedom of Information, the agency shall send a letter to the requester providing the agency's determination as to whether, or the extent to which, the agency will comply with the request, and, if any records are denied, the reasons for the denial.

(1) If all of the records requested have been located and a final determination has been made with respect to disclosure of all of the records requested, the letter shall so state.

(2) If all of the records have not been located or a final determination has not yet been made with respect to disclosure of all of the records requested, e.g., because it is necessary to consult the person affected pursuant to § 20.47, the letter shall state the extent to which the records involved shall be disclosed pursuant to the rules established in this part.

(3)(i) In unusual circumstances, the agency may extend the time for sending the letter for an additional period.

(A) The agency may provide for an extension of up to 10 working days by providing written notice to the requester setting out the reasons for the extension and the date by which a determination is expected to be sent.

(B) The agency may provide for an extension of more than 10 working days by providing written notice to the requester setting out the reasons for the extension. The notice also will give the requester an opportunity to limit the scope of the request so that it may be processed in a shorter time and/or an opportunity to agree on a timeframe longer than the 10 extra working days for processing the request.

(ii) Unusual circumstances may exist under any of the following conditions:

(A) There is a need to search for and collect the requested records from field facilities or other components that are separate from the agency component responsible for processing the request;

(B) There is a need to search for, collect, and appropriately examine a voluminous amount of separate and distinct records that are demanded in a single request; or

(C) There is need for consultation, which shall be conducted with all practicable speed, with another agency having a substantial interest in the determination of the request, or among two or more components of the Food and Drug Administration having substantial subject-matter interest in the determination.

(4) If any record is denied, the letter shall state the right of the person requesting such records to appeal any adverse determination to the Assistant Secretary for Health, Department of Health and Human Services, in accordance with the provisions of 45 CFR 5.34.

(c) The Food and Drug Administration shall provide a determination of whether to provide expedited processing within 10 calendar days of receipt by the Division of Freedom of Information of the request and the required documentation of compelling need in accordance with § 20.44(b).

[42 FR 15616, Mar. 22, 1977, as amended at 46 FR 8456, Jan. 27, 1981; 55 FR 1405, Jan. 16, 1990; 59 FR 533, Jan. 5, 1994; 68 FR 25285, May 12, 2003; 76 FR 31469, June 1, 2011]

§ 20.42 Aggregation of certain requests.

The Food and Drug Administration may aggregate certain requests by the same requester, or by a group of requesters acting in concert, if the requests involve clearly related matters and the agency reasonably believes that such requests actually constitute a single request which would otherwise satisfy the unusual circumstances specified in § 20.41(b)(3)(ii)(B). FDA may extend the time for processing aggregated requests in accordance with the unusual circumstances provisions of § 20.41.

[68 FR 25286, May 12, 2003]

§ 20.43 Multitrack processing.

(a) Each Food and Drug Administration component is responsible for determining whether to use a multitrack system to process requests for records

maintained by that component. A multitrack system provides two or more tracks for processing requests, based on the amount of work and/or time required for a request to be processed. The availability of multitrack processing does not affect expedited processing in accordance with § 20.44.

(b) If multitrack processing is not adopted by a particular agency component, that component will process all requests in a single track, ordinarily on a first-in, first-out basis.

(c) If a multitrack processing system is established by a particular agency component, that component may determine how many tracks to establish and the specific criteria for assigning requests to each track. Multiple tracks may be established for requests based on the amount of work and/or time required for a request to be processed.

(d) Requests assigned to a given track will ordinarily be processed on a first-in, first-out basis within that track.

(e) If a request does not qualify for the fastest processing track, the requester may be provided an opportunity to limit the scope of the request in order to qualify for faster processing.

[68 FR 25286, May 12, 2003]

§ 20.44 Expedited processing.

(a) The Food and Drug Administration will provide expedited processing of a request for records when the requester demonstrates a compelling need, or in other cases as determined by the agency. A compelling need exists when:

(1) A failure to obtain requested records on an expedited basis could reasonably be expected to pose an imminent threat to the life or physical safety of an individual; or

(2) With respect to a request made by a person primarily engaged in disseminating information, there is a demonstrated urgency to inform the public concerning actual or alleged Federal Government activity.

(b) A request for expedited processing made under paragraph (a)(1) of this section must be made by the specific individual who is subject to an imminent threat, or by a family member, medical or health care professional, or other authorized representative of the individual, and must demonstrate a reasonable basis for concluding that failure to obtain the requested records on an expedited basis could reasonably be expected to pose a specific and identifiable imminent threat to the life or safety of the individual.

(c) A request for expedited processing made under paragraph (a)(2) of this section must demonstrate that:

(1) The requester is primarily engaged in disseminating information to the general public and not merely to a narrow interest group;

(2) There is an urgent need for the requested information and that it has a particular value that will be lost if not obtained and disseminated quickly; however, a news media publication or broadcast deadline alone does not qualify as an urgent need, nor does a request for historical information; and

(3) The request for records specifically concerns identifiable operations or activities of the Federal Government.

(d) All requests for expedited processing shall be filed in writing as provided by § 20.40. Each such request shall include information that demonstrates a reasonable basis for concluding that a compelling need exists within the meaning of paragraph (a) of this section and a certification that the information provided in the request is true and correct to the best of the requester's knowledge and belief. Any statements made in support of a request for expedited processing are subject to the False Reports to the Government Act (18 U.S.C. 1001).

(e) The Assistant Commissioner for Public Affairs (or delegatee) will determine whether to grant a request for expedited processing within 10 days of receipt by the Division of Freedom of Information of all information required to make a decision.

(f) If the agency grants a request for expedited processing, the agency shall process the request as soon as practicable.

(g) If the agency denies a request for expedited processing, the agency shall process the request with other nonexpedited requests.

(h) If the agency denies a request for expedited processing, the requester

may appeal the agency's decision by writing to the official identified in the denial letter.

[68 FR 25286, May 12, 2003, as amended at 76 FR 31469, June 1, 2011]

§ 20.45 Fees to be charged.

(a) *Categories of requests.* Paragraphs (a) (1) through (3) of this section state, for each category of request, the type of fees that the Food and Drug Administration will generally charge. However, for each of these categories, the fees may be limited, waived, or reduced for the reasons given in paragraphs (b) and (c) of this section and in § 20.46 or for other reasons.

(1) *Commercial use request.* If the request is for a commercial use, the Food and Drug Administration will charge for the costs of search, review, and duplication.

(2) *Educational and scientific institutions and news media.* If the request is from an educational institution or a noncommercial scientific institution, operated primarily for scholarly or scientific research, or a representative of the news media, and the request is not for a commercial use, the Food and Drug Administration will charge only for the duplication of documents. Also, the Food and Drug Administration will not charge the copying costs for the first 100 pages of duplication.

(3) *Other requests.* If the request is not the kind described in paragraph (a)(1) or (a)(2) of this section, then the Food and Drug Administration will charge only for the search and the duplication. Also, the Food and Drug Administration will not charge for the first 2 hours of search time or for the copying costs of the first 100 pages of duplication.

(b) *General provisions.* (1) The Food and Drug Administration may charge search fees even if the records found are exempt from disclosure or if no records are found.

(2) If, under paragraph (a)(3) of this section, there is no charge for the first 2 hours of search time, and those 2 hours are spent on a computer search, then the 2 free hours are the first 2 hours of the operator's own operation. If the operator spends less than 2 hours on the search, the total search fees will be reduced by the average hourly rate for the operator's time, multiplied by 2.

(3) If, under paragraph (a)(2) or (a)(3) of this section, there is no charge for the first 100 pages of duplication, then those 100 pages are the first 100 pages of photocopies of standard size pages, or the first 100 pages of computer printout. If this method to calculate the fee reduction cannot be used, then the total duplication fee will be reduced by the normal charge for photocopying a standard size page, multiplied by 100.

(4) No charge will be made if the costs of routine collection and processing of the fee are likely to equal or exceed the amount of the fee.

(5) If it is determined that a requester (acting either alone or together with others) is breaking down a single request into a series of requests in order to avoid (or reduce) the fees charged, all these requests may be aggregated for purposes of calculating the fees charged.

(6) Interest will be charged on unpaid bills beginning on the 31st day following the day the bill was sent. Provisions in 45 CFR part 30, the Department of Health and Human Services regulations governing claims collection, will be used in assessing interest, administrative costs, and penalties, and in taking actions to encourage payment.

(c) *Fee schedule.* The Food and Drug Administration charges the following fees in accordance with the regulations of the Department of Health and Human Services at 45 CFR part 5.

(1) *Manual searching for or reviewing of records.* When the search or review is performed by employees at grade GS–1 through GS–8, an hourly rate based on the salary of a GS–5, step 7, employee; when done by a GS–9 through GS–14, an hourly rate based on the salary of a GS–12, step 4, employee; and when done by a GS–15 or above, an hourly rate based on the salary of a GS–15, step 7, employee. In each case, the hourly rate will be computed by taking the current hourly rate for the specified grade and step, adding 16 percent of that rate to cover benefits, and rounding to the nearest whole dollar. When a search involves employees at more than one of

these levels, the Food and Drug Administration will charge the rate appropriate for each.

(2) *Computer searching and printing.* The actual cost of operating the computer plus charges for the time spent by the operator, at the rates given in paragraph (c)(1) of this section.

(3) *Photocopying standard size pages.* $0.10 per page. Freedom of Information Officers may charge lower fees for particular documents where:

(i) The document has already been printed in large numbers;

(ii) The program office determines that using existing stock to answer this request, and any other anticipated Freedom of Information requests, will not interfere with program requirements; and

(iii) The Freedom of Information Officer determines that the lower fee is adequate to recover the prorated share of the original printing costs.

(4) *Photocopying odd-size documents (such as punchcards or blueprints), or reproducing other records (such as tapes).* The actual costs of operating the machine, plus the actual cost of the materials used, plus charges for the time spent by the operator, at the rates given in paragraph (c)(1) of this section.

(5) *Certifying that records are true copies.* This service is not required by the Freedom of Information Act. If the Food and Drug Administration agrees to provide certification, there is a $10 charge per certification.

(6) *Sending records by express mail or other special methods.* This service is not required by the Freedom of Information Act. If the Food and Drug Administration agrees to provide this service, the requester will be required to directly pay, or be directly charged by, the courier. The agency will not agree to any special delivery method that does not permit the requester to directly pay or be directly charged for the service.

(7) *Performing any other special service in connection with a request to which the Food and Drug Administration has agreed.* Actual costs of operating any machinery, plus actual cost of any materials used, plus charges for the time of the Food and Drug Administration's employees, at the rates given in paragraph (c)(1) of this section.

(d) *Procedures for assessing and collecting fees*—(1) *Agreement to pay.* The Food and Drug Administration generally assumes that a requester is willing to pay the fees charged for services associated with the request. The requester may specify a limit on the amount to be spent. If it appears that the fees will exceed the limit, the Food and Drug Administration will consult the requester to determine whether to proceed with the search.

(2) *Advance payment.* If a requester has failed to pay previous bills in a timely fashion, or if the Food and Drug Administration's initial review of the request indicates that the charges will exceed $250, the requester will be required to pay past due fees and/or the estimated fees, or a deposit, before the search for the requested records begins. In such cases, the requester will be notified promptly upon receipt of the request, and the administrative time limits prescribed in § 20.41 will begin only after there is an agreement with the requester over payment of fees, or a decision that fee waiver or reduction is appropriate.

(3) *Billing and payment.* Ordinarily, the requester will be required to pay all fees before the Food and Drug Administration will furnish the records. At its discretion, the Food and Drug Administration may send the requester a bill along with or following the records. For example, the Food and Drug Administration may do this if the requester has a history of prompt payment. The Food and Drug Administration may also, at its discretion, aggregate the charges for certain time periods in order to avoid sending numerous small bills to frequent requesters, or to businesses or agents representing requesters. For example, the Food and Drug Administration might send a bill to such a requester once a month. Fees should be paid in accordance with the instructions furnished by the person who responds to the request.

[59 FR 533, Jan. 5, 1994. Redesignated and amended at 68 FR 25286, May 12, 2003]

§ 20.46 Waiver or reduction of fees.

(a) *Standard.* The Assistant Commissioner for Public Affairs (or delegatee)

will waive or reduce the fees that would otherwise be charged if disclosure of the information meets both of the following tests:

(1) Is in the public interest because it is likely to contribute significantly to public understanding of the operations or activities of the Government; and

(2) It is not primarily in the commercial interest of the requester. These two tests are explained in paragraphs (b) and (c) of this section.

(b) *Public interest.* Disclosure of information satisfies the first test only if it furthers the specific public interest of being likely to contribute significantly to public understanding of Government operations or activities, regardless of any other public interest it may further. In analyzing this question, the Food and Drug Administration will consider the following factors:

(1) Whether the records to be disclosed pertain to the operations or activities of the Federal Government;

(2) Whether disclosure of the records would reveal any meaningful information about Government operations or activities that is not already public knowledge;

(3) Whether disclosure will advance the understanding of the general public as distinguished from a narrow segment of interested persons. Under this factor, the Food and Drug Administration may consider whether the requester is in a position to contribute to public understanding. For example, the Food and Drug Administration may consider whether the requester has such knowledge or expertise as may be necessary to understand the information, and whether the requester's intended use of the information would be likely to disseminate the information to the public. An unsupported claim to be doing research for a book or article does not demonstrate that likelihood, while such a claim by a representative of the news media is better evidence; and

(4) Whether the contribution to public understanding will be a significant one, i.e., will the public's understanding of the Government's operations be substantially greater as a result of the disclosure.

(c) *Not primarily in the requester's commercial interest.* If disclosure passes the test of furthering the specific public interest described in paragraph (b) of this section, the Food and Drug Administration will determine whether disclosure also furthers the requester's commercial interest and, if so, whether this effect outweighs the advancement of that public interest. In applying this second test, the Food and Drug Administration will consider the following factors:

(1) Whether disclosure would further a commercial interest of the requester, or of someone on whose behalf the requester is acting. Commercial interests include interests relating to business, trade, and profit. Both profit and nonprofit-making corporations have commercial interests, as well as individuals, unions, and other associations. The interest of a representative of the news media in using the information for news dissemination purposes will not be considered a commercial interest.

(2) If disclosure would further a commercial interest of the requester, whether that effect outweighs the advancement of the public interest as defined in paragraph (b) of this section.

(d) *Deciding between waiver and reduction.* If the disclosure of the information requested passes both tests described in paragraphs (b) and (c) of this section, the Food and Drug Administration will normally waive fees. However, in some cases the Food and Drug Administration may decide only to reduce the fees. For example, the Food and Drug Administration may do this when disclosure of some but not all of the requested records passes the tests.

(e) *Procedure for requesting a waiver or reduction.* A requester must request a waiver or reduction of fees at the same time as the request for records. The requester should explain why a waiver or reduction is proper under the factors set forth in paragraphs (a) through (d) of this section. Only the Associate Commissioner for Public Affairs may make the decision whether to waive or reduce the fees. If the Food and Drug Administration does not completely grant the request for a waiver or reduction, the denial letter will designate a review official. The requester may appeal the denial to that official. The appeal letter should address reasons for

the Associate Commissioner's decision that are set forth in the denial letter.

[59 FR 534, Jan. 5, 1994. Redesignated and amended at 68 FR 25286, 25287, May 12, 2003]

§ 20.47 Situations in which confidentiality is uncertain.

In situations where the confidentiality of data or information is uncertain and there is a request for public disclosure, the Food and Drug Administration will consult with the person who has submitted or divulged the data or information or who would be affected by disclosure before determining whether or not such data or information is available for public disclosure.

[42 FR 15616, Mar. 22, 1977. Redesignated at 68 FR 25286, May 12, 2003]

§ 20.48 Judicial review of proposed disclosure.

Where the Food and Drug Administration consults with a person who will be affected by a proposed disclosure of data or information contained in Food and Drug Administration records pursuant to § 20.47, and rejects the person's request that part or all of the records not be made available for public disclosure, the decision constitutes final agency action that is subject to judicial review pursuant to 5 U.S.C. chapter 7. The person affected will be permitted 5 days after receipt of notification of such decision within which to institute suit in a United States District Court to enjoin release of the records involved. If suit is brought, the Food and Drug Administration will not disclose the records involved until the matter and all related appeals have been concluded.

[42 FR 15616, Mar. 22, 1977. Redesignated and amended at 68 FR 25286, 25287, May 12, 2003]

§ 20.49 Denial of a request for records.

(a) A denial of a request for records, in whole or in part, shall be signed by the Assistant Commissioner for Public Affairs (or delegatee).

(b) The name and title or position of each person who participated in the denial of a request for records shall be set forth in the letter denying the request. This requirement may be met by attaching a list of such individuals to the letter.

(c) A letter denying a request for records, in whole or in part, shall state the reasons for the denial and shall state that an appeal may be made to the Deputy Assistant Secretary for Public Affairs (Media), Department of Health and Human Services. The agency will also make a reasonable effort to include in the letter an estimate of the volume of the records denied, unless providing such an estimate would harm an interest protected by an exemption under the Freedom of Information Act. This estimate will ordinarily be provided in terms of the approximate number of pages or some other reasonable measure. This estimate will not be provided if the volume of records denied is otherwise indicated through deletions on records disclosed in part.

(d) Minor deletions of nondisclosable data and information from disclosable records shall not be deemed to be a denial of a request for records.

[42 FR 15616, Mar. 22, 1977, as amended at 46 FR 8457, Jan. 27, 1981; 55 FR 1405, Jan. 16, 1990. Redesignated and amended at 68 FR 25286, 25287, May 12, 2003]

§ 20.50 Nonspecific and overly burdensome requests.

The Food and Drug Administration will make every reasonable effort to comply fully with all requests for disclosure of nonexempt records. Nonspecific requests or requests for a large number of documents that require the deployment of a substantial amount of agency man-hours to search for and compile will be processed taking into account the staff-hours required, the tasks from which these resources must be diverted, the impact that this diversion will have upon the agency's consumer protection activities, and the public policy reasons justifying the requests. A decision on the processing of such a request for information shall be made after balancing the public benefit to be gained by the disclosure against the public loss that will result from diverting agency personnel from their other responsibilities. In any situation in which it is determined that a request for voluminous records would unduly burden and interfere with the operations of the Food and Drug Administration, the person making the request will be asked to be more specific

and to narrow the request, and to agree on an orderly procedure for the production of the requested records, in order to satisfy the request without disproportionate adverse effects on agency operations.

[42 FR 15616, Mar. 22, 1977. Redesignated at 68 FR 25286, May 12, 2003]

§ 20.51 Referral to primary source of records.

Upon receipt of a request for a record or document which is contained in Food and Drug Administration files but which is available elsewhere at a lower cost, the person requesting the record or document shall be referred to the primary source of the record or document.

[42 FR 15616, Mar. 22, 1977. Redesignated at 68 FR 25286, May 12, 2003]

§ 20.52 Availability of records at National Technical Information Service.

The Food and Drug Administration is furnishing a number of records to the National Technical Information Service (NTIS), 5285 Port Royal Rd., Springfield, VA 22162, which reproduces and distributes such information to the public at cost. A single copy of each such record shall be available for public review at the Food and Drug Administration. All persons requesting copies of such records shall be answered by referring the person requesting the records to NTIS.

[42 FR 15616, Mar. 22, 1977, as amended at 54 FR 9038, Mar. 3, 1989. Redesignated at 68 FR 25286, May 12, 2003]

§ 20.53 Use of private contractor for copying.

The Food and Drug Administration may furnish requested records to a private contractor for copying after deletion of all nondisclosable data and information. Under these circumstances, the Food and Drug Administration will charge the person requesting the records for all of the fees involved pursuant to § 20.45.

[42 FR 15616, Mar. 22, 1977. Redesignated and amended at 68 FR 25286, 25287, May 12, 2003]

§ 20.54 Request for review without copying.

(a) A person requesting disclosure of records shall be permitted an opportunity to review them without the necessity for copying them where the records involved contain only disclosable data and information. Under these circumstances, the Food and Drug Administration will charge only for the costs of searching for the records.

(b) Where a request is made for review of records without copying, and the records involved contain both disclosable and nondisclosable information, the records containing nondisclosable information shall first be copied with the nondisclosable information blocked out and the Food and Drug Administration will charge for the costs of searching and copying.

[42 FR 15616, Mar. 22, 1977. Redesignated at 68 FR 25286, May 12, 2003]

§ 20.55 Indexing trade secrets and confidential commercial or financial information.

Whenever the Food and Drug Administration denies a request for a record or portion thereof on the grounds that the record or portion thereof is exempt from public disclosure as trade secret or confidential commercial or financial data and information under § 20.61, and the person requesting the record subsequently contests the denial in the courts, the Food and Drug Administration will so inform the person affected, i.e., the person who submitted the record, and will require that such person intervene to defend the exempt status of the record. If a court requires the Food and Drug Administration to itemize and index such records, the Food and Drug Administration will so inform the person affected and will require that such person undertake the itemization and indexing of the records. If the affected person fails to intervene to defend the exempt status of the records and to itemize and index the disputed records, the Food and Drug Administration will take this failure into consideration in deciding whether that person has waived such exemption so as to require the Food and Drug Administration to promptly

make the records available for public disclosure.

[42 FR 15616, Mar. 22, 1977, as amended at 59 FR 535, Jan. 5, 1994. Redesignated at 68 FR 25286, May 12, 2003]

Subpart D—Exemptions

§ 20.60 Applicability of exemptions.

(a) The exemptions established in this subpart shall apply to all Food and Drug Administration records, except as provided in subpart E of this part. Accordingly, a record that is ordinarily available for public disclosure in accordance with the provisions in subpart F of this part or of another regulation cross-referenced in § 20.100(c) is not available for such disclosure to the extent that it falls within an exemption contained in this subpart, except as provided by the limitations on exemptions specified in subpart E of this part. For example, correspondence that is ordinarily disclosable under § 20.103 is not disclosable to the extent that it contains trade secrets exempt from disclosure under § 20.61 and is not subject to discretionary release under § 20.82.

(b) Where application of one or more exemptions results in a record being disclosable in part and nondisclosable in part, the rule established in § 20.22 shall apply.

§ 20.61 Trade secrets and commercial or financial information which is privileged or confidential.

(a) A trade secret may consist of any commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. There must be a direct relationship between the trade secret and the productive process.

(b) Commercial or financial information that is privileged or confidential means valuable data or information which is used in one's business and is of a type customarily held in strict confidence or regarded as privileged and not disclosed to any member of the public by the person to whom it belongs.

(c) Data and information submitted or divulged to the Food and Drug Administration which fall within the definitions of a trade secret or confidential commercial or financial information are not available for public disclosure.

(d) A person who submits records to the Government may designate part or all of the information in such records as exempt from disclosure under exemption 4 of the Freedom of Information Act. The person may make this designation either at the time the records are submitted to the Government or within a reasonable time thereafter. The designation must be in writing. Where a legend is required by a request for proposals or request for quotations, pursuant to 48 CFR 352.215–12, then that legend is necessary for this purpose. Any such designation will expire 10 years after the records were submitted to the Government.

(e) The procedures in this paragraph apply to records on which the submitter has designated information as provided in paragraph (d) of this section. These procedures also apply to records that were submitted to the Food and Drug Administration when the agency has substantial reason to believe that information in the records could reasonably be considered exempt under exemption 4 of the Freedom of Information Act. Certain exceptions to these procedures are set forth in paragraph (f) of this section.

(1) When the Food and Drug Administration receives a request for such records and determines that disclosure may be required, the Food and Drug Administration will make reasonable efforts to notify the submitter about these facts. The notice will include a copy of the request, and it will inform the submitter about the procedures and time limits for submission and consideration of objections to disclosure. If the Food and Drug Administration must notify a large number of submitters, notification may be done by posting or publishing a notice in a place where the submitters are reasonably likely to become aware of it.

(2) The submitter has 5 working days from receipt of the notice to object to disclosure of any part of the records and to state all bases for its objections.

(3) The Food and Drug Administration will give consideration to all bases

that have been stated in a timely manner by the submitter. If the Food and Drug Administration decides to disclose the records, the Food and Drug Administration will notify the submitter in writing. This notice will briefly explain why the agency did not sustain the submitter's objections. The Food and Drug Administration will include with the notice a copy of the records about which the submitter objected, as the agency proposes to disclose them. The notice will state that the Food and Drug Administration intends to disclose the records 5 working days after the submitter receives the notice unless a U.S. District Court orders the agency not to release them.

(4) If a requester files suit under the Freedom of Information Act to obtain records covered by this paragraph, the Food and Drug Administration will promptly notify the submitter.

(5) Whenever the Food and Drug Administration sends a notice to a submitter under paragraph (e)(1) of this section, the Food and Drug Administration will notify the requester that the Food and Drug Administration is giving the submitter a notice and an opportunity to object. Whenever the Food and Drug Administration sends a notice to a submitter under paragraph (e)(3) of this section, the Food and Drug Administration will notify the requester of this fact.

(f) The notice requirements in paragraph (e) of this section do not apply in the following situations:

(1) The Food and Drug Administration decided not to disclose the records;

(2) The information has previously been published or made generally available;

(3) Disclosure is required by a regulation issued after notice and opportunity for public comment, that specifies narrow categories of records that are to be disclosed under the Freedom of Information Act, but in this case a submitter may still designate records as described in paragraph (d) of this section, and in exceptional cases, the Food and Drug Administration may, at its discretion, follow the notice procedures in paragraph (e) of this section;

(4) The information requested has not been designated by the submitter as exempt from disclosure when the submitter had an opportunity to do so at the time of submission of the information or within a reasonable time thereafter, unless the Food and Drug Administration has substantial reason to believe that disclosure of the information would result in competitive harm; or

(5) The designation appears to be obviously frivolous, but in this case the Food and Drug Administration will still give the submitter the written notice required by paragraph (e)(3) of this section (although this notice need not explain our decision or include a copy of the records), and the Food and Drug Administration will notify the requester as described in paragraph (e)(5) of this section.

[42 FR 15616, Mar. 22, 1977, as amended at 59 FR 535, Jan. 5, 1994]

§ 20.62 Inter- or intra-agency memoranda or letters.

All communications within the Executive Branch of the Federal government which are in written form or which are subsequently reduced to writing may be withheld from public disclosure except that factual information which is reasonably segregable in accordance with the rule established in § 20.22 is available for public disclosure.

§ 20.63 Personnel, medical, and similar files, disclosure of which constitutes a clearly unwarranted invasion of personal privacy.

(a) The names or other information which would identify patients or research subjects in any medical or similar report, test, study, or other research project shall be deleted before the record is made available for public disclosure.

(b) The names and other information which would identify patients or research subjects should be deleted from any record before it is submitted to the Food and Drug Administration. If the Food and Drug Administration subsequently needs the names of such individuals, a separate request will be made.

(c) Requests for deletion of business or product names prior to disclosure of any record to the public shall not be granted on the ground of privacy, but such deletion may be justified under

another exemption established in this subpart, e.g., the exemption for trade secrets and confidential commercial or financial information under § 20.61.

(d) Names of individuals conducting investigations, studies, or tests on products or ingredients shall not be deleted prior to disclosure of any record to the public unless extraordinary circumstances are shown.

(e) A request for all records relating to a specific individual will be denied as a clearly unwarranted invasion of personal privacy unless accompanied by the written consent of the individual named.

(f) The names and any information that would identify the voluntary reporter or any other person associated with an adverse event involving a human drug, biologic, or medical device product shall not be disclosed by the Food and Drug Administration or by a manufacturer in possession of such reports in response to a request, demand, or order. Information that would identify the voluntary reporter or persons identified in the report includes, but is not limited to, the name, address, institution, or any other information that would lead to the identities of the reporter or persons identified in a report. This provision does not affect disclosure of the identities of reporters required by a Federal statute or regulation to make adverse event reports. Disclosure of the identities of such reporters is governed by the applicable Federal statutes and regulations.

(1) *Exceptions*. (i) Identities may be disclosed if both the voluntary reporter and the person identified in an adverse event report or that person's legal representative consent in writing to disclosure, but neither FDA nor any manufacturer in possession of such reports shall be required to seek consent for disclosure from the voluntary reporter or the person identified in the adverse event report or that person's legal representative; or

(ii) Identities of the voluntary reporter and the person who experienced the reported adverse event may be disclosed pursuant to a court order in the course of medical malpractice litigation involving both parties; or (iii) The report, excluding the identities of any other individuals, shall be disclosed to the person who is the subject of the report upon request.

(2) *Preemption*. No State or local governing entity shall establish or continue in effect any law, rule, regulation, or other requirement that permits or requires disclosure of the identities of the voluntary reporter or other person identified in an adverse event report except as provided in this section.

[42 FR 15616, Mar. 22, 1977, as amended at 60 FR 16968, Apr. 3, 1995]

§ 20.64 Records or information compiled for law enforcement purposes.

(a) Records or information compiled for law enforcement purposes may be withheld from public disclosure pursuant to the provisions of this section to the extent that disclosure of such records or information:

(1) Could reasonably be expected to interfere with enforcement proceedings;

(2) Would deprive a person to a right to a fair trial or an impartial adjudication;

(3) Could reasonably be expected to constitute an unwarranted invasion of personal privacy;

(4) Could reasonably be expected to disclose the identity of a confidential source, including a State, local, or foreign agency or authority or any private institution which furnished information on a confidential basis; and information furnished by a confidential source in the case of a record compiled by the Food and Drug Administration or any other criminal law enforcement authority in the course of a criminal investigation or by an agency conducting a lawful national security intelligence investigation;

(5) Would disclose techniques and procedures for law enforcement investigations or prosecutions or would disclose guidelines for law enforcement investigations or prosecutions, if such disclosure could reasonably be expected to risk circumvention of the law; or

(6) Could reasonably be expected to endanger the life or physical safety of any individual.

(b) Records include all records relating to regulatory enforcement action, including both administrative and

court action, which have not been disclosed to any member of the public, including any person who is the subject of the investigation.

(c) Any record which is disclosed to any person, including any person who is the subject of a Food and Drug Administration investigation, and any data or information received from any person who is the subject of a Food and Drug Administration investigation relating to such investigation, is available for public disclosure at that time in accordance with the rule established in § 20.21, except that:

(1) Disclosure of such records shall be subject to the other exemptions established in this subpart and to the limitations on exemptions established in subpart E of this part.

(2) The record of a section 305 hearing shall be available for public disclosure only in accordance with the provisions of § 7.87 of this chapter.

(d) Records for law enforcement purposes shall be subject to the following rules:

(1) No such record is available for public disclosure prior to the consideration of regulatory enforcement action based upon that record's being closed, except as provided in § 20.82. The Commissioner will exercise his discretion to disclose records relating to possible criminal prosecution pursuant to § 20.82 prior to consideration of criminal prosecution being closed only very rarely and only under circumstances that demonstrate a compelling public interest.

(2) After the consideration of regulatory enforcement action is closed, such records shall be made available for public disclosure except to the extent that other exemptions from disclosure in this subpart are applicable. No statements of witnesses obtained through promises of confidentiality are available for public disclosure.

(3) The consideration of regulatory enforcement action based upon a particular record shall be deemed to be closed within the meaning of this section:

(i) If it relates to administrative action, when a final decision has been made not to take such action or such action has been taken and the matter has been concluded.

(ii) If it relates to court action, when a final decision has been made not to recommend such action to a United States attorney based upon that record, or a recommendation has been finally refused by a United States attorney, or court action has been instituted and the matter and all related appeals have been concluded, or the statute of limitations runs.

(iii) If it relates to both administrative and court action, when the events described in both paragraph (d)(3) (i) and (ii) of this section have occurred.

(4) Prior to disclosure of any record specifically reflecting consideration of possible criminal prosecution of any individual, all names and other information that would identify an individual who was considered for criminal prosecution but who was not prosecuted shall be deleted unless the Commissioner concludes that there is a compelling public interest in the disclosure of such names.

(e) Names and other information that would identify a Food and Drug Administration employee shall be deleted from records prior to public disclosure only pursuant to § 20.32.

[42 FR 15616, Mar. 22, 1977, as amended at 59 FR 536, Jan. 5, 1994]

§ 20.65 National defense and foreign policy.

(a) Records or information may be withheld from public disclosure if they are:

(1) Specifically authorized under criteria established by an Executive order to be kept secret in the interest of national defense or foreign policy; and

(2) In fact properly classified under such Executive order.

(b) [Reserved]

[70 FR 41958, July 21, 2005]

§ 20.66 Internal personnel rules and practices.

Records or information may be withheld from public disclosure if they are related solely to the internal personnel rules and practices of the Food and Drug Administration (FDA). Under this exemption, FDA may withhold records or information about routine internal agency practices and procedures. Under this exemption, the agency may also

withhold internal records whose release would help some persons circumvent the law.

[70 FR 41958, July 21, 2005]

§ 20.67 Records exempted by other statutes.

Records or information may be withheld from public disclosure if a statute specifically allows the Food and Drug Administration (FDA) to withhold them. FDA may use another statute to justify withholding records and information only if it absolutely prohibits disclosure, sets forth criteria to guide our decision on releasing material, or identifies particular types of matters to be withheld.

[70 FR 41958, July 21, 2005]

Subpart E—Limitations on Exemptions

§ 20.80 Applicability of limitations on exemptions.

(a) The limitations on exemptions established in this subpart shall apply to all Food and Drug Administration records, except as specifically provided herein. Accordingly, a record that is ordinarily exempt from public disclosure in accordance with the provisions in subpart D of this part is available for such disclosure to the extent that it falls within a limitation on the exemption contained in this subpart. For example, an investigatory record that is ordinarily exempt from disclosure under § 20.64 is disclosable to Congress in accordance with the provisions of § 20.87.

(b) Disclosure of a record to any member of the public pursuant to the provisions in § 20.81, data and information previously disclosed to the public, in § 20.82, discretionary disclosure by the Commissioner, and in § 20.83, disclosure pursuant to a court order, shall involve the rule established in § 20.21 that the record shall be made available for disclosure to all members of the public who request it. Disclosure of a record only to the limited categories of persons and under the conditions specified in § 20.84, special government employees, in § 20.85, other Federal government departments and agencies, in § 20.86, in camera disclosure in administrative or court proceedings, in § 20.87(b), Congress, in § 20.88, State and local government officials, in § 20.89, foreign government officials, and in § 20.90, contractors, which does not result in disclosure of the record to any member of the public in an authorized manner, shall not invoke the rule established in § 20.21.

(c) Disclosure to government employees and special government employees of records exempt from public disclosure shall subject those persons to the same restrictions with respect to the disclosure of such records as any Food and Drug Administration employee.

(d) In the case of a record in a Privacy Act Record System, as defined in § 21.3(c) of this chapter:

(1) The availability to an individual, as defined in § 21.3(a), of a record about himself that is retrieved by the individual's name or other personal identifier and is contained in a Privacy Act Record System shall be subject to the special requirements of part 21 of this chapter (the privacy regulations) and shall not be subject to the exemptions in subpart D of this part except that where the system is exempt and the requested record is not available under § 21.61 of this chapter, the provisions of this part shall apply.

(2) The availability of a record about an individual to persons other than the individual who is the subject of the record shall be subject to the special requirements of part 21, subpart G, of this chapter (restrictions on disclosure in the privacy regulations), and shall not be subject to the limitations on exemptions in this subpart except as provided in part 21, subpart G, of this chapter.

§ 20.81 Data and information previously disclosed to the public.

(a) Any Food and Drug Administration record that is otherwise exempt from public disclosure pursuant to subpart D of this part is available for public disclosure to the extent that it contains data or information that have previously been disclosed in a lawful manner to any member of the public, other than an employee or consultant or pursuant to other commerical arrangements with appropriate safeguards for secrecy.

(1) For purposes of this section, an individual shall be deemed to be a consultant only if disclosure of the information was necessary in order to perform that specific consulting service and the purpose of the disclosure was solely to obtain that service. The number of consultants who have received such information shall have been limited to the number reasonably needed to perform that particular consulting service.

(2) For purposes of this section, other commercial arrangements shall include licenses, contracts, and similar legal relationships between business associates.

(3) For purposes of this section, data and information disclosed to clinical investigators or members of institutional review committees, whether required by regulations of the Food and Drug Administration, or made voluntarily, if accompanied by appropriate safeguards to assure secrecy and otherwise in accordance with this section, are not deemed to have been previously disclosed to any member of the public within the meaning of paragraph (a) of this section.

(b) Any statement relating to prior public disclosure is subject to the False Reports to the Government Act, 18 U.S.C. 1001.

[42 FR 15616, Mar. 22, 1977, as amended at 54 FR 9038, Mar. 3, 1989; 59 FR 536, Jan. 5, 1994; 68 FR 25287, May 12, 2003]

§ 20.82 Discretionary disclosure by the Commissioner.

(a) Except as provided in paragraph (b) of this section, the Commissioner may, in his discretion, disclose part or all of any Food and Drug Administration record that is otherwise exempt from disclosure pursuant to subpart D of this part. The Commissioner shall exercise his discretion to disclose such records whenever he determines that such disclosure is in the public interest, will promote the objectives of the act and the agency, and is consistent with the rights of individuals to privacy, the property rights of persons in trade secrets, and the need for the agency to promote frank internal policy deliberations and to pursue its regulatory activities without disruption.

(b) The Commissioner shall not make available for public disclosure any record that is:

(1) Exempt from public disclosure pursuant to § 20.61.

(2) Exempt from public disclosure pursuant to § 20.63.

(3) Prohibited from public disclosure under statute.

(4) Contained in a Privacy Act Record System where disclosure would constitute a clearly unwarranted invasion of personal privacy or is otherwise in violation of 5 U.S.C. 552a(b), as applied in part 21, subpart G, of this chapter (restrictions on disclosure in the privacy regulations).

(c) Discretionary disclosure of a record pursuant to this section shall invoke the requirement that the record shall be disclosed to any person who requests it pursuant to § 20.21, but shall not set a precedent for discretionary disclosure of any similar or related record and shall not obligate the Commissioner to exercise his discretion to disclose any other record that is exempt from disclosure.

[42 FR 15616, Mar. 22, 1977, as amended at 70 FR 41958, July 21, 2005]

§ 20.83 Disclosure required by court order.

(a) Records of the Food and Drug Administration which the Commissioner has determined are not available for public disclosure, in the form of a regulation published or cross-referenced in this part, shall nevertheless be made available for public disclosure in compliance with a final court order requiring such disclosure.

(b) Where the Food and Drug Administration record ordered disclosed under paragraph (a) of this section is a record about an individual that is not available for public disclosure under § 20.63, the Food and Drug Administration shall attempt to notify the individual who is the subject of the record of the disclosure, by sending a notice to the individual's last known address.

(c) Paragraph (b) of this section shall not apply where the name or other personal identifying information is deleted prior to disclosure.

[42 FR 15616, Mar. 22, 1977, as amended at 68 FR 25287, May 12, 2003]

§ 20.84 Disclosure to consultants, advisory committees, State and local government officials commissioned pursuant to 21 U.S.C. 372(a), and other special government employees.

Data and information otherwise exempt from public disclosure may be disclosed to Food and Drug Administration consultants, advisory committees, State and local government officials commissioned pursuant to 21 U.S.C. 372(a), and other special government employees for use only in their work with the Food and Drug Administration. Such persons are thereafter subject to the same restrictions with respect to the disclosure of such data and information as any other Food and Drug Administration employee.

§ 20.85 Disclosure to other Federal government departments and agencies.

Any Food and Drug Administration record otherwise exempt from public disclosure may be disclosed to other Federal government departments and agencies, except that trade secrets and confidential commercial or financial information prohibited from disclosure by 21 U.S.C. 331(j), 21 U.S.C. 360(j)(c), 42 U.S.C. 263g(d) and 42 U.S.C. 263i(e) may be released only as provided by those sections. Any disclosure under this section shall be pursuant to a written agreement that the record shall not be further disclosed by the other department or agency except with the written permission of the Food and Drug Administration.

[47 FR 10804, Mar. 12, 1982, as amended at 59 FR 536, Jan. 5, 1994]

§ 20.86 Disclosure in administrative or court proceedings.

Data and information otherwise exempt from public disclosure may be revealed in Food and Drug Administration administrative proceedings pursuant to parts 10, 12, 13, 14, 15, 17, and 19 of this chapter or court proceedings, where data or information are relevant. The Food and Drug Administration will take appropriate measures, or request that appropriate measures be taken, to reduce disclosure to the minimum necessary under the circumstances.

[42 FR 15616, Mar. 22, 1977, as amended at 60 FR 38633, July 27, 1995]

§ 20.87 Disclosure to Congress.

(a) All records of the Food and Drug Administration shall be disclosed to Congress upon an authorized request.

(b) An authorized request for Food and Drug Administration records by Congress shall be made by the chairman of a committee or subcommittee of Congress acting pursuant to committee business.

(c) An individual member of Congress who requests a record for his own use or on behalf of any constituent shall be subject to the same rules in this part that apply to any other member of the public.

[42 FR 15616, Mar. 22, 1977, as amended at 59 FR 536, Jan. 5, 1994]

§ 20.88 Communications with State and local government officials.

(a) A State or local government official commissioned by the Food and Drug Administration pursuant to 21 U.S.C. 372(a) shall have the same status with respect to disclosure of Food and Drug Administration records as any special government employee.

(b) Communications with State and local government officials with respect to law enforcement activities undertaken pursuant to a contract between the Food and Drug Administration and such officials shall be subject to the rules for public disclosure established in § 20.64.

(c) Communications with State and local government officials who are not commissioned pursuant to 21 U.S.C. 372(a) or under a contract to perform law enforcement activities shall have the same status as communications with any member of the public, except that:

(1) Investigatory records compiled for law enforcement purposes by State and local government officials who perform counterpart functions to the Food and Drug Administration at the State and local level, and trade secrets and confidential commercial or financial information obtained by such officials, which are voluntarily disclosed to the

Food and Drug Administration as part of cooperative law enforcement and regulatory efforts, shall be exempt from public disclosure to the same extent to which the records would be so exempt pursuant to §§ 20.61 and 20.64, as if they had been prepared by or submitted directly to Food and Drug Administration employees, except that investigatory records shall be exempt from disclosure for a longer period of time if the State or local government officials so require as a condition of their furnishing the information to the Food and Drug Administration.

(2) Disclosure of investigatory records compiled for law enforcement purposes by the Food and Drug Administration to State and local government officials who perform counterpart functions to the Food and Drug Administratrion at the State and local level as part of cooperative law enforcement efforts does not invoke the rule established in § 20.21 that such records shall be made available for disclosure to all members of the public.

(d)(1) The Commissioner of Food and Drugs, or any other officer or employee of the Food and Drug Administration whom the Commissioner may designate to act on his or her behalf for the purpose, may authorize the disclosure of confidential commercial information submitted to the Food and Drug Administration, or incorporated into agency-prepared records, to State government officials as part of cooperative law enforcement or regulatory efforts, provided that:

(i) The State government agency has provided both a written statement establishing its authority to protect confidential commercial information from public disclosure and a written commitment not to disclose any such information provided without the written permission of the sponsor or written confirmation by the Food and Drug Administration that the information no longer has confidential status; and

(ii) The Commissioner of Food and Drugs or the Commissioner's designee makes one or more of the following determinations:

(A) The sponsor of the product application has provided written authorization for the disclosure;

(B) Disclosure would be in the interest of public health by reason of the State government's possessing information concerning the safety, effectiveness, or quality of a product or information concerning an investigation, or by reason of the State government being able to exercise its regulatory authority more expeditiously than the Food and Drug Administration; or

(C) The disclosure is to a State government scientist visiting the Food and Drug Administration on the agency's premises as part of a joint review or long-term cooperative training effort authorized under section 708 of the Federal Food, Drug, and Cosmetic Act (the act), the review is in the interest of public health, the Food and Drug Administration retains physical control over the information, the Food and Drug Administration requires the visiting State government scientist to sign a written commitment to protect the confidentiality of the information, and the visiting State government scientist provides a written assurance that he or she has no financial interest in the regulated industry of the type that would preclude participation in the review of the matter if the individual were subject to the conflict of interest rules applicable to the Food and Drug Administration advisory committee members under § 14.80(b)(1) of this chapter. Subject to all the foregoing conditions, a visiting State government scientist may have access to trade secret information, entitled to protection under section 301(j) of the act, in those cases where such disclosures would be a necessary part of the joint review or training.

(2) Except as provided under paragraph (d)(1)(ii)(C) of this section, this provision does not authorize the disclosure to State government officials of trade secret information concerning manufacturing methods and processes prohibited from disclosure by section 301(j) of the act, unless pursuant to an express written authorization provided by the submitter of the information.

(3) Any disclosure under this section of information submitted to the Food and Drug Administration or incorporated into agency-prepared records does not invoke the rule established in

§ 20.21 that such records shall be made available to all members of the public.

(e)(1) The Senior Associate Commissioner for Policy, Planning, and Legislation, or the Deputy Commissioner for International and Constituent Relations, or any other officer or employee of the Food and Drug Administration whom the Senior Associate Commissioner for Policy, Planning, and Legislation or the Deputy Commissioner for International and Constituent Relations may designate to act on their behalf for the purpose, may authorize the disclosure to, or receipt from, an official of a State government agency of nonpublic, predecisional documents concerning the Food and Drug Administration's or the other government agency's regulations or other regulatory requirements, or other nonpublic information relevant to either agency's activities, as part of efforts to improve Federal-State uniformity, cooperative regulatory activities, or implementation of Federal-State agreements, provided that:

(i) The State government agency has the authority to protect such nonpublic documents from public disclosure and will not disclose any such documents provided without the written confirmation by the Food and Drug Administration that the documents no longer have nonpublic status; and

(ii) The Senior Associate Commissioner for Policy, Planning, and Legislation or the Deputy Commissioner for International and Constituent Relations or their designee makes the determination that the exchange is reasonably necessary to improve Federal-State uniformity, cooperative regulatory activities, or implementation of Federal-State agreements.

(2) Any exchange under this section of nonpublic documents does not invoke the rule established at § 20.21 that such records shall be made available to all members of the public.

(3) For purposes of this paragraph, the term *official of a State government agency* includes, but is not limited to, an agent contracted by the State government, and an employee of an organization of State officials having responsibility to facilitate harmonization of State standards and requirements in FDA's areas of responsibility. For such officials, the statement and commitment required by paragraph (e)(1)(i) of this section shall be provided by both the organization and the individual.

[42 FR 15616, Mar. 22, 1977, as amended at 60 FR 63381, Dec. 8, 1995; 65 FR 11887, Mar. 7, 2000]

§ 20.89 Communications with foreign government officials.

Communications with foreign government officials shall have the same status as communications with any member of the public, except that:

(a) Investigatory records compiled for law enforcement purposes by foreign government officials who perform counterpart functions to the Food and Drug Administration in a foreign country, and trade secrets and confidential commercial or financial information obtained by such officials, which are voluntarily disclosed to the Food and Drug Administration as part of cooperative law enforcement and regulatory efforts, shall be exempt from public disclosure to the same extent to which the records would be so exempt pursuant to §§ 20.61 and 20.64, as if they had been prepared by or submitted directly to Food and Drug Administration employees, except that investigatory records shall be exempt from disclosure for a longer period of time if the foreign government officials so require as a condition of their furnishing the information to the Food and Drug Administration.

(b) Disclosure of investigatory records compiled for law enforcement purposes by the Food and Drug Administration to foreign government officials who perform counterpart functions to the Food and Drug Administration in a foreign country as part of cooperative law enforcement efforts does not invoke the rule established in § 20.21 that such records shall be made available for disclosure to all members of the public.

(c)(1) The Commissioner of Food and Drugs, or any other officer or employee of the Food and Drug Administration whom the Commissioner may designate to act on his or her behalf for the purpose, may authorize the disclosure of confidential commercial information

submitted to the Food and Drug Administration, or incorporated into agency-prepared records, to foreign government officials who perform counterpart functions to the Food and Drug Administration as part of cooperative law enforcement or regulatory efforts, provided that:

(i) The foreign government agency has provided both a written statement establishing its authority to protect confidential commercial information from public disclosure and a written commitment not to disclose any such information provided without the written permission of the sponsor or written confirmation by the Food and Drug Administration that the information no longer has confidential status; and

(ii) The Commissioner of Food and Drugs or the Commissioner's designee makes one or more of the following determinations:

(A) The sponsor of the product application has provided written authorization for the disclosure;

(B) Disclosure would be in the interest of public health by reason of the foreign government's possessing information concerning the safety, efficacy, or quality of a product or information concerning an investigation; or

(C) The disclosure is to a foreign scientist visiting the Food and Drug Administration on the agency's premises as part of a joint review or long-term cooperative training effort authorized under section 708 of the act, the review is in the interest of public health, the Food and Drug Administration retains physical control over the information, the Food and Drug Administration requires the visiting foreign scientist to sign a written commitment to protect the confidentiality of the information, and the scientist provides a written assurance that he or she has no financial interest in the regulated industry of the type that would preclude participation in the review of the matter if the individual were subject to the conflict of interest rules applicable to the Food and Drug Administration advisory committee members under § 14.80(b)(1) of this chapter. Subject to all of the foregoing conditions, visiting foreign scientists may have access to trade secret information, entitled to protection under section 301(j) of the Federal Food, Drug, and Cosmetic Act (the act), in those cases where such disclosures would be a necessary part of the joint review or training.

(2) Except as provided under paragraph (c)(1)(ii)(C) of this section, this provision does not authorize the disclosure to foreign government officials of other countries of trade secret information concerning manufacturing methods and processes prohibited from disclosure by section 301(j) of the act, unless pursuant to an express written authorization provided by the submitter of the information.

(3) Any disclosure under this section of information submitted to the Food and Drug Administration or incorporated into agency-prepared records does not invoke the rule established in § 20.21 that such records shall be made available to all members of the public.

(d)(1) The Senior Associate Commissioner for Policy, Planning, and Legislation, or the Deputy Commissioner for International and Constituent Relations, or any other officer or employee of the Food and Drug Administration whom the Senior Associate Commissioner for Policy, Planning, and Legislation or the Deputy Commissioner for International and Constituent Relations may designate to act on their behalf for the purpose, may authorize the disclosure to, or receipt from, an official of a foreign government agency of nonpublic, predecisional documents concerning the Food and Drug Administration's or the other government agency's regulations or other regulatory requirements, or other nonpublic information relevant to either agency's activities, as part of cooperative efforts to facilitate global harmonization of regulatory requirements, cooperative regulatory activities, or implementation of international agreements, provided that:

(i) The foreign government agency has the authority to protect such nonpublic documents from public disclosure and will not disclose any such documents provided without the written confirmation by the Food and Drug Administration that the documents no longer have nonpublic status; and

(ii) The Senior Associate Commissioner for Policy, Planning, and Legislation or the Deputy Commissioner for

International and Constituent Relations or their designee makes the determination that the exchange is reasonably necessary to facilitate global harmonization of regulatory requirements, cooperative regulatory activities, or implementation of international agreements.

(2) Any exchange under this section of nonpublic documents does not invoke the rule established in § 20.21 that such records shall be made available to all members of the public.

(e) For purposes of this section, the term ''official of a foreign government agency'' includes, but is not limited to, employees (whether temporary or permanent) of and agents contracted by the foreign government, or by an international organization established by law, treaty, or other governmental action and having responsibility to facilitate global or regional harmonization of standards and requirements in FDA's areas of responsibility or to promote and coordinate public health efforts. For such officials, the statement and commitment required by paragraph (c)(1)(i) of this section shall be provided on behalf of both the organization and the individual.

[42 FR 15616, Mar. 22, 1977, as amended at 58 FR 61603, Nov. 19, 1993; 60 FR 63382, Dec. 8, 1995; 65 FR 11888, Mar. 7, 2000]

§ 20.90 Disclosure to contractors.

(a) Data and information otherwise exempt from public disclosure may be disclosed to contractors with the Food and Drug Administration and their employees for use only in their work for the Food and Drug Administration. Contractors and their employees are thereafter subject to the same legal restrictions and penalties with respect to the disclosure of such data and information as Food and Drug Administration employees.

(b) A written agreement between the Food and Drug Administration and any contractor shall be entered into before data and information otherwise exempt from public disclosure may be disclosed to the contractor. The contractor shall agree to establish and follow security precautions considered by the Food and Drug Administration to be necessary to ensure proper and confidential handling of the data and information. The written agreement shall include, where appropriate, provisions establishing:

(1) Restrictions on access to the data and information by the contractor, its employees, or other persons;

(2) Physical storage requirements;

(3) Requirements for the handling and accountability of the data and information by the contractor and its employees;

(4) Limitations on reproduction, transmission, and disclosure of the data and information;

(5) A requirement of advance approval by the Food and Drug Administration of the use by the contractor of subcontractors, vendors, or suppliers;

(6) Procedures to be followed when the contractor employs time-shared computer operations;

(7) Methods of destroying source documents or related waste material; and

(8) The period during which the contractor may retain such data and information.

§ 20.91 Use of data or information for administrative or court enforcement action.

Nothing in this part or this chapter shall prevent the Food and Drug Administration from using any data or information, whether obtained voluntarily or involuntarily and whether or not it is available for public disclosure, as the basis for taking any administrative or court enforcement action within its jurisdiction. Data and information otherwise exempt from public disclosure are nevertheless available for public disclosure to the extent necessary to effectuate such action, e.g., the brand name, code designation, and distribution information are released when a product is recalled.

Subpart F—Availability of Specific Categories of Records

§ 20.100 Applicability; cross-reference to other regulations.

(a) The provisions set forth in this subpart or cross-referenced in paragraph (c) of this section state the way in which specific categories of Food and Drug Administration records are handled upon a request for public disclosure. The exemptions established in

subpart D of this part and the limitations on exemptions established in subpart E of this part shall be applicable to all Food and Drug Administration records, as provided in §§ 20.60 and 20.80. Accordingly, a record that is ordinarily available for public disclosure in accordance with this part or under other regulations is not available for such disclosure to the extent that it falls within an exemption contained in subpart D of this part except as provided by the limitations on exemptions specified in subpart E of this part.

(b) The Commissioner, on his own initiative or on the petition of any interested person, may amend this subpart or promulgate and cross-reference additional regulations to state the status of additional categories of documents to settle pending questions or to reflect court decisions.

(c) In addition to the provisions of this part, rules on the availability of the following specific categories of Food and Drug Administration records are established by regulations in this chapter:

(1) Section 305 hearing records, in § 7.87(c) of this chapter.

(2) Flavor ingredient records and notes, in § 101.22(i)(4)(iv) of this chapter.

(3) Environmental assessments; finding of no significant impact, in § 25.51 of this chapter, or draft and final environmental impact statements, in § 25.52 of this chapter.

(4) Color additive petitions, in § 71.15 of this chapter.

(5) Food standard temporary permits, in § 130.17(k) of this chapter.

(6) Information on thermal processing of low-acid foods packaged in hermetically sealed containers, in § 108.35(l) of this chapter.

(7) Food additive petitions, in §§ 171.1(h) and 571.1(h) of this chapter.

(8) Action levels for natural and unavoidable defects in food for human use, in § 110.110(e) of this chapter.

(9) Drug establishment registrations and drug listings, in § 207.81 of this chapter.

(10) Investigational new animal drug notices, in § 514.12 of this chapter.

(11) New animal drug application files, in § 514.11 of this chapter.

(12) Investigational new animal drug notice and a new animal drug application file for an antibiotic drug, in § 514.10 of this chapter.

(13) Methadone patient records, in § 291.505(g) of this chapter.

(14) Investigational new drug notice, in § 312.130 of this chapter.

(15) Labeling for and lists of approved new drug applications, in § 314.430 of this chapter.

(16) Master file for a new drug application, in § 312.420 of this chapter.

(17) New drug application file, in § 314.430 of this chapter.

(18) Data and information submitted for in vitro diagnostic products, in § 809.4 of this chapter.

(19) Data and information submitted for OTC drug review, in § 330.10(a)(2) of this chapter.

(20) Investigational new drug notice for an antibiotic drug, in § 431.70 of this chapter.

(21) Antibiotic drug file, in § 314.430 of this chapter.

(22) [Reserved]

(23) Investigational new drug notice for a biological product, in § 601.50 of this chapter.

(24) Applications for biologics licenses for biological products, in § 601.51 of this chapter.

(25) Cosmetic establishment registrations, in § 710.7 of this chapter.

(26) Cosmetic product ingredient and cosmetic raw material composition statements, § 720.8 of this chapter.

(27) Cosmetic product experience reports, in § 730.7 of this chapter.

(28) Device premarket notification submissions, in § 807.95 of this chapter.

(29) Electronic product information, in §§ 1002.4 and 1002.42 of this chapter.

(30) Data and information submitted to the Commissioner or to classification panels in connection with the classification or reclassification of devices intended for human use, in § 860.5 of this chapter.

(31) Data and information submitted in offers to develop a proposed performance standard for medical devices, in § 861.26 of this chapter.

(32) Investigational device exemptions in § 812.38 of this chapter.

(33) Health claims petitions, in § 101.70 of this chapter.

(34) Premarket approval application, in § 814.9 of this chapter.

(35) Report of certain adverse experiences with a medical device, in § 803.9 of this chapter.

(36) Disqualification determination of an institutional review board, in § 56.122 of this chapter.

(37) Disqualification determination of a nonclinical laboratory, in § 58.213 of this chapter.

(38) Minutes or records regarding a public advisory committee, in § 14.65(c) of this chapter.

(39) Data submitted regarding persons receiving an implanted pacemaker device or lead, in § 805.25 of this chapter.

(40) Humanitarian device exemption application, in § 814.122 of this chapter.

(41) Premarket notifications for food contact substances, in § 170.102 of this chapter.

(42) Registration of food facilities, in § 1.243 of this chapter.

(43) Minor-use or minor-species (MUMS) drug designations, in § 516.52 of this chapter.

(44) Minor-species drug index listings, in § 516.171 of this chapter.

(45) Postmarket notifications of a permanent discontinuance or an interruption in manufacturing of certain drugs or biological products, in §§ 310.306, 314.81(b)(3)(iii), and 600.82 of this chapter.

(46) Generally recognized as safe (GRAS) notices, in part 170, subpart E and part 570, subpart E of this chapter.

[42 FR 15616, Mar. 22, 1977, as amended at 42 FR 19989, Apr. 15, 1977; 42 FR 42526, Aug. 28, 1977; 42 FR 58889, Nov. 11, 1977; 43 FR 32993, July 28, 1978; 51 FR 22475, June 19, 1986; 54 FR 9038, Mar. 3, 1989; 58 FR 2533, Jan. 6, 1993; 59 FR 536, Jan. 5, 1994; 61 FR 33244, June 26, 1996; 62 FR 40592, July 29, 1997; 64 FR 56448, Oct. 20, 1999; 67 FR 13717, Mar. 26, 2002; 67 FR 35729, May 21, 2002; 68 FR 58965, Oct. 10, 2003; 72 FR 41017, July 26, 2007; 72 FR 69118, Dec. 6, 2007; 80 FR 38938, July 8, 2015; 81 FR 45409, July 14, 2016; 81 FR 55046, Aug. 17, 2016; 81 FR 60212, Aug. 31, 2016]

§ 20.101 Administrative enforcement records.

(a) All Food and Drug Administration records relating to administrative enforcement action disclosed to any member of the public, including the person who is the subject of such action, are available for public disclosure at the time such disclosure is first made. Such records include correspondence with companies following factory inspection, recall or detention requests, notice of refusal of admission of an imported product, regulatory letters, information letters, Forms FD–483 and FD–2275 furnished to companies after factory inspection, and similar records.

(b) To the extent that any of such records fall within the exemption for investigatory records established in § 20.64, the Commissioner determines that they are subject to discretionary release pursuant to § 20.82.

(c) Records relating to administrative enforcement action that are not disclosed to any member of the public constitute investigatory records that are subject to the rules for disclosure established in § 20.64. For example, an establishment inspection report is an investigatory record and thus subject to § 20.64 except insofar as the Commissioner exercises his discretion to release it pursuant to § 20.82.

§ 20.102 Court enforcement records.

(a) All records and documents filed in the courts are available for public disclosure unless the court orders otherwise. The Food and Drug Administration will make available for public disclosure such records or documents if the agency can determine that it has an accurate copy of the actual record or document filed in the court. If the Food and Drug Administration cannot determine whether it has an accurate copy of such a record or document, the person requesting a copy shall be referred to the court involved.

(b) After a recommendation for court action has been finally refused by a United States attorney, the correspondence with the United States attorney and the Department of Justice with respect to that recommendation, including the pleadings recommended for filing with the court, is available for public disclosure. Prior to disclosure of any record specifically reflecting consideration of possible criminal prosecution of any individual, all names and other information that would identify an individual who was considered for criminal prosecution but

who was not prosecuted shall be deleted unless the Commissioner concludes that there is a compelling public interest in the disclosure of such names.

§ 20.103 Correspondence.

(a) All correspondence to and from members of the public, members of Congress, organization or company officials, or other persons, except members of the Executive Branch of the Federal Government and special government employees, is available for public disclosure.

(b) Any such correspondence is available for public disclosure at the time that it is sent or received by the Food and Drug Administration unless a different time for such disclosure is specified in other rules established or cross-referenced in this part, e.g., correspondence relating to an IND notice or an NDA in § 314.430 of this chapter.

[42 FR 15616, Mar. 22, 1977, as amended at 54 FR 9038, Mar. 3, 1989]

§ 20.104 Summaries of oral discussions.

(a) All written summaries of oral discussions, whether in person or by telephone, with members of the public, members of Congress, organization or company officials, or other persons, except members of the Executive Branch of the Federal government or special government employees, are available for public disclosure.

(b) Any such summary is available for public disclosure at the time that it is prepared by the Food and Drug Administration unless a different time for such disclosure is specified in other rules established or cross-referenced in this part, e.g., summaries of oral discussions relating to a food additive petition in § 171.1(h)(3) of this chapter.

(c) If more than one summary of an oral discussion exists in a Food and Drug Administration file, all such summaries shall be disclosed in response to any request for such summary.

§ 20.105 Testing and research conducted by or with funds provided by the Food and Drug Administration.

(a) Any list that may be prepared by the Food and Drug Administration of testing and research being conducted by or with funds provided by the Food and Drug Administration is available for public disclosure.

(b) Any contract relating to agency testing and research, and any progress report relating thereto, is available for public disclosure.

(c) The results of all testing or research conducted by or with funds provided by the Food and Drug Administration, such as toxicological testing, compliance assays, methodology studies, and product testing, are available for public disclosure when the final report is complete and accepted by the responsible Food and Drug Administration official, after deletion of any information that would reveal confidential investigative techniques and procedures, e.g., the use of ''markers'' to document adulteration of a product. If such results are disclosed in an authorized manner to any member of the public before the final report is available, they are immediately available for public disclosure to any member of the public who requests them.

(d) Access to all raw data, slides, worksheets, and other similar working materials shall be provided at the same time that the final report is disclosed.

§ 20.106 Studies and reports prepared by or with funds provided by the Food and Drug Administration.

(a) The following types of reports and studies prepared by or with funds provided by the Food and Drug Administration are available for public disclosure upon their acceptance by the responsible agency official:

(1) Quarterly and annual reports of the agency.

(2) External investigations or review of agency needs and performance.

(3) Surveys, compilations, and summaries of data and information.

(4) Consumer surveys.

(5) Compliance surveys.

(6) Compliance programs, except that names of specific firms, the location of specific activities, and details about sampling numbers or sizes shall be deleted until implementation of the program is completed.

(7) Work plans prepared by Food and Drug Administration centers, field offices, and other components, except

that names of specific firms, the location of specific activities, and details about sampling numbers or sizes shall be deleted until implementation of the plan is completed.

(b) The following types of reports and studies prepared by or with funds provided by the Food and Drug Administration are not available for public disclosure:

(1) Internal audits of agency needs and performance.

(2) Records relating to the internal planning and budget process.

(3) Legislative proposals or comments prior to submission to Congress.

[42 FR 15616, Mar. 22, 1977, as amended at 50 FR 8995, Mar. 6, 1985]

§ 20.107 Food and Drug Administration manuals.

(a) Food and Drug Administration administrative staff manuals and instructions that affect a member of the public are available for public disclosure. An index of all such manuals is available by writing to the Division of Freedom of Informationat the address located on the agency's web site at *http://www.fda.gov.*; or by visiting the Division of Freedom of Information Public Reading Room, located in rm. 1050, at the same address. The index and all manuals created by the agency on or after November 1, 1996, will be made available through the Internet at *http://www.fda.gov*.

(b) Manuals relating solely to internal personnel rules and practices are not available for public disclosure except to the extent that the Commissioner determines that they should be disclosed pursuant to § 20.82.

(c) All Food and Drug Administration action levels which are used to determine when the agency will take regulatory action against a violative product, limits of sensitivity and variability of analytical methods which are used in determining whether a product violates the law, and direct reference levels above which Food and Drug Administration field offices may request legal action directly to the office of the General Counsel, are available for public disclosure.

[42 FR 15616, Mar. 22, 1977, as amended at 46 FR 8457, Jan. 27, 1981; 46 FR 14340, Feb. 27, 1981; 68 FR 25287, May 12, 2003; 76 FR 31469, June 1, 2011; 79 FR 68115, Nov. 14, 2014]

§ 20.108 Agreements between the Food and Drug Administration and other departments, agencies, and organizations.

(a) All written agreements and understandings signed by the Food and Drug Administration and other departments, agencies, and organizations are available for public disclosure.

(b) All written agreements and memoranda of understanding between FDA and any entity, including, but not limited to other departments, Agencies, and organizations will be made available through the Food and Drug Administration Web site at *http://www.fda.gov* once finalized.

(c) Agreements and understandings signed by officials of FDA with respect to activities of the Office of Criminal Investigations are exempt from the requirements set forth in paragraph (b) of this section. Although such agreements and understandings will not be made available through the FDA Web site, these agreements will be available for disclosure in response to a request from the public after deletion of information that would disclose confidential investigative techniques or procedures, or information that would disclose guidelines for law enforcement investigations if such disclosure could reasonably be expected to risk circumvention of the law.

[42 FR 15616, Mar. 22, 1977, as amended at 46 FR 8457, Jan. 27, 1981; 58 FR 48794, 48796, Sept. 20, 1993; 76 FR 31470, June 1, 2011; 77 FR 50591, Aug. 22, 2012]

§ 20.109 Data and information obtained by contract.

(a) All data and information obtained by the Food and Drug Administration by contract, including all progress reports pursuant to a contract, are available for public disclosure when accepted by the responsible agency official except to the extent that they remain subject to an exemption established in subpart D of this part, e.g., they relate

to law enforcement matters as provided in § 20.88(b).

(b) Upon the awarding of a contract by the Food and Drug Administration, the technical proposal submitted by the successful offeror will be available for public disclosure. All cost proposals and the technical proposals of unsuccessful offerors submitted in response to a request for proposals are exempt from disclosure as confidential commercial or financial information pursuant to § 20.61.

§ 20.110 Data and information about Food and Drug Administration employees.

(a) The name, title, grade, position description, salary, work address, and work telephone number for every Food and Drug Administration employee are available for public disclosure. The home address and home telephone number of any such employee are not available for public disclosure.

(b) Statistics on the prior employment experience of present agency employees, and subsequent employment of past agency employees, are available for public disclosure.

§ 20.111 Data and information submitted voluntarily to the Food and Drug Administration.

(a) The provisions of this section shall apply only to data and information submitted voluntarily to the Food and Drug Administration, whether in the course of a factory inspection or at any other time, and not as a part of any petition, application, master file, or other required submission or request for action. Data and information that may be required to be submitted to the Food and Drug Administration but that are submitted voluntarily instead are not subject to the provisions of this section and will be handled as if they had been required to be submitted.

(b) A determination that data or information submitted voluntarily will be held in confidence and will not be available for public disclosure shall be made only in the form of a regulation published or cross-referenced in this part.

(c) The following data and information submitted voluntarily to the Food and Drug Administration are available for public disclosure unless extraordinary circumstances are shown:

(1) All safety, effectiveness, and functionality data and information for a marketed ingredient or product, except as provided in § 330.10(a)(2) of this chapter for OTC drugs.

(2) A protocol for a test or study, unless it is shown to fall within the exemption established in § 20.61 for trade secrets and confidential commercial or financial information.

(3) Adverse reaction reports, product experience reports, consumer complaints, and other similar data and information shall be disclosed as follows:

(i) If submitted by a consumer or user of the product, the record is available for public disclosure after deletion of names and other information that would identify the person submitting the information.

(ii) If submitted by the manufacturer of the product, the record is available for public disclosure after deletion of:

(*a*) Names and any information that would identify the person using the product.

(*b*) Names and any information that would identify any third party involved with the report, such as a physician or hospital or other institution.

(*c*) Names and any other information that would identify the manufacturer or the brand designation of the product, but not the type of product or its ingredients.

(iii) If submitted by a third party, such as a physician or hospital or other institution, the record is available for public disclosure after deletion of:

(*a*) Names and any information that would identify the person using the product.

(*b*) Names and any information that would identify any third party involved with the report, such as a physician or hospital or other institution.

(iv) If obtained through a Food and Drug Administration investigation, the record shall have the same status as the initial report which led to the investigation, i.e., it shall be disclosed in accordance with paragraph (c)(3)(i) through (iii) of this section.

(v) Any compilation of data, information, and reports prepared in a way that does not reveal data or information which is not available for public

disclosure under this section is available for public disclosure.

(vi) If a person requests a copy of any such record relating to a specific individual or a specific incident, such request will be denied unless accompanied by the written consent to such disclosure of the person who submitted the report to the Food and Drug Administration and the individual who is the subject of the report. The record will be disclosed to the individual who is the subject of the report upon request.

(4) A list of all ingredients contained in a food or cosmetic, whether or not it is in descending order of predominance, or a list of all active ingredients and any inactive ingredients previously disclosed to the public as defined in § 20.81 contained in a drug, or a list of all ingredients or components in a device.

(5) An assay method or other analytical method, unless it serves no regulatory or compliance purpose and is shown to fall within the exemption established in § 20.61.

(d) The following data and information submitted voluntarily to the Food and Drug Administration are not available for public disclosure unless they have been previously disclosed to the public as defined in § 20.81 or they relate to a product or ingredient that has been abandoned and they no longer represent a trade secret or confidential commercial or financial information as defined in § 20.61:

(1) All safety, effectiveness, and functionality data and information for a developmental ingredient or product that has not previously been disclosed to the public as defined in § 20.81.

(2) Manufacturing methods or processes, including quality control procedures.

(3) Production, sales, distribution, and similar data and information, except that any compilation of such data and information aggregated and prepared in a way that does not reveal data or information which is not available for public disclosure under this provision is available for public disclosure.

(4) Quantitative or semiquantitative formulas.

(e) For purposes of this regulation, safety, effectiveness, and functionality data include all studies and tests of an ingredient or a product on animals and humans and all studies and tests on the ingredient or product for identity, stability, purity, potency, bioavailability, performance, and usefulness.

[42 FR 15616, Mar. 22, 1977, as amended at 68 FR 25287, May 12, 2003]

§ 20.112 Voluntary drug experience reports submitted by physicians and hospitals.

(a) A voluntary drug experience report to the Food and Drug Administration on FDA Form 3500 shall be handled in accordance with the rules established in § 20.111(c)(3)(iii).

(b) If a person requests a copy of any such record relating to a specific individual or a specific incident, such request will be denied unless accompanied by the written consent to such disclosure of the person who submitted the report to the Food and Drug Administration and the individual who is the subject of the report.

[42 FR 15616, Mar. 22, 1977, as amended at 54 FR 9038, Mar. 3, 1989; 62 FR 52249, Oct. 7, 1997]

§ 20.113 Voluntary product defect reports.

Voluntary reports of defects in products subject to the jurisdiction of the Food and Drug Administration are available for public disclosure:

(a) If the report is submitted by the manufacturer, after deletion of data and information falling within the exemptions established in § 20.61 for trade secrets and confidential commercial or financial information and in § 20.63 for personal privacy.

(b) If the report is submitted by any person other than the manufacturer, after deletion of names and other information that would identify the person submitting the report and any data or information falling within the exemption established in § 20.63 for personal privacy.

§ 20.114 Data and information submitted pursuant to cooperative quality assurance agreements.

Data and information submitted to the Food and Drug Administration pursuant to a cooperative quality assurance agreement shall be handled in accordance with the rules established in § 20.111.

§ 20.115 Product codes for manufacturing or sales dates.

Data or information in Food and Drug Administration files which provide a means for deciphering or decoding a manufacturing date or sales date or use date contained on the label or in labeling or otherwise used in connection with a product subject to the jurisdiction of the Food and Drug Administration are available for public disclosure.

§ 20.116 Drug and device registration and listing information.

Information submitted to the Food and Drug Administration pursuant to section 510(a) through (j) of the Federal Food, Drug, and Cosmetic Act shall be subject only to the special disclosure provisions established in §§ 207.81 and 807.37 of this chapter.

[81 FR 60212, Aug. 31, 2016]

§ 20.117 New drug information.

(a) The following computer printouts are available for public inspection in the Food and Drug Administration's Freedom of Information Public Room:

(1) A numerical listing of all new drug applications and abbreviated new drug applications approved since 1938, showing the NDA number, the trade name, the applicant, the approval date, and, where applicable, the date the approval was withdrawn and the date the Food and Drug Administration was notified that marketing of the product was discontinued.

(2) A numerical listing of all new drug applications and abbreviated new drug applications approved since 1938 which are still approved, showing the same information as is specified in paragraph (a)(1) of this section except that it does not show a withdrawal date.

(3) A listing of new drug applications, abbreviated new drug applications, which were approved since 1938 and which are still approved, covering marketed prescription drug products except prescription drug products covered by applications deemed approved under the Drug Amendments of 1962 and not yet determined to be effective in the Drug Efficacy Study Implementation program. The listing includes the name of the active ingredient, the type of dosage form, the route of administration, the trade name of the product, the name of the application holder, and the strength or potency of the product. The listing also includes, for each active ingredient in a particular dosage form for which there is more than one approved application, an evaluation of the therapeutic equivalence of the drug products covered by such applications.

(b) Other computer printouts containing IND and NDA information are available to the extent that they do not reveal data or information prohibited from disclosure under §§ 20.61, 312.130, and 314.430 of this chapter.

[42 FR 15616, Mar. 22, 1977, as amended at 45 FR 72608, Oct. 31, 1980; 46 FR 8457, Jan. 27, 1981; 54 FR 9038, Mar. 3, 1989; 64 FR 399, Jan. 5, 1999]

§ 20.118 Advisory committee records.

All advisory committee records shall be handled in accordance with the rules established in parts 10, 12, 13, 14, 15, 16, and 19 of this chapter.

§ 20.119 Lists of names and addresses.

Names and addresses of individuals in Food and Drug Administration records shall not be sold or rented. Names and addresses shall not be disclosed if disclosure is prohibited as a clearly unwarranted invasion of personal privacy, e.g., lists of names and home addresses of Food and Drug Administration employees, which shall not be disclosed under § 20.110.

§ 20.120 Records available in Food and Drug Administration Public Reading Rooms.

(a) The Freedom of Information Staff and the Division of Dockets Management Public Reading Room are located at the same address. Both are located

in rm. 1061, 5630 Fishers Lane, Rockville, MD 20852. The telephone number for the Division of Docket Management is 301–827–6860; the telephone number for the Freedom of Information Staff's Public Reading Room is located at the address on the agency's web site at *http://www.fda.gov*. Both public reading rooms are open from 9 a.m. to 4 p.m., Monday through Friday, excluding legal public holidays.

(b) The following records are available at the Division of Freedom of Information Public Reading Room:

(1) A guide for making requests for records or information from the Food and Drug Administration;

(2) Administrative staff manuals and instructions to staff that affect a member of the public;

(3) Food and Drug Administration records which have been released to any person in response to a Freedom of Information request and which the agency has determined have become or are likely to become the subject of subsequent requests for substantially the same records;

(4) Indexes of records maintained in the Division of Freedom of Information Public Reading Room; and

(5) Such other records and information as the agency determines are appropriate for inclusion in the public reading room.

(c) The following records are available in the Division of Dockets Management's Public Reading Room:

(1) Final opinions, including concurring and dissenting opinions, as well as orders, made in the adjudication of cases;

(2) Statements of policy and interpretation adopted by the agency that are still in force and not published in the FEDERAL REGISTER;

(3) Indexes of records maintained in the Division of Dockets Management's Public Reading Room; and

(4) Such other records and information as the agency determines are appropriate for inclusion in the public reading room.

(d) The agency will make reading room records created by the Food and Drug Administration on or after November 1, 1996, available electronically through the Internet at the agency's World Wide Web site which can be found at *http://www.fda.gov*. At the agency's discretion, the Food and Drug Administration may also make available through the Internet such additional records and information it believes will be useful to the public.

[68 FR 25287, May 12, 2003; 68 FR 65392, Nov. 20, 2003, as amended at 76 FR 31470, June 1, 2011; 79 FR 68115, Nov. 14, 2014]

PART 21—PROTECTION OF PRIVACY

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AUTHORITY: 21 U.S.C. 371; 5 U.S.C. 552, 552a.

SOURCE: 42 FR 15626, Mar. 22, 1977, unless otherwise noted.

Subpart A—General Provisions

§21.1 Scope.

(a) This part establishes procedures to implement the Privacy Act of 1974 (5 U.S.C. 552a). It applies to records about individuals that are maintained, collected, used, or disclosed by the Food and Drug Administration and contained in Privacy Act Record Systems.

(b) This part does not:

(1) Apply to Food and Drug Administration record systems that are not Privacy Act Record Systems or make available to an individual records that may include references to him but that are not retrieved by his name or other personal identifier, whether or not contained in a Privacy Act Record System. part 20 of this chapter (the public information regulations) and other regulations referred to therein determine when records are made available in such cases.

(2) Make any records available to persons other than (i) individuals who are the subjects of the records, (ii) persons accompanying such individuals under §21.43, (iii) persons provided records pursuant to individual consent under §21.72, or (iv) persons acting on behalf of such individuals as legal guardians under §21.75. Part 20 of this chapter (the public information regulations) and other regulations referred to therein determine when Food and Drug Administration records are disclosable to members of the public generally. Subpart G of this part limits the provisions of part 20 of this chapter with respect to disclosures of records about individuals from Privacy Act Record Systems to persons other than individuals who are the subjects of the records.

(3) Make available information compiled by the Food and Drug Administration in reasonable anticipation of court litigation or formal administrative proceedings. The availability of such information to any member of the public, including any subject individual or party to such litigation or proceeding shall be governed by applicable constitutional principles, rules of discovery, and part 20 of this chapter (the public information regulations).

(4) Apply to personnel records maintained by the Division of Human Resources Management, Food and Drug Administration, except as provided in §21.32. Such records are subject to regulations of the Office of Personnel Management in 5 CFR parts 293, 294, and 297.

[42 FR 15626, Mar. 22, 1977, as amended at 46 FR 8457, Jan. 27, 1981; 50 FR 52278, Dec. 23, 1985]

§21.3 Definitions.

As used in this part:

(a) *Individual* means a natural living person who is a citizen of the United States or an alien lawfully admitted for permanent residence. Individual does not include sole proprietorships, partnerships, or corporations engaged in the production or distribution of products regulated by the Food and Drug Administration or with which the Food and Drug Administration has business dealings. Any such business enterprise that is identified by the name of one or more individuals is not an individual within the meaning of this part. Employees of regulated business enterprises are considered individuals. Accordingly, physicians and other health professionals who are engaged in business as proprietors of establishments regulated by the Food and Drug Administration are not considered individuals; however, physicians and

other health professionals who are engaged in clinical investigations, employed by regulated enterprises, or the subjects of records concerning their own health, e.g., exposure to excessive radiation, are considered individuals. Food and Drug Administration employees, consultants, and advisory committee members, State and local officials, and consumers are considered individuals.

(b) *Records about individuals* means items, collections, or groupings of information about individuals contained in Privacy Act Record Systems, including, but not limited to education, financial transactions, medical history, criminal history, or employment history, that contain names or personal identifiers.

(c) *Privacy Act Record System* means a system of records about individuals under the control of the Food and Drug Administration from which information is retrieved by individual names or other personal identifiers. The term includes such a system of records whether subject to a notice published by the Food and Drug Administration, the Department, or another agency. Where records are retrieved only by personal identifiers other than individual names, a system of records is not a Privacy Act Record System if the Food and Drug Administration cannot, by reference to information under its control, or by reference to records of contractors that are subject to this part under § 21.30, ascertain the identity of individuals who are the subjects of the records.

(d) *Personal identifiers* includes individual names, identifying numbers, symbols, or other identifying designations assigned to individuals. *Personal identifiers* does not include names, numbers, symbols, or other identifying designations that identify products, establishments, or actions.

(e) *Personnel records* means any personal information maintained in a Privacy Act Record System that is needed for personnel management programs or processes such as staffing, employee development, retirement, and grievances and appeals.

(f) *Department* means Department of Health and Human Services.

§ 21.10 Policy concerning records about individuals.

Information about individuals in Food and Drug Administration records shall be collected, maintained, used, and disseminated so as to protect the right to privacy of the individual to the fullest possible extent consistent with laws relating to disclosure of information to the general public, the law enforcement responsibilities of the agency, and administrative and program management needs.

Subpart B—Food and Drug Administration Privacy Act Record Systems

§ 21.20 Procedures for notice of Food and Drug Administration Privacy Act Record Systems.

(a) The Food and Drug Administration shall issue in the FEDERAL REGISTER on or before August 30 of each year a notice concerning each Privacy Act Record System as defined in § 21.3(c) that is not covered by a notice published by the Department, the Office of Personnel Management, or another agency.

(b) The notice shall include the following information:

(1) The name and location(s) of the system.

(2) The categories of individuals about whom records are maintained in the system.

(3) The categories of records maintained in the system.

(4) The authority for the system.

(5) Each routine use of the records contained in the system (i.e., use outside the Department of Health and Human Services that is compatible with the purpose for which the records were collected and described in the notice) including the categories of users and the purposes of such use.

(6) The policies and practices of the Food and Drug Administration regarding storage, retrievability (i.e., how the records are indexed and what intra-agency uses are made of the records), access controls, retention, and disposal of the records in that system.

(7) The title and business address of the official who is responsible for the system of records.

(8) The notification procedure, i.e., the address of the FDA Privacy Act Coordinator, whom any individual can contact to seek notification whether the system contains a record about him/her.

(9) The record access and contest procedures, which shall be the same as the notification procedure except that a reference shall be included to any exemption from access and contest.

(10) Where any records in the system are subject to an exemption under § 21.61, a reference to this exemption.

(11) The categories of sources of records in the system.

[42 FR 15626, Mar. 22, 1977, as amended at 46 FR 8457, Jan. 27, 1981]

§ 21.21 Changes in systems and new systems.

(a) The Food and Drug Administration shall notify the designated Department official, the Office of Management and Budget (Information Systems Division), and the Congress of proposals to change or establish Privacy Act Record Systems in accordance with procedures of the Department and the Office of Management and Budget.

(b) The Food and Drug Administration shall issue a notice, in accordance with paragraph (d) of this section and § 21.20(b), of any change in a Privacy Act Record System which:

(1) Increases the number or types of individuals about whom records are maintained;

(2) Expands the type or amount of information about individuals that is maintained;

(3) Increases the number of categories of agencies or other persons who may have access to those records;

(4) Alters the manner in which the records are organized so as to change the nature or scope of those records, such as the combining of two or more existing systems;

(5) Modifies the way in which the system operates or its location(s) in a manner that alters the process by which individuals can exercise their rights under this part, such as the ways in which they seek access or request amendment of a record; or

(6) Changes the equipment configuration on which the system is operated so as to create the potential for greater access, such as adding a telecommunications capability.

(c) The Food and Drug Administration shall issue a notice of its intention to establish new Privacy Act Record Systems in accordance with paragraph (d) of this section and § 21.20(b).

(d) Notices under paragraphs (b) and (c) of this section shall be published in the FEDERAL REGISTER for comment at least 30 days prior to implementation of the proposed changes or establishment of new systems. Interested persons shall have the opportunity to submit written data, views, or arguments on such proposed new uses or systems.

Subpart C—Requirements for Specific Categories of Records

§ 21.30 Records of contractors.

(a) Systems of records that are required to be operated, or as a matter of practical necessity must be operated, by contractors to accomplish Food and Drug Administration functions, from which information is retrieved by individual names or other personal identifiers, may be subject to the provisions of this part. If the contract is agreed to on or after September 27, 1975, the criminal penalties set forth in 5 U.S.C. 552a(i) are applicable to such contractor, and any employee of such contractor, for disclosures prohibited in § 21.71 or for maintenance of a system of records without notice as required in § 21.20.

(b) A contract is considered to accomplish a Food and Drug Administration function if the proposal or activity it supports is principally operated on behalf of and is under the direct management of the Food and Drug Administration. Systems of records from which information is retrieved by individual names or other personal identifiers and that are operated under contracts to accomplish Food and Drug Administration functions are deemed to be maintained by the agency and shall be subject to the procedures and requirements of this part.

(c) A contract is not considered to accomplish a Food and Drug Administration function if the program or activity it supports is not principally operated on behalf of, or is not under the direct

management of, the Food and Drug Administration. For example, this part does not apply to systems of records:

(1) Operated under contract with the Food and Drug Administration by State or local government agencies, or organizations representing such agencies, when such agencies or organizations are also performing State or local government functions.

(2) Operated by contractors with the Food and Drug Administration by individuals or organizations whose primary function is delivery of health services, such as hospitals, physicians, pharmacists, and other health professionals, and that report information concerning products, e.g., injuries or product defects, to the Food and Drug Administration. Before such contractors submit information to the Food and Drug Administration, the names and other personal identifiers of patients or research subjects in any medical or similar report, test, study, or other research project shall be deleted, unless the contract provides otherwise. If the Food and Drug Administration subsequently needs the names of such individuals, a separate request will be made.

(3) Relating to individuals whom the contractor employs, or with whom the contractor otherwise deals, in the course of providing goods and services to the Food and Drug Administration.

(4) Operated under grants.

(d) The requirements of this part shall apply when a contractor who operates a system of records not subject to this part reports to the Food and Drug Administration information that is a system of records about individuals from which personal information is retrieved by names or other personal identifiers. Where the information would be a new Privacy Act Record System, or a change in an existing Privacy Act Record System of a type described in § 21.21, the Food and Drug Administration shall comply with the requirements of § 21.21.

(e) The Food and Drug Administration will review all contracts before award to determine whether operation of a system from which information is retrieved by individual names or other personal identifiers will be required of the contractor, by the terms of the contract or as a matter of practical necessity. If such operation will be required, the solicitation and contract shall include the following clause, or a clause of similar effect:

> Whenever the contractor or any of his employees is required by this contract to operate a system of records from which information is retrieved by individual names or other personal identifiers in order to accomplish a Food and Drug Administration function, the contractor and every employee is considered to be an employee of the Food and Drug Administration and shall operate such system of records in accordance with the Privacy Act of 1974 (5 U.S.C. 552a), regulations of the Food and Drug Administration in 21 CFR part 21, and rules of conduct that apply to Food and Drug Administration employees who work with such systems of records. The contractor and his employees are subject to the criminal penalties set forth in 5 U.S.C. 552a(i) for violations of the Privacy Act.

§ 21.31 Records stored by the National Archives and Records Administration.

(a) Food and Drug Administration records that are stored, processed, and serviced by the National Archives and Records Administration in accordance with 44 U.S.C. 3103 shall be considered to be maintained by the Food and Drug Administration. The National Archives and Records Administration shall not disclose the record except to authorized Food and Drug Administration employees.

(b) Each Food and Drug Administration record pertaining to an identifiable individual that was transferred to the National Archives of the United States as a record determined by the National Archives to have sufficient historical or other value to warrant its continued preservation shall be considered to be maintained by the National Archives and shall not be subject to the provisions of this part.

[42 FR 15626, Mar. 22, 1977, as amended at 50 FR 52278, Dec. 23, 1985]

§ 21.32 Personnel records.

(a) Present and former Food and Drug Administration employees desiring access to personnel records about themselves should consult system notices applicable to the agency's personnel records that are published by

the Office of Personnel Management and the Department as well as any notice issued by the Food and Drug Administration.

(b)(1) The procedures of the Office of Personnel Management at 5 CFR parts 293, 294, and 297 rather than the procedures in § 21.33 and subparts D through F of this part, govern systems of personnel records about Food and Drug Administration employees that are subject to notice published by the Office of Personnel Management, i.e., systems that:

(i) The Office of Personnel Management maintains.

(ii) Are maintained by the Division of Human Resources Management, Food and Drug Administration.

(iii) Are maintained by Department Regional Offices, concerning field employees.

(2) The Office of Personnel Management's procedures may, if necessary, be supplemented in the Food and Drug Administration Staff Manual Guide. Current Food and Drug Administration employees should mail or deliver written requests under the Privacy Act for access to personnel records described in this paragraph to the Office of Personnel Management in accordance with 5 CFR 297.106, the Director, Division of Human Resources Management HR–BETHPL RM7114, HFA–705, 7700 Wisconsin Ave., 7th & 8th floors, Bethesda, MD 20814, or the personnel officer in the servicing HHS Regional Personnel Office. An employee may consult with or direct his or her request to the FDA Privacy Act Coordinator (the Privacy Act Coordinator is part of the Freedom of Information Staff, the address for which is located on the Agency Web site at *http://www.fda.gov*). Requests for access to personnel records of former employees that are located in Federal Records Centers should be directed to the Office of Personnel Management. Requests under the Privacy Act for amendment of personnel records should be directed to these same officials who are responsible for access to personnel records under this paragraph.

(3) With respect to records subject to paragraph (b)(1) of this section:

(i) Refusal to grant access to a record, or refusal to amend a record upon request of an employee, shall only be made by the Associate Commissioner for Management and Operations or his or her designate; and

(ii) Appeals of refusals under paragraph (b)(3)(i) of this section may be made to the Office of Personnel Management in accordance with 5 CFR 297.108(g)(3) and 297.113(b).

(c) Any other Privacy Act Record Systems that contain personnel records, or records that otherwise concern agency employees, that are maintained by offices of the Food and Drug Administration rather than the Division of Human Resources Management but which are not subject to the Department's notice for personnel records in operating offices are subject to this part, except that refusals under this part to grant access to or amend records about present or former employees shall be made by the Associate Commissioner for Management and Operations rather than the Associate Commissioner for Public Affairs.

(d) The following procedures shall govern requests under the Privacy Act for personnel records that are maintained by the operating offices of the Food and Drug Administration in which employees work:

(1) An employee shall upon request be told whether records about him are maintained. An employee shall be given access to records about himself that are subject to this paragraph in response to an oral or written request and through informal procedures, rather than the procedures specified in §§ 21.40 through 21.43.

(2) Employee identity may be verified, if necessary, by an FDA ID card rather than in accordance with § 21.44.

(3) Generally no fee shall be charged for records requested under this paragraph. However, in cases where the records requested are voluminous, a fee may be charged in accordance with § 21.45.

(4) Records that are subject to this paragraph shall be available for access to an individual, except to the extent that access is refused by the Associate Commissioner for Management and Operations or his or her designate on the grounds that the record is subject to an exemption under § 21.61 or 5 CFR 297.111.

(5) Requests under the Privacy Act for amendment of records subject to this paragraph should be directed to the Director, Division of Human Resources Management (HFA–400). Such requests shall be reviewed in accordance with subpart E of this part. Refusal to amend a record subject to this paragraph (d)(5) shall only be made by the Associate Commissioner for Management and Operations or his or her designate.

(6) Appeals of refusals under paragraph (d) (4) or (5) of this section may be made to the Commissioner of Food and Drugs, except where the Associate Commissioner for Management and Operations or his or her designate indicates with his or her refusal that the appeal should be made to the Office of Personnel Management.

(7) Disclosures of records subject to this paragraph are subject to subpart G of this part.

[42 FR 15626, Mar. 22, 1977, as amended at 46 FR 8457, Jan. 27, 1981; 50 FR 52278, Dec. 23, 1985; 76 FR 31470, June 1, 2011; 79 FR 68115, Nov. 14, 2014]

§ 21.33 Medical records.

(a) In general, an individual is entitled to have access to any medical records about himself in Privacy Act Record Systems maintained by the Food and Drug Administration.

(b) The Food and Drug Administration may apply the following special procedures in disclosing medical records to an individual:

(1) The agency may review the records to determine whether disclosure of the record to the individual who is the subject of the records might have an adverse effect on him. If it is determined that disclosure is not likely to have an adverse effect on the individual, the record shall be disclosed to him. If it is determined that disclosure is very likely to have an adverse effect on the individual, he may be requested to designate, in writing, a representative to whom the record shall be disclosed. Such representative may be a physician, other health professional, or other responsible person who would be willing to review the record and discuss it with the individual.

(2) The availability of the record may be subject to any procedures for disclosure to an individual of medical records about himself under part 20 of this chapter, in addition to or in lieu of the procedures in paragraph (b)(1), that are not inconsistent with § 21.41(f).

Subpart D—Procedures for Notification of and Access to Records in Privacy Act Record Systems

§ 21.40 Procedures for submitting requests for notification and access.

(a) An individual may request that the Food and Drug Administration notify him whether a Privacy Act Record System contains records about him that are retrieved by reference to his name or other personal identifier. An individual may at the same time, or after receiving notification that such a record about him exists, requests that he be given access to the record.

(b) An individual desiring notification or access to records shall mail or deliver a request for records in any Food and Drug Administration Privacy Act Records System to the FDA Privacy Act Coordinator (address is located on the agency web site at *http://www.gov.fda*).

(c) Requests shall be in writing and shall name the Privacy Act Record System or Systems concerning which the individual requests notification of whether there are records about him that are retrieved by reference to his name or other personal identifier. To help assure a prompt response, an individual should indicate that he is making a ''Privacy Act Request'' on the envelope and in a prominent manner in the letter.

(d) An individual who merely wishes to be notified whether a Privacy Act Record System contains a record about him ordinarily need not provide any verification of his identity other than his name. The mere fact that the Food and Drug Administration has a record about an individual in any of its Privacy Act Records Systems would not be likely to constitute a clearly unwarranted invasion of personal privacy. Where mere disclosure of the fact that a record about the individual exists would be a clearly unwarranted invasion of personal privacy, further

verification of the identity of the individual shall be required.

(e) An individual who requests that he be given access to a copy of records about himself, if any exist, should indicate whether he prefers (1) to have copies of any such records mailed to him in accordance with §21.43(a)(1), which may involve a fee under §21.45, including information to verify his identity under §21.44 or (2) to use the procedures for access in person under §21.43(a)(2).

(f) A request for notification and access may be submitted under this subpart concerning any Privacy Act Record System that is exempt under §21.61, as indicated in the notice for the system. An individual seeking access to records under §21.65(b)(2) to investigatory records compiled for law enforcement purposes other than criminal law enforcement purposes should submit a description of the right, benefit, or privilege that he believes he was denied as the result of the Food and Drug Administration's maintenance of the records. Where the system is exempt under §21.61, and access to the requested records is not granted under §21.65, the request shall be handled under the provisions of part 20 of this chapter (the public information regulations).

[42 FR 15626, Mar. 22, 1977, as amended at 46 FR 8458, Jan. 27, 1981; 50 FR 52278, Dec. 23, 1985; 76 FR 31470, June 1, 2011; 79 FR 68115, Nov. 14, 2014]

§21.41 Processing of requests.

(a) An individual or his guardian under §21.75 shall not be required to show any justification or need to obtain notification under §21.42 or access to a record under §21.43.

(b) The Food and Drug Administration will determine whether a request by an individual for records about himself is appropriately treated as a request under this subpart, or under the provision of part 20 of this chapter (the public information regulations), or both. Where appropriate, the Food and Drug Administration will consult with the individual concerning the appropriate treatment of the request.

(c) The FDA Privacy Act Coordinator in the Division of Freedom of Information (address is located on the agency web site at *http://www.gov.fda*) shall be responsible for the handling of Privacy Act requests received by the Food and Drug Administration. Requests mailed or delivered to any other office shall be promptly redirected to the FDA Privacy Act Coordinator. Where this procedure would unduly delay the agency's response, however, the agency employee who received the request should consult with the FDA Privacy Act Coordinator and obtain advice as to whether the employee can respond to the request directly.

(d) Upon receipt of a request by the FDA Privacy Act Coordinator, a record shall promptly be made that a request has been received and the date.

(e) A letter in accordance with §21.42 responding to the request for notification shall issue as promptly as possible after receipt of the request by the Food and Drug Administration. Upon determination by the Division of Freedom of Information (address is located on the agency web site at *http://www.gov.fda*) that a request for access to records is appropriately treated as a request under part 20 of this chapter rather than part 21, or under both parts, the time limitations prescribed in §21.41 shall apply. In any case, access to available records shall be provided as promptly as possible.

(f) Except as provided in §21.32, an individual's access to records about him/herself that are retrieved by his/her name or other personal identifiers and contained in any Privacy Act Record System may only be denied by the Associate Commissioner for Public Affairs or his or her designate. An individual shall not be denied access to any record that is otherwise available to him/her under this part except on the grounds that it is exempt under §21.65(a)(2), that it was compiled in reasonable anticipation of court litigation of formal administrative proceedings, or to the extent that it is exempt or prohibited from disclosure because it includes a trade secret or commercial or financial information that is privileged or confidential information the disclosure of which would constitute a clearly unwarranted invasion of personal privacy of another individual.

(g) The FDA Privacy Act Coordinator shall ensure that records are maintained of the number, status, and disposition of requests under this subpart, including the number of requests for records exempt from access under this subpart and other information required for purposes of the annual report to Congress under the Privacy Act. These temporary administrative management records shall not be considered to be Privacy Act Record Systems. All records required to be kept under this paragraph shall only include requesting individuals' names or personal identifiers for so long as any request for notification, access, or amendment is pending. The identity of individuals making request under this subpart shall be regarded as confidential and shall not be disclosed under part 20 of this chapter (the public information regulations) to any other person or agency except as is necessary for the processing of requests under this subpart.

[42 FR 15626, Mar. 22, 1977, as amended at 46 FR 8458, Jan. 27, 1981; 76 FR 31470, June 1, 2011; 79 FR 68115, Nov. 14, 2014]

§ 21.42 Responses to requests.

(a) The FDA shall respond to an individual's request for notification as to whether a Privacy Act Record System contains records about him that are retrieved by his name or other personal identifier by sending a letter under this paragraph.

(1) If there are no records about the individual that are retrieved by his name or other personal identifier in the named Privacy Act Record System, or the requester is not an ''individual'' under § 21.3(a), the letter shall so state. Where appropriate, the letter shall indicate that the Food and Drug Administration's public information regulations in part 20 of this chapter prescribe general rules governing the availability of information to members of the public, and that a request may be made in accordance with part 20 of this chapter for records that are not retrieved by the requester's name or other personal identifier from a Privacy Act Record System.

(2) If there are records about the individual that are retrieved by his name or other personal identifier and the named Privacy Act Record System is not exempt from individual access and contest under § 21.61, or the system is exempt but access is allowed or required under § 21.65, the letter shall inform him that the records exist and shall either:

(i) Enclose a copy of the records under § 21.43(a)(1) or indicate that the records will be sent under separate cover, where there has been adequate verification of the identity of the individual under § 21.44 and the fees under § 21.45 do not exceed $25, or

(ii) Inform the individual of the procedures to obtain access to the records by mail or in person under § 21.43(a)(2), as well as the approximate dates by which the requested records can be provided (if the records are not then available), the locations at which access in person may be had, and the information needed, if any, to verify the identity of the individual under § 21.44.

(3) If the named Privacy Act Record System contains records about the individual that are retrieved by his name or other personal identifier, and the system is exempt from individual access and contest under § 21.61 and access is not allowed or required under § 21.65, the letter should inform him that the records are exempted from access and contest by § 21.61. The letter shall also inform him if the records sought are not available because they were compiled in reasonable anticipation of court litigation or formal administrative proceedings or are otherwise not available under § 21.41(b). Where appropriate, the letter shall also indicate whether the records are available under part 20 of this chapter (the public information regulations), and it may disclose the records in accordance with part 20.

(4) If the named Privacy Act Record System contains records about the individual that are retrieved by his name or other personal identifier, but a final determination has not yet been made with respect to disclosure of all of the records covered by the request, e.g., because it is necessary to consult another person or agency having an interest in the confidentiality of the records, the letter shall explain the circumstances and indicate when a final answer will be given.

(b) Except as provided in § 21.32, access to a record may only be denied by the Associate Commissioner for Public Affairs or his or her designate. If access to any record is denied wholly or in substantial part, the letter shall state the right of the individual to appeal to the Commissioner of Food and Drugs.

(c) If a request for a copy of the records will result in a fee of more than $25, the letter shall specify or estimate the fee involved. Where the individual has requested a copy of any records about him and copying the records would result in a fee of over $50, the Food and Drug Administration shall require advance deposit as well as payment of any amount not yet received as a result of any previous request by the individual for a record about himself, under this subpart or part 20 of this chapter (the public information regulations) before the records are made available. If the fee is less than $50, prepayment shall not be required unless payment has not yet been received for records disclosed as a result of a previous request by the individual for a record about himself under this subpart or part 20 of this chapter.

[42 FR 15626, Mar. 22, 1977, as amended at 46 FR 8458, Jan. 27, 1981]

§ 21.43 Access to requested records.

(a) Access may be granted to requested records by:

(1) Mailing a copy of the records to the requesting individual, or

(2) Permitting the requesting individual to review the records in person between 9 a.m. and 4 p.m. at the office of the FDA Privacy Act Coordinator, at the Division of Freedom of Information Public Reading Room (address is located on the agency's web site at *http://www.fda.gov*), or at any Food and Drug Administration field office, listed in part 5, subpart M of this chapter, or at another location or time upon which the Food and Drug Administration and the individual agree. Arrangement for such review can be made by consultation between the FDA Privacy Act Coordinator and the individual. An individual seeking to review records in person shall generally be permitted access to the file copy, except that where the records include nondisclosable information, a copy shall be made of that portion of the records, with the nondisclosable information blocked out. Where the individual is not given a copy of the record to retain, no charge shall be made for the cost of copying a record to make it available to an individual who reviews a record in person under this paragraph.

(b) An individual may request that a record be disclosed to or discussed in the presence of another individual, such as an attorney. The individual may be required to furnish a written statement authorizing the disclosure or discussion in such other individual's presence.

(c) The Food and Drug Administration will make every reasonable effort to assure that records made available under this section can be understood by the individual, such as by providing an oral or written explanation of the records.

[42 FR 15626, Mar. 22, 1977, as amended at 46 FR 8458, Jan. 27, 1981; 69 FR 17290, Apr. 2, 2004; 76 FR 31470, June 1, 2011; 79 FR 68115, Nov. 14, 2014]

§ 21.44 Verification of identity.

(a) An individual seeking access to records in a Privacy Act Record System may be required to comply with reasonable requirements to enable the Food and Drug Administration to determine his identity. The identification required shall be suitable considering the nature of the records sought. No identification shall be required to receive access to information that is required to be disclosed to any member of the public under part 20 of this chapter (the public information regulations).

(b) An individual who appears in person for access to records about himself shall be required to provide at least one document to identify himself, e.g., driver's license, passport, or alien or voter registration card to verify his identity. If an individual does not have any such document or requests access to records about himself without appearing in person under circumstances in which his identity cannot be verified from the request itself, he shall be required to certify in writing that he is the individual he claims to be and that he understands that the knowing and willful request for or acquisition of a

record pertaining to an individual under false pretenses is a criminal offense subject to a $5,000 fine.

(c) In making requests under § 21.75, a parent of a minor child or legal guardian of an incompetent individual may be required to verify his relationship to the minor child or the incompetent individual, in addition to verifying his own identity, by providing a copy of the minor's birth certificate, a court order, or other evidence of guardianship.

(d) Where an individual seeks access to particularly sensitive records, such as medical records, the individual may be required to provide additional information beyond that specified in paragraph (b) or (c) of this section, such as the individual's years of attendance at a particular educational institution, rank attained in the uniformed services, date or place of birth, names of parents, an occupation, or the specific times the individual received medical treatment.

§ 21.45 Fees.

(a) Where applicable, fees for copying records shall be charged in accordance with the schedule set forth in this section. Fees may only be charged where an individual has requested that a copy be made of a record to which he is granted access. No fee may be charged for making a search of a Privacy Act Record System whether the search is manual, mechanical, or electronic. Where a copy of the record must be made to provide access to the record, e.g., computer printout where no screen reading is available, the copy shall be made available to the individual without cost. Where a medical record is made available to a representative designated by the individual under § 21.33, no fee will be charged.

(b) The fee schedule is as follows:

(1) Copying of records susceptible to photocopying—$.10 per page.

(2) Copying of records not susceptible to photocopying, e.g., punch cards or magnetic tapes—at actual cost to the determined on a case-by-case basis.

(3) No charge will be made if the total amount of copying for an individual does not exceed $25.

(c) When a fee is to be assessed, the individual shall be notified prior to the processing of the copies, and be given an opportunity to amend his request. Payment shall be made by check or money order made payable to the ''Food and Drug Administration,'' and shall be sent to the Accounting Branch (HFA–120), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Advance deposit shall be required where the total amount exceeds $50.

[42 FR 15626, Mar. 22, 1977, as amended at 54 FR 9038, Mar. 3, 1989]

Subpart E—Procedures for Requests for Amendment of Records

§ 21.50 Procedures for submitting requests for amendment of records.

(a) An individual who received access to a record about himself under subpart D of this part may request that the record be amended if he believes that the record or an item of information is not accurate, relevant to a Food and Drug Administration purpose, timely, or complete.

(b) Amendments under this subpart shall not violate existing statute, regulation, or administrative procedure.

(1) This subpart does not permit alteration of evidence presented in the course of judicial proceedings or Food and Drug Administration adjudicatory or rule making proceedings or collateral attack upon that which has already been the subject of any such proceedings.

(2) If the accuracy, relevancy, timeliness, or completeness of the records may be contested in any other pending or imminent agency proceeding, the Food and Drug Administration may refer the individual to the other proceeding as the appropriate means to obtain relief. If the accuracy, relevance, timeliness, or completeness of a record is, or has been, an issue in another agency proceeding, the request under this section shall be disposed of in accordance with the decision in the other proceeding, absent unusual circumstances.

(c) Requests to amend records shall be submitted, in writing, to the FDA Privacy Act Coordinator in accordance with § 21.40(b). Such requests shall include information sufficient to enable

the Food and Drug Administration to locate the record, a brief description of the items of information requested to be amended, and the reasons why the record should be amended together with any appropriate documentation or arguments in support of the requested amendment. An edited copy of the record showing the described amendment may be included. Verification of identity should be provided in accordance with § 21.44.

(d) Written acknowledgement of the receipt of a request to amend a record shall be provided within 10 working days to the individual who requested the amendment. Such acknowledgement may request any additional information needed to verify identity or make a determination. No acknowledgement need be made if the request can be reviewed, processed, and the individual notified of the agency's agreement with the request or refusal within the 10-day period.

[42 FR 15626, Mar. 22, 1977, as amended at 46 FR 8459, Jan. 27, 1981]

§ 21.51 Responses to requests for amendment of records.

(a) The Food and Drug Administration shall take one of the following actions on a request for amendment of records as promptly as possible:

(1) Amend any portion of the record which the agency has determined, based upon a preponderance of the evidence, is not accurate, relevant to a Food and Drug Administration purpose, timely, or complete, and, in accordance with paragraph (d)(3) of this section, inform the individual and previous recipients of the record that has been amended of the amendment.

(2) Inform the individual of its refusal to amend any portion of the record in the manner requested, the reason for the refusal, and the opportunity for administrative appeal to the Commissioner of Food and Drugs. Except as provided in § 21.32, such refusal may only be issued by the Associate Commissioner for Public Affairs or his or her designate.

(3) Where another agency was the source of and has control of the record, refer the request to that agency.

(b) The agency may, for good cause, extend the period for taking action an additional 30 working days if notice is provided to the individual explaining the circumstances of the delay.

(c) The officials charged with reviewing a record to determine how to respond to a request to amend it, shall assess its accuracy, relevance to a Food and Drug Administration purpose, timeliness, or completeness. The determination shall be made in the light of the purpose for which the records or system is used, the agency's need for the record, and the possible adverse consequences to the individual from the record if not amended. Whenever the Food and Drug Administration receives a request for deletion of a record, or portions of a record, it shall consider anew whether the contested information in the record is relevant and necessary to a Food and Drug Administration purpose.

(d) If the Food and Drug Administration agrees with an individual's request, it shall take the following actions:

(1) So inform the individual in writing.

(2) In accordance with statute, regulation, or procedure, amend the record to make it accurate, relevant to a Food and Drug Administration purpose, timely, or complete, making note of the date and fact of the amendment.

(3) If an accounting was made under § 21.71(d) of a disclosure of the record under § 21.71(a), provide a copy of the record as amended, to all previous recipients of the record.

[42 FR 15626, Mar. 22, 1977, as amended at 46 FR 8459, Jan. 27, 1981]

§ 21.52 Administrative appeals of refusals to amend records.

(a) If an individual disagrees with a refusal under § 21.51(a)(2) to amend a record, he or she may appeal that refusal to the Commissioner of Food and Drugs,(see the address on the agency's web site at *http://www.fda.gov*).

(b) If, upon appeal, the Commissioner upholds the refusal to amend the record as requested, he shall inform the individual:

(1) Of his decision and the reasons for it.

(2) Of the individual's right to file with the Food and Drug Administration a concise statement of the individual's reasons for disagreeing with the agency's decision not to amend the record as requested.

(3) That the statement of disagreement will be made available to all persons listed in an accounting as having previously received the record and any person to whom the record is subsequently disclosed together with, in the discretion of the Food and Drug Administration, a brief statement summarizing its reasons for refusing to amend the record. Any individual who includes false information in the statement of disagreement filed with the Food and Drug Administration may be subject to penalties under 18 U.S.C. 1001, the False Reports to the Government Act.

(4) That the individual has a right to seek judicial review of the refusal to amend the record.

(c) If the Commissioner on administrative appeal or a court on judicial review determines that the record should be amended in accordance with the individual's request, the Food and Drug Administration shall proceed in accordance with § 21.51(d).

(d) A final determination on the individual's administrative appeal of the initial refusal to amend the record shall be concluded within 30 working days of the request for such review under paragraph (a) of this section, unless the Commissioner extends such period for good cause and informs the individual in writing of the reasons for the delay and of the approximate date on which a decision of the appeal can be expected.

[42 FR 15626, Mar. 22, 1977, as amended at 50 FR 52278, Dec. 23, 1985; 79 FR 68115, Nov. 14, 2014]

§ 21.53 Notation and disclosure of disputed records.

When an individual has filed a statement of disagreement under § 21.52(b)(2), the Food and Drug Administration shall:

(a) Mark any portion of the record that is disputed to assure that the record will clearly show that portion is disputed whenever the record is disclosed.

(b) In any subsequent disclosure under § 21.70 or § 21.71(a), provide a copy of the statement of disagreement and, if the Food and Drug Administration deems it appropriate, a concise statement of the agency's reasons for not making the amendment(s) requested. While the individual shall have access to any such statement, it shall not be subject to a request for amendment under § 21.50.

(c) If an accounting was made under § 21.71(d) and (e) of a disclosure of the record under § 21.71(a), provide to all previous recipients of the record a copy of the statement of disagreement and the agency statement, if any.

§ 21.54 Amended or disputed records received from other agencies.

Whenever the Food and Drug Administration is notified that a record that it received from another agency was amended or is the subject of a statement of disagreement, the Food and Drug Administration shall:

(a) Discard the record, or clearly note the amendment or the fact of disagreement in its copy of the record, and

(b) Refer persons who subsequently request the record to the agency that provided it.

(c) If an accounting was made under § 21.71 (d) and (e) of the disclosure of the record under § 21.71(a), inform all previous recipients of the record about the amendment or provide to them the statement of disagreement and the agency statement, if any.

Subpart F—Exemptions

§ 21.60 Policy.

It is the policy of the Food and Drug Administration that record systems should be exempted from the Privacy Act only to the extent essential to the performance of law enforcement functions under the laws that are administered and enforced by the Food and Drug Administration or that govern the agency.

§ 21.61 Exempt systems.

(a) Investigatory records compiled for law enforcement purposes, including criminal law enforcement purposes, in the Food and Drug Administration Privacy Act Record Systems listed in

paragraph (b) of this section are exempt from the following provisions of the Privacy Act (5 U.S.C. 552a) and of this part:

(1) Such records are exempt from 5 U.S.C. 552a(c)(3) and § 21.71(e)(4), requiring that an individual be provided with the accounting of disclosures of records about himself from a Privacy Act Record System.

(2) Except where access is required under 5 U.S.C. 552a(k)(2) and § 21.65(a)(2), (such records are exempt from 5 U.S.C. 552a(d)(1) through (4) and (f)) and §§ 21.40 through 21.54, requiring procedures for an individual to be given notification of and access to records about himself in a Privacy Act Record System and to be allowed to challenge the accuracy, relevance, timeliness, and completeness of such records.

(3) Such records are exempt from 5 U.S.C. 552a(e)(4)(G) and (H) and § 21.20(b)(1) requiring inclusion in the notice for the system of information about agency procedures for notification, access, and contest.

(4) Such records are exempt from 5 U.S.C. 552a(e)(3) requiring that individuals asked to supply information be provided a form outlining the authority for the request, the purposes for which the information will be used, the routine uses in the notice for the Privacy Act Record System, and the consequences to the individual of not providing the information, but only with respect to records compiled by the Food and Drug Administration in a criminal law enforcement investigation where the conduct of the investigation would be prejudiced by such procedures.

(b) Records in the following Food and Drug Administration Privacy Act Record Systems that concern individuals who are subject to Food and Drug Administration enforcement action and consist of investigatory records compiled for law enforcement purposes, including criminal law enforcement purposes, are exempt under 5 U.S.C. 552a(j)(2) and (k)(2) from the provisions enumerated in paragraph (a) of this section:

(1) Bio-research Monitoring Information System—HHS/FDA/09–10–0010.

(2) Regulated Industry Employee Enforcement Records—HHS/FDA/ACMO/09–10–002.

(3) Employee Conduct Investigative Records—HHS/FDA/ACMO/09–10–0013.

(c) The system described in paragraph (b)(3) of this section includes investigatory records compiled solely for the purpose of determining suitability, eligibility, or qualification for Federal civilian employment, military service, Federal contracts, and access to classified information. These records are exempt from disclosure under 5 U.S.C. 552a(k)(5) to the extent that the disclosure would reveal the identity of a source who furnished information to the Government under a promise of confidentiality, which must be an express promise if the information was furnished after September 27, 1975. Any individual who is refused access to a record that would reveal a confidential source shall be advised in a general way that the record includes information that would reveal a confidential source.

(d) Records in the following Food and Drug Administration Privacy Act Records Systems are exempt under 5 U.S.C. 552a(k)(2) and (k)(5) from the provisions enumerated in paragraph (a)(1) through paragraph (a)(3) of this section: FDA Records Related to Research Misconduct Proceedings, HHS/FDA/OC, 09–10–0020.

[42 FR 15626, Mar. 22, 1977, as amended at 46 FR 8459, Jan. 27, 1981; 50 FR 52278, Dec. 23, 1985; 78 FR 39186, July 1, 2013]

§ 21.65 Access to records in exempt systems.

(a) Where a Privacy Act Record System is exempt and the requested records are unavailable under § 21.61, an individual may nevertheless make a request under § 21.40 for notification concerning whether any records about him exist and request access to such records where they are retrieved by his name or other personal identifier.

(b) An individual making a request under paragraph (a) of this section;

(1) May be given access to the records where available under part 20 of this chapter (the public information regulations) or the Commissioner may, in his discretion, entertain a request under

any or all of the provisions of §§ 21.40 through 21.54; and

(2) Shall be given access upon request if the records requested are subject to 5 U.S.C. 552a(k)(2) and not to 5 U.S.C. 552a(j)(2) (i.e., because they consist of investigatory material compiled for law enforcement purposes other than criminal law enforcement purposes) and maintenance of the records resulted in denial to the individual of any right, benefit, or privilege to which he would otherwise be entitled by Federal law, or for which he would otherwise be eligible. An individual given access to a record under this paragraph (b)(2) is not entitled to seek amendment under subpart E of this part. The FDA may refuse to disclose a record that would reveal the identity of a source who furnished information to the Government under a promise of confidentiality, which must be an express promise if the information was furnished on or after September 27, 1975. Any individual refused access to a record that would reveal a confidential source shall be advised in a general way that the record contains information that would reveal a confidential source.

(c) The Commissioner shall not make available any record that is prohibited from public disclosure under § 20.82(b) of this chapter.

(d) Discretionary disclosure of a record pursuant to paragraph (b)(1) of this section shall not set a precedent for discretionary disclosure of a similar or related record and shall not obligate the Commissioner to exercise his discretion to disclose any other record in a system that is exempt under § 21.61.

Subpart G—Disclosure of Records in Privacy Act Record Systems to Persons Other Than the Subject Individual

§ 21.70 Disclosure and intra-agency use of records in Privacy Act Record Systems; no accounting required.

(a) A record about an individual which is contained in a Privacy Act Record System may be disclosed:

(1) To the individual who is the subject of the record, or his legal guardian under § 21.75;

(2) To a third party pursuant to a written request by, or within a written consent of, the individual to whom the record pertains, or his legal guardian under § 21.75;

(3) To any person:

(i) Where the names and other identifying information are first deleted, and under circumstances in which the recipient is unlikely to know the identity of the subject of the record;

(ii) Where disclosure is required by part 20 of this chapter (the public information regulations); or

(4) Within the Department of Health and Human Services to officers and employees who have a need for the record in the performance of their duties in connection with the laws administered and enforced by the Food and Drug Administration or that govern the agency. For purposes of this section, officers or employees of the Department shall include the following categories of individuals, who shall thereafter be subject to the same restrictions with respect to disclosure as any Food and Drug Administration employee: Food and Drug Administration consultants and advisory committees, State and local government employees for use only in their work with the Food and Drug Administration, and contractors and their employees to the extent that the records of such contractors are subject to the requirements of this part under § 21.30.

(b) No accounting is required for any disclosure or use under paragraph (a) of this section.

§ 21.71 Disclosure of records in Privacy Act Record Systems; accounting required.

(a) Except as provided in § 21.70, a record about an individual that is contained in a Privacy Act Record System shall not be disclosed by any method of communication except under any of the following circumstances, which are subject to the limitations of paragraphs (b) and (c) of this section and to the accounting requirement of paragraph (d) of this section:

(1) To those officers and employees of the agency which maintains the record

who have a need for the record in the perfomance of their duties;

(2) Required under section 552 of the Freedom of Information Act;

(3) For a routine use as described in the routine use section of each specific system notice;

(4) To the Bureau of Census for purposes of planning or carrying out a census or survey or related activity pursuant to the provisions of title 13 of the U.S. Code;

(5) To a recipient who has provided the agency with advance adequate written assurance that the record will be used solely as a statistical research or reporting record, and that the record is to be transferred in a form that is not individually identifiable;

(6) To the National Archives and Records Administration of the United States as a record which has sufficient historical or other value to warrant its continued preservation by the U.S. Government, or to the Archivist of the United States or his or her designee for evaluation to determine whether the record has such value;

(7) To another agency or to an instrumentality of any government jurisdiction within or under the control of the United States for a civil or criminal law enforcement activity if the activity is authorized by law, and if the head of the agency or instrumentality has made a written request to the agency which maintains the record specifying the particular portion desired and the law enforcement activity for which the record is sought;

(8) To a person pursuant to a showing of compelling circumstances affecting the health or safety of an individual if, upon such disclosure, notification is transmitted to the last known address of such individual;

(9) To either House of Congress or, to the extent of matter within its jurisdiction, any committee or subcommittee thereof, any joint committee of Congress or subcommittee of any such joint committee;

(10) To the Comptroller General, or any of his or her authorized representatives in the course of the performance of the duties of the General Accounting Office;

(11) Pursuant to the order of a court of competent jurisdiction; or

(12) To a consumer reporting agency in accordance with section 3(d) of the Federal Claims Collection Act of 1966 (31 U.S.C. 952(d)). (This ''Special Disclosure'' statement does not apply to any FDA system of records.)

(b) The Food and Drug Administration may in its discretion refuse to make a disclosure permitted under paragraph (a) of this section, if the disclosure would in the judgment of the agency, invade the privacy of the individual or be inconsistent with the purpose for which the information was collected.

(c) The Food and Drug Administration may require any person requesting a disclosure of a record under paragraph (a) of this section to provide:

(1) Information about the purposes to which the disclosed record is to be put, and

(2) A written statement certifying that the record will be used only for the stated purposes and will not be further disclosed without the written permission of the Food and Drug Administration.

Under 5 U.S.C. 552a(i)(3), any person who knowingly or willfully requests or obtains any record concerning an individual from an agency under false pretenses shall be guilty of a misdemeanor and fined not more than $5,000. Such person may also be subject to prosecution under the False Reports to the Government Act, 18 U.S.C. 1001.

(d) An accounting shall be made, in accordance with paragraph (e) of this section, of any disclosure under paragraph (a) of this section of a record that is not a disclosure under §21.70.

(e) Where an accounting is required under paragraph (d) of this section, the Food and Drug Administration shall:

(1) Record the name and address of the person or agency to whom the disclosure is made and the date, nature, and purpose of the disclosure. The accounting shall not be considered a Privacy Act Record System.

(2) Retain the accounting for 5 years or for the life of the record, whichever is longer, following the disclosure.

(3) Notify those recipients listed in the accounting of amendments or disputes concerning the records previously disclosed to them pursuant to §21.51(d)(3), §21.53(c), or §21.54(c).

(4) Except when the record is exempt from individual access and contest under § 21.61 or to the extent that the accounting describes a transfer for a law enforcement purpose pursuant to paragraph (a)(7) of this section, make the accounting available to the individual to whom the record pertains, in accordance with procedures of subpart D of this part.

(f) A single accounting may be used to cover disclosure(s) that consist of a continuing dialogue between two agencies over a prolonged period, such as discussion of an enforcement action between the Food and Drug Administration and the Department of Justice. In such cases, a general notation may be made that, as of a certain date, contract was initiated, to continue until resolution of the matter.

[42 FR 15626, Mar. 22, 1977, as amended at 50 FR 52278, Dec. 23, 1985; 54 FR 9038, Mar. 3, 1989]

§ 21.72 Individual consent to disclosure of records to other persons.

(a) Individuals may consent to disclosure of records about themselves to other persons in several ways, for example:

(1) An individual may give consent at the time that the information is collected for disclosure for specific purposes or to specific persons.

(2) An individual may give consent for disclosure of his records to a specific person.

(3) An individual may request the Food and Drug Administration to transcribe a specific record for submission to another person.

(b) In each case the consent shall be in writing and shall specify the individual, organizational unit, or class of individuals or organizational units to whom the record may be disclosed, which record may be disclosed, and, if applicable, for what time period. A blanket consent to release all of an individual's records to unspecified individuals or organizational units will not be honored. Verification of the identity of the individual and, where applicable, of the person to whom the record is to be disclosed shall be made in accordance with § 21.44. Consent documents shall be retained for a period of at least 2 years. If such documents are used as a means of accounting for the disclosure, they shall be retained as provided in § 21.71(e)(2).

§ 21.73 Accuracy, completeness, timeliness, and relevance of records disclosed from Privacy Act Record Systems.

(a) The Food and Drug Administration shall make reasonable efforts to assure that a record about an individual in a Privacy Act Record System is accurate, relevant to a Food and Drug Administration purpose, timely, and complete before such record is disclosed under § 21.71.

(b) Paragraph (a) of this section shall not apply to disclosures that are required under part 20 of this chapter (the public information regulations) or made to other Federal Government departments and agencies. Where appropriate, the letter disclosing the information shall indicate that the Food and Drug Administration has not reviewed the record to assure that it is accurate, relevant, timely, and complete.

§ 21.74 Providing notice that a record is disputed.

Whenever an individual has filed a statement of disagreement with the Food and Drug Administration concerning a refusal to amend a record under § 21.51(a)(2) or with another agency that provides the record to the Food and Drug Administration, the Food and Drug Administration shall in any subsequent disclosure under this subpart provide a copy of the statement of disagreement and a concise statement by the agency, if one has been prepared, of the reasons for not making the amendment(s) requested.

§ 21.75 Rights of legal guardians.

For the purposes of this part, the parent of any individual who is a minor or the legal guardian of any individual who has been declared to be incompetent due to physical or mental incapacity or age by a court of competent jurisdiction may act on behalf of the individual.

PART 25—ENVIRONMENTAL IMPACT CONSIDERATIONS

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AUTHORITY: 21 U.S.C. 321–393; 42 U.S.C. 262, 263b–264; 42 U.S.C. 4321, 4332; 40 CFR parts 1500–1508; E.O. 11514, 35 FR 4247, 3 CFR, 1971 Comp., p. 531–533 as amended by E.O. 11991, 42 FR 26967, 3 CFR, 1978 Comp., p. 123–124 and E.O. 12114, 44 FR 1957, 3 CFR, 1980 Comp., p. 356–360.

SOURCE: 62 FR 40592, July 29, 1997, unless otherwise noted.

Subpart A—General Provisions

§ 25.1 Purpose.

The National Environmental Policy Act of 1969 (NEPA), as amended, directs that, to the fullest extent possible, the policies, regulations, and public laws of the United States shall be interpreted and administered in accordance with the policies set forth in NEPA. All agencies of the Federal Government shall comply with the procedures in section 102(2) of NEPA except where compliance would be inconsistent with other statutory requirements. The regulations in this part implement section 102(2) of NEPA in a manner that is consistent with FDA's authority under the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act. This part also supplements the regulations for implementing the procedural provisions of NEPA that were published by the Council on Environmental Quality (CEQ) in 40 CFR parts 1500 through 1508 and the procedures included in the ''HHS General Administration Manual, part 30: Environmental Protection'' (45 FR 76519 to 76534, November 19, 1980).

§ 25.5 Terminology.

(a) Definitions that apply to the terms used in this part are set forth in the CEQ regulations under 40 CFR part 1508. The terms and the sections of 40 CFR part 1508 in which they are defined follow:

(1) Categorical exclusion (40 CFR 1508.4).

(2) Cooperating agency (40 CFR 1508.5).

(3) Cumulative impact (40 CFR 1508.7).

(4) Effects (40 CFR 1508.8).

(5) Environmental assessment (EA) (40 CFR 1508.9).

(6) Environmental document (40 CFR 1508.10).

(7) Environmental impact statement (EIS) (40 CFR 1508.11).

(8) Federal agency (40 CFR 1508.12).

(9) Finding of no significant impact (40 CFR 1508.13).

(10) Human environment (40 CFR 1508.14).

(11) Lead agency (40 CFR 1508.16).

(12) Legislation (40 CFR 1508.17).

(13) Major Federal action (40 CFR 1508.18).

(14) Mitigation (40 CFR 1508.20).

(15) NEPA process (40 CFR 1508.21).

(16) Notice of intent (40 CFR 1508.22).

(17) Proposal (40 CFR 1508.23).

(18) Scope (40 CFR 1508.25).

(19) Significantly (40 CFR 1508.27).

(b) The following terms are defined solely for the purpose of implementing the supplemental procedures provided by this part and are not necessarily applicable to any other statutory or regulatory requirements:

(1) *Abbreviated application* applies to an abbreviated new drug application and an abbreviated new animal drug application.

(2) *Active moiety* means the molecule or ion, excluding those appended portions of the molecule that cause the drug to be an ester, salt (including a salt with hydrogen or coordination bonds), or other noncovalent derivative (such as a complex chelate or clathrate) of the molecule responsible for the physiological or pharmacological action of the drug substance.

(3) *Agency* means the Food and Drug Administration (FDA).

(4) *Increased use* of a drug or biologic product may occur if the drug will be administered at higher dosage levels, for longer duration or for different indications than were previously in effect, or if the drug is a new molecular entity. The term ''use'' also encompasses disposal of FDA-regulated articles by consumers.

(5) *Responsible agency official* means the agency decisionmaker designated in the delegated authority for the underlying actions.

(c) The following acronyms are used in this part:

(1) CEQ—Council on Environmental Quality.

(2) CGMP—Current good manufacturing practice.

(3) EA—Environmental assessment.

(4) EIS—Environmental impact statement.

(5) The act—Federal Food, Drug, and Cosmetic Act.

(6) FIFRA—Federal Insecticide, Fungicide, and Rodenticide Act.

(7) FONSI—Finding of no significant impact.

(8) GLP—Good laboratory practice.

(9) GRAS—Generally recognized as safe.

(10) HACCP—Hazard analysis critical control point.

(11) IDE—Investigational device exemption.

(12) IND—Investigational new drug application.

(13) INAD—Investigational new animal drug application.

(14) NADA—New animal drug application.

(15) NDA—New drug application.

(16) NEPA—National Environmental Policy Act of 1969.

(17) OTC—Over-the-counter.

(18) PDP—Product development protocol.

(19) PMA—Premarket approval application.

[62 FR 40592, July 29, 1997, as amended at 64 FR 399, Jan. 5, 1999; 69 FR 17291, Apr. 2, 2004]

§ 25.10 Policies and NEPA planning.

(a) All FDA's policies and programs will be planned, developed, and implemented to achieve the policies declared by NEPA and required by CEQ's regulations to ensure responsible stewardship of the environment for present and future generations.

(b) Assessment of environmental factors continues throughout planning and is integrated with other program planning at the earliest possible time to ensure that planning and decisions reflect environmental values, to avoid delays later in the process, and to avoid potential conflicts.

(c) For actions initiated by the agency, the NEPA process will begin when the agency action under consideration is first identified. For actions initiated by applicants or petitioners, NEPA planning begins when FDA receives from an applicant or petitioner an EA or a claim that a categorical exclusion applies, or when FDA personnel consult with applicants or petitioners on the NEPA-related aspects of their requested actions. FDA may issue a public call for environmental data or otherwise consult with affected individuals or groups when a contemplated action in which it is or may be involved poses potential significant environmental effects.

(d) Environmental documents shall concentrate on timely and significant issues, not amass needless detail.

(e) If a proposed action for which an EIS will be prepared involves possible environmental effects that are required to be considered under statutes or Executive Orders other than those referred to under ''Authority'' in this part, these effects shall be considered in the NEPA review, consistent with 40 CFR 1502.25 and the HHS General Administration Manual, part 30: Environmental Protection.

Subpart B—Agency Actions Requiring Environmental Consideration

§ 25.15 General procedures.

(a) All applications or petitions requesting agency action require the submission of an EA or a claim of categorical exclusion. A claim of categorical exclusion shall include a statement of compliance with the categorical exclusion criteria and shall state that to the applicant's knowledge, no extraordinary circumstances exist. Failure to submit an adequate EA for an application or petition requesting action by the agency of a type specified in § 25.20, unless the agency can determine that the action qualifies for exclusion under §§ 25.30, 25.31, 25.32, 25.33, 25.34, or 25.35 is sufficient grounds for FDA to refuse to file or approve the application or petition. An EA adequate for filing is one that addresses the relevant environmental issues. An EA adequate for approval is one that contains sufficient information to enable the agency to determine whether the proposed action may significantly affect the quality of the human environment.

(b) The responsible agency officials will evaluate the information contained in the EA to determine whether it is accurate and objective, whether the proposed action may significantly affect the quality of the human environment, and whether an EIS will be prepared. If significant effects requiring the preparation of an EIS are identified, FDA will prepare an EIS for the action in accordance with the procedures in subparts D and E of this part. If significant effects requiring the preparation of an EIS are not identified, resulting in a decision not to prepare an EIS, the responsible agency official will prepare a FONSI in accordance with § 25.41.

(c) Classes of actions that individually or cumulatively do not significantly affect the quality of the human environment ordinarily are excluded from the requirement to prepare an EA or an EIS. The classes of actions that qualify as categorical exclusions are set forth in §§ 25.30, 25.31, 25.32, 25.33, 25.34, or 25.35.

(d) A person submitting an application or petition of a type subject to categorical exclusion under §§ 25.30, 25.31, 25.32, 25.33, 25.34, or 25.35, or proposing to dispose of an article as provided in § 25.30(d) or 25.32(h), is not required to submit an EA if the person states that the action requested qualifies for a categorical exclusion, citing the particular categorical exclusion that is claimed, and states that to the applicant's knowledge, no extraordinary circumstances exist.

[62 FR 40592, July 29, 1997, as amended at 80 FR 57535, Sept. 24, 2015]

§ 25.16 Public health and safety emergencies.

There are certain regulatory actions that, because of their immediate importance to the public health or safety, may make full adherence to the procedural provisions of NEPA and CEQ's regulations impossible. For such actions, the responsible agency official shall consult with CEQ about alternative arrangements before the action is taken, or after the action is taken, if time does not permit prior consultation with CEQ.

§ 25.20 Actions requiring preparation of an environmental assessment.

Any proposed action of a type specified in this section normally requires at least the preparation of an EA, unless it is an action in a specific class that qualifies for exclusion under §§ 25.30, 25.31, 25.32, 25.33, 25.34, or 25.35:

(a) Major recommendations or reports made to Congress on proposals for legislation in instances where the agency has primary responsibility for the subject matter involved.

(b) Destruction or other disposition of articles condemned after seizure or

whose distribution or use has been enjoined, unless categorically excluded in §§ 25.30(d) or 25.32(h).

(c) Destruction or other disposition of articles following detention or recall at agency request, unless categorically excluded in §§ 25.30(d) or 25.32(h).

(d) Disposition of FDA laboratory waste materials, unless categorically excluded in § 25.30(m).

(e) Intramural and extramural research supported in whole or in part through contracts, other agreements, or grants, unless categorically excluded in § 25.30 (e) or (f).

(f) Establishment by regulation of labeling requirements, a standard, or a monograph, unless categorically excluded in §§ 25.30(k) or 25.31 (a), (b), (c), (h), (i), or (j), or 25.32 (a) or (p).

(g) Issuance, amendment, and enforcement of FDA regulations, or an exemption or variance from FDA regulations, unless categorically excluded in § 25.30 (h), (i), or (j), or § 25.32 (e), (g), (n), or (p).

(h) Withdrawal of existing approvals of FDA-approved articles, unless categorically excluded in §§ 25.31 (d) or (k), 25.32(m), or 25.33 (g) or (h).

(i) Approval of food additive petitions and color additive petitions, approval of requests for exemptions for investigational use of food additives, the granting of requests for exemption from regulation as a food additive under § 170.39 of this chapter, and allowing notifications submitted under 21 U.S.C. 348(h) to become effective, unless categorically excluded in § 25.32(b), (c), (i), (j), (k), (l), (o), (q), or (r).

(j) Establishment of a tolerance for unavoidable poisonous or deleterious substances in food or in packaging materials to be used for food.

(k) Establishment or amendment of a regulation for a food substance as GRAS under the conditions of its intended use for humans or animals under parts 182, 184, 186, 582, or 584 of this chapter, or establishment or amendment of a regulation for a prior-sanctioned food ingredient, as defined in §§ 170.3(l) and 181.5(a) of this chapter, unless categorically excluded in § 25.32(f), (i), (j), (k), or (r).

(l) Approval of NDA's, abbreviated applications, applications for marketing approval of a biologic product, supplements to such applications, and actions on IND's, unless categorically excluded in § 25.31 (a), (b), (c), (e), or (l).

(m) Approval of NADA's, abbreviated applications, supplements, actions on INAD's, and granting of requests for determination of eligibility for indexing, unless categorically excluded under § 25.33 (a), (c), (d), or (e).

(n) Approval of PMA's for medical devices, notices of completion of PDP's for medical devices, authorizations to commence clinical investigation under an approved PDP, or applications for an IDE, unless categorically excluded in § 25.34.

(o) Issuance of an order finding a tobacco product substantially equivalent under the Federal Food, Drug, and Cosmetic Act, or granting of a request for an exemption under 21 CFR part 1107 from the requirement of demonstrating substantial equivalence, unless categorically excluded under § 25.35.

(p) Issuance of an order authorizing marketing of a new tobacco product under section 910 of the Federal Food, Drug, and Cosmetic Act or an order authorizing marketing of a modified risk tobacco product under section 911 of the Federal Food, Drug, and Cosmetic Act, unless categorically excluded under § 25.35.

[62 FR 40592, July 29, 1997, as amended at 65 FR 30355, May 11, 2000; 72 FR 69118, Dec. 6, 2007; 80 FR 57535, Sept. 24, 2015; 81 FR 55047, Aug. 17, 2016]

§ 25.21 Extraordinary circumstances.

As required under 40 CFR 1508.4, FDA will require at least an EA for any specific action that ordinarily would be excluded if extraordinary circumstances indicate that the specific proposed action may significantly affect the quality of the human environment (see 40 CFR 1508.27 for examples of significant impacts). Examples of such extraordinary circumstances include:

(a) Actions for which available data establish that, at the expected level of exposure, there is the potential for serious harm to the environment; and

(b) Actions that adversely affect a species or the critical habitat of a species determined under the Endangered Species Act or the Convention on International Trade in Endangered

Species of Wild Flora and Fauna to be endangered or threatened or wild flora or fauna that are entitled to special protection under some other Federal law.

§ 25.22 Actions requiring the preparation of an environmental impact statement.

(a) There are no categories of agency actions that routinely significantly affect the quality of the human environment and that therefore ordinarily require the preparation of an EIS.

(b) EIS's are prepared for agency actions when evaluation of data or information in an EA or otherwise available to the agency leads to a finding by the responsible agency official that a proposed action may significantly affect the quality of the human environment.

Subpart C—Categorical Exclusions

§ 25.30 General.

The classes of actions listed in this section and §§ 25.31 through 25.35 are categorically excluded and, therefore, ordinarily do not require the preparation of an EA or an EIS:

(a) Routine administrative and management activities, including inspections, and issuance of field compliance programs, program circulars, or field investigative assignments.

(b) Recommendation for an enforcement action to be initiated in a Federal court.

(c) Agency requests for initiation of recalls.

(d) Destruction or disposition of any FDA-regulated article condemned after seizure or the distribution or use of which has been enjoined or following detention or recall at agency request if the method of destruction or disposition of the article, including packaging material, is in compliance with all Federal, State, and local requirements.

(e) Extramural contracts, other agreements, or grants for statistical and epidemiological studies, surveys and inventories, literature searches, and report and manual preparation, or any other studies that will not result in the production or distribution of any substance and, therefore, will not result in the introduction of any substance into the environment.

(f) Extramural contracts, other agreements, and grants for research for such purposes as to develop analytical methods or other test methodologies.

(g) Activities of voluntary Federal-State cooperative programs, including issuance of model regulations proposed for State adoption.

(h) Issuance, amendment, or revocation of procedural or administrative regulations and guidance documents, including procedures for submission of applications for product development, testing and investigational use, and approval.

(i) Corrections and technical changes in regulations.

(j) Issuance of CGMP regulations, HACCP regulations, establishment standards, emergency permit control regulations, GLP regulations, and issuance or denial of permits, exemptions, variances, or stays under these regulations.

(k) Establishment or repeal by regulation of labeling requirements for marketed articles if there will be no increase in the existing levels of use or change in the intended uses of the product or its substitutes.

(l) Routine maintenance and minor construction activities such as:

(1) Repair to or replacement of equipment or structural components (e.g., door, roof, or window) of facilities controlled by FDA;

(2) Lease extensions, renewals, or succeeding leases;

(3) Construction or lease construction of 10,000 square feet or less of occupiable space;

(4) Relocation of employees into existing owned or currently leased space;

(5) Acquisition of 20,000 square feet or less of occupiable space in a structure that was substantially completed before the issuance of solicitation for offers; and

(6) Acquisition of between 20,000 square feet and 40,000 square feet of occupiable space if it constitutes less than 40 percent of the occupiable space in a structure that was substantially completed before the solicitation for offers.

(m) Disposal of low-level radioactive waste materials (as defined in the Nuclear Regulatory Commission regulations at 10 CFR 61.2) and chemical waste materials generated in the laboratories serviced by the contracts administered by FDA, if the waste is disposed of in compliance with all applicable Federal, State, and local requirements.

[62 FR 40592, July 29, 1997, as amended at 65 FR 56479, Sept. 19, 2000; 80 FR 57535, Sept. 24, 2015]

§ 25.31 Human drugs and biologics.

The classes of actions listed in this section are categorically excluded and, therefore, ordinarily do not require the preparation of an EA or an EIS:

(a) Action on an NDA, abbreviated application, application for marketing approval of a biologic product, or a supplement to such applications, or action on an OTC monograph, if the action does not increase the use of the active moiety.

(b) Action on an NDA, abbreviated application, or a supplement to such applications, or action on an OTC monograph, if the action increases the use of the active moiety, but the estimated concentration of the substance at the point of entry into the aquatic environment will be below 1 part per billion.

(c) Action on an NDA, abbreviated application, application for marketing approval of a biologic product, or a supplement to such applications, or action on an OTC monograph, for substances that occur naturally in the environment when the action does not alter significantly the concentration or distribution of the substance, its metabolites, or degradation products in the environment.

(d) Withdrawal of approval of an NDA or an abbreviated application.

(e) Action on an IND.

(f) Testing and release by the Food and Drug Administration of lots or batches of a licensed biologic product.

(g) Establishment of bioequivalence requirements for a human drug or a comparability determination for a biologic product subject to licensing.

(h) Issuance, revocation, or amendment of a standard for a biologic product.

(i) Revocation of a license for a biologic product.

(j) Action on an application for marketing approval for marketing of a biologic product for transfusable human blood or blood components and plasma.

[62 FR 40592, July 29, 1997, as amended at 63 FR 26697, May 13, 1998; 64 FR 399, Jan. 5, 1999; 70 FR 14980, Mar. 24, 2005]

§ 25.32 Foods, food additives, and color additives.

The classes of actions listed in this section are categorically excluded and, therefore, ordinarily do not require the preparation of an EA or an EIS:

(a) Issuance, amendment, or repeal of a food standard.

(b) Action on a request for exemption for investigational use of a food additive if the food additive to be shipped under the request is intended to be used for clinical studies or research.

(c) Approval of a color additive petition to change a provisionally listed color additive to permanent listing for use in food, drugs, devices, or cosmetics.

(d) Testing and certification of batches of a color additive.

(e) Issuance of an interim food additive regulation.

(f) Establishment or amendment of a regulation for a food substance as GRAS under the conditions of its intended use for humans or animals under parts 182, 184, 186, 582, or 584 of this chapter, and establishment or amendment of a regulation for a prior-sanctioned food ingredient, as defined in §§ 170.3(l) and 181.5(a) of this chapter, if the substance or food ingredient is already marketed in the United States for the proposed use.

(g) Issuance and enforcement of regulations relating to the control of communicable diseases or to interstate conveyance sanitation under parts 1240 and 1250 of this chapter.

(h) Approval of a request for diversion of adulterated or misbranded food for humans or animals to use as animal feeds.

(i) Approval of a food additive petition, establishment or amendment of a regulation for a food substance as GRAS under the conditions of its intended use for humans or animals under parts 182, 184, 186, 582, or 584 of

this chapter, the granting of a request for exemption from regulation as a food additive under § 170.39 of this chapter, or allowing a notification submitted under 21 U.S.C. 348(h) to become effective, when the substance is present in finished food-packaging material at not greater than 5 percent-by-weight and is expected to remain with finished food-packaging material through use by consumers or when the substance is a component of a coating of a finished food-packaging material.

(j) Approval of a food additive petition, establishment or amendment of a regulation for a food substance as GRAS under the conditions of its intended use for humans or animals under parts 182, 184, 186, 582, or 584 of this chapter, the granting of a request for exemption from regulation as a food additive under § 170.39 of this chapter, or allowing a notification submitted under 21 U.S.C. 348(h) to become effective, when the substance is to be used as a component of a food-contact surface of permanent or semipermanent equipment or of another food-contact article intended for repeated use.

(k) Approval of a food additive petition or color additive petition, establishment or amendment of a regulation for a food substance as GRAS under the conditions of its intended use for humans or animals under parts 182, 184, 186, 582, or 584 of this chapter, or allowing a notification submitted under 21 U.S.C. 348(h) to become effective, for substances added directly to food that are intended to remain in food through ingestion by consumers and that are not intended to replace macronutrients in food.

(l) Approval of a petition for color additives used in contact lenses, sutures, filaments used as supporting haptics in intraocular lenses, bone cement, and in other FDA-regulated products having similarly low levels of use.

(m) Action to prohibit or otherwise restrict or reduce the use of a substance in food, food packaging, or cosmetics.

(n) Issuance, amendment, or revocation of a regulation pertaining to infant formulas.

(o) Approval of a food additive petition for the intended expression product(s) present in food derived from new plant varieties.

(p) Issuance, amendment, or revocation of a regulation in response to a reference amount petition as described in § 101.12(h) of this chapter, a nutrient content claim petition as described in § 101.69 of this chapter, a health claim petition as described in § 101.70 of this chapter, or a petition pertaining to the label declaration of ingredients as described in § 10.30 of this chapter.

(q) Approval of a food additive petition, the granting of a request for exemption from regulation as a food additive under § 170.39 of this chapter, or allowing a notification submitted under 21 U.S.C. 348(h) to become effective for a substance registered by the Environmental Protection Agency under FIFRA for the same use requested in the petition, request for exemption, or notification.

(r) Approval of a food additive petition or color additive petition, establishment or amendment of a regulation for a food substance as GRAS under the conditions of its intended use for humans or animals under parts 182, 184, 186, 582, or 584 of this chapter, or allowing a notification submitted under 21 U.S.C. 348(h) to become effective for a substance that occurs naturally in the environment, when the action does not alter significantly the concentration or distribution of the substance, its metabolites, or degradation products in the environment.

[62 FR 40592, July 29, 1997, as amended at 65 FR 30355, May 11, 2000; 76 FR 59248, Sept. 26, 2011; 81 FR 55047, Aug. 17, 2016]

§ 25.33 Animal drugs.

The classes of actions listed in this section are categorically excluded and, therefore, ordinarily do not require the preparation of an EA or an EIS:

(a) Action on an NADA, abbreviated application, request for determination of eligibility for indexing, a supplement to such applications, or a modification of an index listing, if the action does not increase the use of the drug. Actions to which this categorical exclusion applies may include:

(1) An animal drug to be marketed under the same conditions of approval as a previously approved animal drug;

(2) A combination of previously approved animal drugs;

(3) A new premix or other formulation of a previously approved animal drug;

(4) Changes specified in § 514.8(b)(3), (b)(4), or (c)(3) of this chapter;

(5) A change of sponsor;

(6) A previously approved animal drug to be contained in medicated feed blocks under § 510.455 of this chapter or as a liquid feed supplement under § 558.5 of this chapter; or

(7) Approval of a drug for use in animal feeds if such drug has been approved under § 514.2 or 514.9 of this chapter for other uses.

(b) [Reserved]

(c) Action on an NADA, abbreviated application, request for determination of eligibility for indexing, a supplement to such applications, or a modification of an index listing, for substances that occur naturally in the environment when the action does not alter significantly the concentration or distribution of the substance, its metabolites, or degradation products in the environment.

(d) Action on an NADA, abbreviated application, request for determination of eligibility for indexing, a supplement to such applications, or a modification of an index listing, for:

(1) Drugs intended for use in nonfood animals;

(2) Anesthetics, both local and general, that are individually administered;

(3) Nonsystemic topical and ophthalmic animal drugs;

(4) Drugs for minor species, including wildlife and endangered species, when the drug has been previously approved for use in another or the same species where similar animal management practices are used; and

(5) Drugs intended for use under prescription or veterinarian's order for therapeutic use in terrestrial species.

(e) Action on an INAD.

(f) Action on an application submitted under section 512(m) of the act.

(g) Withdrawal of approval of an NADA or an abbreviated NADA or removal of a new animal drug from the index.

(h) Withdrawal of approval of a food additive petition that reduces or eliminates animal feed uses of a food additive.

[62 FR 40592, July 29, 1997, as amended at 71 FR 74782, Dec. 13, 2006; 72 FR 69119, Dec. 6, 2007]

§ 25.34 Devices and electronic products.

The classes of actions listed in this section are categorically excluded and, therefore, ordinarily do not require the preparation of an EA or an EIS:

(a) Action on a device premarket notification submission under subpart E of part 807 of this chapter.

(b) Classification or reclassification of a device under part 860 of this chapter, including the establishment of special controls, if the action will not result in increases in the existing levels of use of the device or changes in the intended use of the device or its substitutes.

(c) Issuance, amendment, or repeal of a standard for a class II medical device or an electronic product, and issuance of exemptions or variances from such a standard.

(d) Approval of a PMA or a notice of completion of a PDP or amended or supplemental applications or notices for a class III medical device if the device is of the same type and for the same use as a previously approved device.

(e) Changes in the PMA or a notice of completion of a PDP for a class III medical device that do not require submission of an amended or supplemental application or notice.

(f) Issuance of a restricted device regulation if it will not result in increases in the existing levels of use or changes in the intended uses of the product or its substitutes.

(g) Action on an application for an IDE or an authorization to commence a clinical investigation under an approved PDP.

(h) Issuance of a regulation exempting from preemption a requirement of a State or political subdivision concerning a device, or a denial of an application for such exemption.

(i) Approval of humanitarian device exemption under subpart H of part 814 of this chapter.

[62 FR 40592, July 29, 1997, as amended at 70 FR 69277, Nov. 15, 2005]

§ 25.35 Tobacco product applications.

The classes of actions listed in this section are categorically excluded and, therefore, normally do not require the preparation of an EA or an EIS:

(a) Issuance of an order finding a tobacco product substantially equivalent under section 910(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act;

(b) Issuance of an order finding a tobacco product not substantially equivalent under section 910(a) of the Federal Food, Drug, and Cosmetic Act, denial of a request for an exemption under 21 CFR part 1107 from the requirement of demonstrating substantial equivalence, issuance of an order under section 910(c) of the Federal Food, Drug, and Cosmetic Act that a new tobacco product may not be introduced or delivered for introduction into interstate commerce, or issuance of an order under section 911 of the Federal Food, Drug, and Cosmetic Act that a modified risk tobacco product may not be introduced or delivered for introduction into interstate commerce;

(c) Rescission or temporary suspension of an order authorizing the marketing of a new tobacco product under section 910 of the Federal Food, Drug, and Cosmetic Act;

(d) Rescission of an order authorizing the marketing of a modified risk tobacco product under section 911 of the Federal Food, Drug, and Cosmetic Act; and

(e) Rescission of an order granting an exemption request under § 1107.1 of this chapter.

[80 FR 57535, Sept. 24, 2015]

Subpart D—Preparation of Environmental Documents

§ 25.40 Environmental assessments.

(a) As defined by CEQ in 40 CFR 1508.9, an EA is a concise public document that serves to provide sufficient evidence and analysis for an agency to determine whether to prepare an EIS or a FONSI. The EA shall include brief discussions of the need for the proposal, of alternatives as required by section 102(2)(E) of NEPA, of the environmental impacts of the proposed action and alternatives, and a listing of agencies and persons consulted. An EA shall be prepared for each action not categorically excluded in § 25.30, § 25.31, § 25.32, § 25.33, or § 25.34, or § 25.35. The EA shall focus on relevant environmental issues relating to the use and disposal from use of FDA-regulated articles and shall be a concise, objective, and well-balanced document that allows the public to understand the agency's decision. If potentially adverse environmental impacts are identified for an action or a group of related actions, the EA shall discuss any reasonable alternative course of action that offers less environmental risk or that is environmentally preferable to the proposed action. The use of a scientifically justified tiered testing approach, in which testing may be stopped when the results suggest that no significant impact will occur, is an acceptable approach.

(b) Generally, FDA requires an applicant to prepare an EA and make necessary corrections to it. Ultimately, FDA is responsible for the scope and content of EA's and may include additional information in environmental documents when warranted.

(c) Information concerning the nature and scope of information that an applicant or petitioner shall submit in an EA may be obtained from the center or other office of the agency having responsibility for the action that is the subject of the environmental evaluation. Applicants and petitioners are encouraged to submit proposed protocols for environmental studies for technical review by agency staff. Applicants and petitioners also are encouraged to consult applicable FDA EA guidance documents, which provide additional advice on how to comply with FDA regulations.

(d) Consistent with 40 CFR 1500.4(j) and 1502.21, EA's may incorporate by reference information presented in other documents that are available to FDA and to the public.

(e) The agency evaluates the information contained in an EA and any public input to determine whether it is accurate and objective, whether the proposed action may significantly affect the quality of the human environment, and whether an EIS or a FONSI will be prepared. The responsible agency official examines the environmental

risks of the proposed action and the alternative courses of action, selects a course of action, and ensures that any necessary mitigating measures are implemented as a condition for approving the selected course of action.

[62 FR 40592, July 29, 1997, as amended at 69 FR 17291, Apr. 2, 2004; 80 FR 57535, Sept. 24, 2015]

§ 25.41 Findings of no significant impact.

(a) As defined by the CEQ regulations (40 CFR 1508.13), a FONSI is a document prepared by a Federal agency stating briefly why an action, not otherwise excluded, will not significantly affect the human environment and for which, therefore, an EIS will not be prepared. A FONSI includes the EA or a summary of it and a reference to any other related environmental documents.

(b) The agency official(s) responsible for approving the FONSI will sign the document, thereby establishing that the official(s) approve(s) the conclusion not to prepare an EIS for the action under consideration.

§ 25.42 Environmental impact statements.

(a) As defined by CEQ regulations (40 CFR 1508.11) and section 102(2)(C) of NEPA, an EIS should be a clear, concise, and detailed written statement describing:

(1) The environmental impacts of a proposed action;

(2) Any adverse effects that cannot be avoided if the action is implemented;

(3) Alternatives to the action;

(4) The relationship between local short-term uses of the environment and the maintenance and enhancement of long-term productivity; and

(5) Any irreversible and irretrievable commitments of resources that would be involved in the proposed action should it be implemented.

(b) The CEQ regulations (40 CFR 1501.7 and part 1502) describe the process for determining the scope of an EIS and provide detailed requirements for the preparation of draft and final EIS's. CEQ format and procedures for preparing EIS shall be followed.

(c) Under the conditions prescribed in 40 CFR 1502.9, the agency will prepare a supplement for a draft or final EIS and introduce the supplement into the administrative record.

§ 25.43 Records of decision.

(a) In cases requiring environmental impact statements, at the time of its decision, the agency shall prepare a concise public record of decision.

(b) The record of decision shall:

(1) State what the decision was;

(2) Identify and discuss alternatives considered by the agency in reaching its decision;

(3) State whether all practicable means to avoid or minimize environmental harm have been adopted, and if not, why not; and

(4) Summarize the program for monitoring and enforcing the practicable means adopted to avoid or minimize the environmental harm.

§ 25.44 Lead and cooperating agencies.

For actions requiring the preparation of an EIS, FDA and other affected Federal agencies will agree which will be the lead agency and which will be the cooperating agencies. The responsibilities of lead agencies and cooperating agencies are described in the CEQ regulations (40 CFR 1501.5 and 1501.6, respectively). If an action affects more than one center within FDA, the Commissioner of Food and Drugs will designate one of these units to be responsible for coordinating the preparation of any required environmental documentation.

§ 25.45 Responsible agency official.

(a) The responsible agency official prepares the environmental documents or ensures that they are prepared.

(b) The responsible agency official will weigh any environmental impacts of each alternative course of action, including possible mitigation measures, and will balance environmental impacts with the agency's objectives in choosing an appropriate course of action. The weighing of any environmental impacts of alternatives in selecting a final course of action will be reflected in the agency's record of formal decisionmaking as required by 40 CFR 1505.2.

[62 FR 40592, July 29, 1997, as amended at 69 FR 17291, Apr. 2, 2004]

Subpart E—Public Participation and Notification of Environmental Documents

§ 25.50 General information.

(a) To the extent actions are not protected from disclosure by existing law applicable to the agency's operation, FDA will involve the public in preparing and implementing its NEPA procedures and will provide public notice of NEPA-related hearings, public meetings, and the availability of environmental documents.

(b) Many FDA actions involving investigations, review, and approval or market authorization of applications, and premarket notifications for human drugs, animal drugs, biologic products, devices, and tobacco products are protected from disclosure under the Trade Secret Act, 18 U.S.C. 1905, and section 301(j) of the Federal Food, Drug, and Cosmetic Act. These actions are also protected from disclosure under FDA's regulations including part 20, §§ 312.130(a), 314.430(b), 514.11(b), 514.12(a), 601.50(a), 601.51(a), 807.95(b), 812.38(a), and 814.9(b) of this chapter. Even the existence of applications for human drugs, animal drugs, biologic products, devices, and tobacco products is protected from disclosure under these regulations. Therefore, unless the existence of applications for human drugs, animal drugs, biologic products, tobacco products, or premarket notification for devices has been made publicly available, the release of the environmental document before approval or authorization of human drugs, animal drugs, biologic products, devices and tobacco products is inconsistent with statutory requirements imposed on FDA. Appropriate environmental documents, comments, and responses will be included in the administrative record to the extent allowed by applicable laws.

[62 FR 40592, July 29, 1997, as amended at 80 FR 57535, Sept. 24, 2015]

§ 25.51 Environmental assessments and findings of no significant impact.

(a) Data and information that are protected from disclosure by 18 U.S.C. 1905 or 21 U.S.C. 331(j) or 360j(c) shall not be included in the portion of environmental documents that is made public. When such data and information are pertinent to the environmental review of a proposed action, an applicant or petitioner shall submit such data and information separately in a confidential section and shall summarize the confidential data and information in the EA to the extent possible.

(b) FONSI's and EA's will be available to the public in accordance with 40 CFR 1506.6 as follows:

(1) When the proposed action is the subject of a notice of proposed rulemaking or a notice of filing published in the FEDERAL REGISTER, the notice shall state that no EIS is necessary and that the FONSI and the EA are available for public inspection at FDA's Division of Dockets Management. If the responsible agency official is unable to complete environmental consideration of the proposed action before a notice of filing of a food or color additive petition is required to be published under the act, and if the subsequent environmental analysis leads to the conclusion that no EIS is necessary, the final regulation rather than the notice of filing shall state that no EIS is necessary and that the FONSI and the EA are available upon request and filed in FDA's Division of Dockets Management.

(2) For actions for which notice is not published in the FEDERAL REGISTER, the FONSI and the EA shall be made available to the public upon request according to the procedures in 40 CFR 1506.6.

(3) For a limited number of actions, the agency may make the FONSI and EA available for public review (including review by State and areawide information clearinghouses) for 30 days before the agency makes its final determination whether to prepare an EIS and before the action may begin, as described in 40 CFR 1501.4(e). This procedure will be followed when the proposed action is, or is closely similar to, one that normally requires an EIS or when the proposed action is one without precedent.

§ 25.52 Environmental impact statements.

(a) If FDA determines that an EIS is necessary for an action involving investigations, approvals, or market authorizations for drugs, animal drugs, biologic products, devices, or tobacco products, an EIS will be prepared but will become available only at the time of the approval or market authorization of the product. The EIS will in all other respects conform to the requirements for EIS's as specified in 40 CFR part 1502 and 1506.6(f).

(b) Comments on the EIS may be submitted after the approval or market authorization of the drug, animal drug, biologic product, device, or tobacco product. Those comments can form the basis for the Agency to consider beginning an action to withdraw the approval or market authorization of applications for a drug, animal drug, biologic product, or tobacco product, or to withdraw premarket notifications or premarket approval applications for devices.

(c) In those cases where the existence of applications and premarket notifications for drugs, animal drugs, biologic products, devices, or tobacco products has already been disclosed before the Agency approves the action, the Agency will ensure appropriate public involvement consistent with 40 CFR 1506.6 and part 1503 in preparing and implementing the NEPA procedures related to preparing EISs while following its own disclosure requirements including those listed in part 20 and §§ 312.130(b), 314.430(d), 514.11(d), 514.12(b), 601.51(d), 807.95(e), 812.38(b), and 814.9(d) of this chapter.

(d) Draft and final EIS's, comments, and responses will be included in the administrative record and will be available from the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

[62 FR 40592, July 29, 1997, as amended at 68 FR 24879, May 9, 2003; 80 FR 57535, Sept. 24, 2015]

Subpart F—Other Requirements

§ 25.60 Environmental effects abroad of major agency actions.

(a) In accordance with Executive Order 12114, ''Environmental Effects Abroad of Major Federal Actions'' of January 4, 1979 (44 FR 1957, January 9, 1979), the responsible agency official, in analyzing actions under his or her program, shall consider the environmental effects abroad, including whether the actions involve:

(1) Potential environmental effects on the global commons and areas outside the jurisdiction of any nation, e.g., oceans and the upper atmosphere.

(2) Potential environmental effects on a foreign nation not participating with or otherwise involved in an FDA activity.

(3) The export of products (or emissions) that in the United States are prohibited or strictly regulated because their effects on the environment create a serious public health risk.

(4) Potential environmental effects on natural and ecological resources of global importance designated under the Executive Order.

(b) Before deciding on any action falling into the categories specified in paragraph (a) of this section, the responsible agency official shall determine, in accordance with section 2–3 of the Executive Order, whether such actions may have a significant environmental effect abroad.

(c) If the responsible agency official determines that an action may have a significant environmental effect abroad, the responsible agency official shall determine, in accordance with section 2–4 (a) and (b) of the Executive Order, whether the subject action calls for:

(1) An EIS;

(2) A bilateral or multilateral environmental study; or

(3) A concise environmental review.

(d) In preparing environmental documents under this subpart, the responsible official shall:

(1) Determine, as provided in section 2–5 of the Executive Order, whether proposed actions are subject to the exemptions, exclusions, and modification in contents, timing, and availability of documents.

(2) Coordinate all communications with foreign governments concerning environmental agreements and other arrangements in implementing the Executive Order.

PART 26—MUTUAL RECOGNITION OF PHARMACEUTICAL GOOD MANUFACTURING PRACTICE REPORTS, MEDICAL DEVICE QUALITY SYSTEM AUDIT REPORTS, AND CERTAIN MEDICAL DEVICE PRODUCT EVALUATION REPORTS: UNITED STATES AND THE EUROPEAN COMMUNITY

Sec.
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AUTHORITY: 5 U.S.C. 552; 15 U.S.C. 1453, 1454, 1455; 18 U.S.C. 1905; 21 U.S.C. 321, 331, 351, 352, 355, 360, 360b, 360c, 360d, 360e, 360f, 360g, 360h, 360i, 360j, 360l, 360m, 371, 374, 381, 382, 383, 393; 42 U.S.C. 216, 241, 242l, 262, 264, 265.

SOURCE: 63 FR 60141, Nov. 6, 1998, unless otherwise noted.

§ 26.0 General.

This part substantially reflects relevant provisions of the framework agreement and its sectoral annexes on pharmaceutical good manufacturing practices (GMP's) and medical devices of the ''Agreement on Mutual Recognition Between the United States of America and the European Community'' (the MRA), signed at London May 18, 1998. For codification purposes, certain provisions of the MRA have been modified for use in this part. This modification is done for purposes of clarity only and shall not affect the text of the MRA concluded between the United States and the European Community (EC), or the rights and obligations of the United States or the EC under that agreement. Whereas the parties to the MRA are the United States and EC, this part is relevant only to the Food and Drug Administration's (FDA's) implementation of the MRA, including the sectoral annexes reflected in subparts A and B of this part. This part does not govern implementation of the MRA by the EC, which will implement the MRA in accordance with its internal procedures, nor does this part address implementation of the MRA by other concerned U.S. Federal agencies. For purposes of this part, the terms ''party'' or ''parties,'' where relevant to FDA's implementation of the MRA, should be considered as referring to FDA only. If the parties to the MRA subsequently amend or terminate the MRA, FDA will modify this part accordingly, using appropriate administrative procedures.

Subpart A—Specific Sector Provisions for Pharmaceutical Good Manufacturing Practices

§ 26.1 Definitions.

(a) *Enforcement* means action taken by an authority to protect the public from products of suspect quality, safety, and effectiveness or to assure that products are manufactured in compliance with appropriate laws, regulations, standards, and commitments made as part of the approval to market a product.

(b) *Equivalence* of the regulatory systems means that the systems are sufficiently comparable to assure that the process of inspection and the ensuing inspection reports will provide adequate information to determine whether respective statutory and regulatory requirements of the authorities have been fulfilled. Equivalence does not require that the respective regulatory systems have identical procedures.

(c) *Good Manufacturing Practices* (GMP's). [The United States has clarified its interpretation that under the MRA, paragraph (c)(1) of this section has to be understood as the U.S. definition and paragraph (c)(2) as the EC definition.]

(1) GMP's mean the requirements found in the legislations, regulations, and administrative provisions for methods to be used in, and the facilities or controls to be used for, the manufacturing, processing, packing, and/or holding of a drug to assure that such drug meets the requirements as to safety, and has the identity and strength, and meets the quality and purity characteristics that it purports or is represented to possess.

(2) GMP's are that part of quality assurance which ensures that products are consistently produced and controlled to quality standards. For the purpose of this subpart, GMP's include, therefore, the system whereby the manufacturer receives the specifications of the product and/or process from the marketing authorization/product authorization or license holder or applicant and ensures the product is made in compliance with its specifications (qualified person certification in the EC).

(d) *Inspection* means an onsite evaluation of a manufacturing facility to determine whether such manufacturing facility is operating in compliance with GMP's and/or commitments made as part of the approval to market a product.

(e) *Inspection report* means the written observations and GMP's compliance assessment completed by an authority listed in appendix B of this subpart.

(f) *Regulatory system* means the body of legal requirements for GMP's, inspections, and enforcements that ensure public health protection and legal authority to assure adherence to these requirements.

[63 FR 60141, Nov. 6, 1998; 64 FR 16348, Apr. 5, 1999]

§ 26.2 Purpose.

The provisions of this subpart govern the exchange between the parties and normal endorsement by the receiving regulatory authority of official good manufacturing practices (GMP's) inspection reports after a transitional period aimed at determination of the equivalence of the regulatory systems of the parties, which is the cornerstone of this subpart.

§ 26.3 Scope.

(a) The provisions of this subpart shall apply to pharmaceutical inspections carried out in the United States and Member States of the European Community (EC) before products are marketed (hereafter referred to as ''preapproval inspections'') as well as during their marketing (hereafter referred to as ''postapproval inspections'').

(b) Appendix A of this subpart names the laws, regulations, and administrative provisions governing these inspections and the good manufacturing practices (GMP's) requirements.

(c) Appendix B of this subpart lists the authorities participating in activities under this subpart.

(d) Sections 26.65, 26.66, 26.67, 26.68, 26.69, and 26.70 of subpart C of this part do not apply to this subpart.

§ 26.4 Product coverage.

(a) The provisions of this subpart will apply to medicinal products for human or animal use, intermediates and starting materials (as referred to in the European Community (EC)) and to drugs for human or animal use, biological products for human use, and active pharmaceutical ingredients (as referred to in the United States), only to the extent they are regulated by the authorities of both parties as listed in appendix B of this subpart.

(b) Human blood, human plasma, human tissues and organs, and veterinary immunologicals (under 9 CFR 101.2, ''veterinary immunologicals'' are referred to as ''veterinary biologicals'') are excluded from the scope of this subpart. Human plasma derivatives (such as immunoglobulins and albumin), investigational medicinal products/new drugs, human radiopharmaceuticals, and medicinal gases are also excluded during the transition phase; their situation will be reconsidered at the end of the transition period. Products regulated by the Food and Drug Administration's Center for Biologics Evaluation and Research or Center for Drug Evaluation and Research as devices are not covered under this subpart.

(c) Appendix C of this subpart contains an indicative list of products covered by this subpart.

[63 FR 60141, Nov. 6, 1998, as amended at 70 FR 14980, Mar. 24, 2005]

§ 26.5 Length of transition period.

A 3-year transition period will start immediately after the effective date described in § 26.80(a).

§ 26.6 Equivalence assessment.

(a) The criteria to be used by the parties to assess equivalence are listed in appendix D of this subpart. Information pertaining to the criteria under European Community (EC) competence will be provided by the EC.

(b) The authorities of the parties will establish and communicate to each other their draft programs for assessing the equivalence of the respective regulatory systems in terms of quality assurance of the products and consumer protection. These programs will be carried out, as deemed necessary by the regulatory authorities, for post- and preapproval inspections and for various product classes or processes.

(c) The equivalence assessment shall include information exchanges (including inspection reports), joint training, and joint inspections for the purpose of assessing regulatory systems and the authorities' capabilities. In conducting the equivalence assessment, the parties will ensure that efforts are made to save resources.

(d) Equivalence assessment for authorities added to appendix B of this subpart after the effective date described in § 26.80(a) will be conducted as described in this subpart, as soon as practicable.

§ 26.7 Participation in the equivalence assessment and determination.

The authorities listed in appendix B of this subpart will actively participate in these programs to build a sufficient body of evidence for their equivalence determination. Both parties will exercise good faith efforts to complete equivalence assessment as expeditiously as possible to the extent the resources of the authorities allow.

§ 26.8 Other transition activities.

As soon as possible, the authorities will jointly determine the essential information which must be present in inspection reports and will cooperate to develop mutually agreed inspection report format(s).

§ 26.9 Equivalence determination.

(a) Equivalence is established by having in place regulatory systems covering the criteria referred to in appendix D of this subpart, and a demonstrated pattern of consistent performance in accordance with these criteria. A list of authorities determined as equivalent shall be agreed to by the Joint Sectoral Committee at the end of the transition period, with reference to any limitation in terms of inspection type (e.g., postapproval or preapproval) or product classes or processes.

(b) The parties will document insufficient evidence of equivalence, lack of opportunity to assess equivalence or a determination of nonequivalence, in sufficient detail to allow the authority being assessed to know how to attain equivalence.

§ 26.10 Regulatory authorities not listed as currently equivalent.

Authorities not currently listed as equivalent, or not equivalent for certain types of inspections, product classes or processes may apply for reconsideration of their status once the necessary corrective measures have been taken or additional experience is gained.

§ 26.11 Start of operational period.

(a) The operational period shall start at the end of the transition period and its provisions apply to inspection reports generated by authorities listed as equivalent for the inspections performed in their territory.

(b) In addition, when an authority is not listed as equivalent based on adequate experience gained during the transition period, the Food and Drug Administration (FDA) will accept for normal endorsement (as provided in § 26.12) inspection reports generated as a result of inspections conducted jointly by that authority on its territory and another authority listed as equivalent, provided that the authority of the Member State in which the inspection is performed can guarantee enforcement of the findings of the inspection report and require that corrective measures be taken when necessary. FDA has the option to participate in these inspections, and based on experience gained during the transition period, the parties will agree on procedures for exercising this option.

(c) In the European Community (EC), the qualified person will be relieved of responsibility for carrying the controls laid down in Article 22 paragraph 1(b) of Council Directive 75/319/EEC (see appendix A of this subpart) provided that these controls have been carried out in the United States and that each batch/lot is accompanied by a batch certificate (in accordance with the World Health Organization Certification Scheme on the Quality of Medicinal Products) issued by the manufacturer certifying that the product complies with requirements of the marketing authorization and signed by the person responsible for releasing the batch/lot.

§ 26.12 Nature of recognition of inspection reports.

(a) Inspection reports (containing information as established under § 26.8), including a good manufacturing practice (GMP) compliance assessment, prepared by authorities listed as equivalent, will be provided to the authority of the importing party. Based on the determination of equivalence in light of the experience gained, these inspection reports will normally be endorsed by the authority of the importing party, except under specific and delineated circumstances. Examples of such circumstances include indications of material inconsistencies or inadequacies in an inspection report, quality defects identified in the postmarket surveillance or other specific evidence of serious concern in relation to product quality or consumer safety. In such cases, the authority of the importing party may request clarification from the authority of the exporting party which may lead to a request for reinspection. The authorities will endeavor to respond to requests for clarification in a timely manner.

(b) Where divergence is not clarified in this process, an authority of the importing country may carry out an inspection of the production facility.

§ 26.13 Transmission of postapproval inspection reports.

Postapproval good manufacturing practice (GMP) inspection reports concerning products covered by this subpart will be transmitted to the authority of the importing country within 60-calendar days of the request. Should a new inspection be needed, the inspection report will be transmitted within 90-calendar days of the request.

§ 26.14 Transmission of preapproval inspection reports.

(a) A preliminary notification that an inspection may have to take place will be made as soon as possible.

(b) Within 15-calendar days, the relevant authority will acknowledge receipt of the request and confirm its ability to carry out the inspection. In the European Community (EC), requests will be sent directly to the relevant authority, with a copy to the European Agency for the Evaluation of Medicinal Products (EMEA). If the authority receiving the request cannot carry out the inspection as requested, the requesting authority shall have the right to conduct the inspection.

(c) Reports of preapproval inspections will be sent within 45-calendar days of the request that transmitted the appropriate information and detailed the precise issues to be addressed during the inspection. A shorter time may be necessary in exceptional cases and these will be described in the request.

§ 26.15 Monitoring continued equivalence.

Monitoring activities for the purpose of maintaining equivalence shall include review of the exchange of inspection reports and their quality and timeliness; performance of a limited number of joint inspections; and the conduct of common training sessions.

§ 26.16 Suspension.

(a) Each party has the right to contest the equivalence of a regulatory authority. This right will be exercised in an objective and reasoned manner in writing to the other party.

(b) The issue shall be discussed in the Joint Sectoral Committee promptly upon such notification. Where the Joint Sectoral Committee determines that verification of equivalence is required, it may be carried out jointly by the parties in a timely manner, under § 26.6.

(c) Efforts will be made by the Joint Sectoral Committee to reach unanimous consent on the appropriate action. If agreement to suspend is reached in the Joint Sectoral Committee, an authority may be suspended immediately thereafter. If no agreement is reached in the Joint Sectoral Committee, the matter is referred to the Joint Committee as described in § 26.73. If no unanimous consent is reached within 30 days after such notification, the contested authority will be suspended.

(d) Upon the suspension of authority previously listed as equivalent, a party

is no longer obligated to normally endorse the inspection reports of the suspended authority. A party shall continue to normally endorse the inspection reports of that authority prior to suspension, unless the authority of the receiving party decides otherwise based on health or safety considerations. The suspension will remain in effect until unanimous consent has been reached by the parties on the future status of that authority.

§ 26.17 Role and composition of the Joint Sectoral Committee.

(a) A Joint Sectoral Committee is set up to monitor the activities under both the transitional and operational phases of this subpart.

(b) The Joint Sectoral Committee will be cochaired by a representative of the Food and Drug Administration (FDA) for the United States and a representative of the European Community (EC) who each will have one vote. Decisions will be taken by unanimous consent.

(c) The Joint Sectoral Committee's functions will include:

(1) Making a joint assessment, which must be agreed by both parties, of the equivalence of the respective authorities;

(2) Developing and maintaining the list of equivalent authorities, including any limitation in terms of inspecting type or products, and communicating the list to all authorities and the Joint Committee;

(3) Providing a forum to discuss issues relating to this subpart, including concerns that an authority may be no longer equivalent and opportunity to review product coverage; and

(4) Consideration of the issue of suspension.

(d) The Joint Sectoral Committee shall meet at the request of either party and, unless the cochairs otherwise agree, at least once each year. The Joint Committee will be kept informed of the agenda and conclusions of meetings of the Joint Sectoral Committee.

§ 26.18 Regulatory collaboration.

(a) The parties and authorities shall inform and consult one another, as permitted by law, on proposals to introduce new controls or to change existing technical regulations or inspection procedures and to provide the opportunity to comment on such proposals.

(b) The parties shall notify each other in writing of any changes to appendix B of this subpart.

§ 26.19 Information relating to quality aspects.

The authorities will establish an appropriate means of exchanging information on any confirmed problem reports, corrective actions, recalls, rejected import consignments, and other regulatory and enforcement problems for products subject to this subpart.

§ 26.20 Alert system.

(a) The details of an alert system will be developed during the transitional period. The system will be maintained in place at all times. Elements to be considered in developing such a system are described in appendix E of this subpart.

(b) Contact points will be agreed between both parties to permit authorities to be made aware with the appropriate speed in case of quality defect, recalls, counterfeiting, and other problems concerning quality, which could necessitate additional controls or suspension of the distribution of the product.

§ 26.21 Safeguard clause.

Each party recognizes that the importing country has a right to fulfill its legal responsibilities by taking actions necessary to ensure the protection of human and animal health at the level of protection it deems appropriate. This includes the suspension of the distribution, product detention at the border of the importing country, withdrawal of the batches and any request for additional information or inspection as provided in § 26.12.

APPENDIX A TO SUBPART A OF PART 26—LIST OF APPLICABLE LAWS, REGULATIONS, AND ADMINISTRATIVE PROVISIONS

1. For the European Community (EC):

[Copies of EC documents may be obtained from the European Document Research, 1100 17th St. NW., suite 301, Washington, DC 20036.

EC documents may be viewed on the European Commission Pharmaceuticals Units web site at *http://dg3.eudra.org*.]

Council Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by law, regulation, or administrative action relating to proprietary medicinal products as extended, widened, and amended.

Council Directive 75/319/EEC of 20 May 1975 on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products as extended, widened and amended.

Council Directive 81/851/EEC of 28 September 1981 on the approximation of the laws of the Member States relating to veterinary medicinal products, as widened and amended.

Commission Directive 91/356/EEC of 13 June 1991 laying down the principles and guidelines of good manufacturing practice for medicinal products for human use.

Commission Directive 91/412/EEC of 23 July 1991 laying down the principles and guidelines of good manufacturing practice for veterinary medicinal products.

Council Regulation EEC No 2309/93 of 22 July 1993 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products.

Council Directive 92/25/EEC of 31 March 1992 on the wholesale distribution of medicinal products for human use.

Guide to Good Distribution Practice (94/C 63/03).

Current version of the Guide to Good Manufacturing Practice, Rules Governing Medicinal Products in the European Community, Volume IV.

2. For the United States:

[Copies of FDA documents may be obtained from the Government Printing Office, 1510 H St. NW., Washington, DC 20005. FDA documents, except the FDA Compliance Program Guidance Manual, may be viewed on FDA's Internet web site at *http://www.fda.gov*.]

Relevant sections of the United States Federal Food, Drug, and Cosmetic Act and the United States Public Health Service Act.

Relevant sections of Title 21, United States Code of Federal Regulations (CFR) Parts 1–99, Parts 200–299, Parts 500–599, and Parts 600–799.

Relevant sections of the FDA Investigations Operations Manual, the FDA Regulatory Procedures Manual, the FDA Compliance Policy Guidance Manual, the FDA Compliance Program Guidance Manual, and other FDA guidances.

APPENDIX B TO SUBPART A OF PART 26—LIST OF AUTHORITIES

1. For the United States: In the United States, the regulatory authority is the Food and Drug Administration.

2. For the European Community: In the European Community, the regulatory authorities are the following:

Belgium: Inspection générale de la Pharmacie, Algemene Farmaceutische Inspectie.

Denmark: Laegemiddelstyrelsen.

Germany: Bundesministerium für Gesundheit for immunologicals: Paul-Ehrlich-Institut, Federal Agency for Sera and Vaccines.

Greece: Εθνικως Ωργανισμως Φαρμακων, Ministry of Health and Welfare, National Drug Organization (E.O.F).

Spain: For medicinal products for human use: Ministerio de Sanidad y Consumo, Subdirección General de Control Farmacéutico. For medicinal products for veterinary use: Ministerio de Agricultura, Pesca y Alimentación (MAPA), Dirección General de la Producción Agraria.

France: For medicinal products for human use: Agence du Médicament. For veterinary medicinal products: Agence Nationale du Médicament Vétérinaire.

Ireland: Irish Medicines Board.

Italy: For medicinal products for human use: Ministero della Sanità, Dipartimento Farmaci e Farmacovigilanza. For medicinal products for veterinary use: Ministero della Sanità, Dipartimento alimenti e nutrizione e sanità pubblica veterinaria-Div. IX.

Luxembourg: Division de la Pharmacie et des Médicaments.

Netherlands: Staat der Nederlanden.

Austria: Bundesministerium für Arbeit, Gesundheit und Soziales.

Portugal: Instituto da Farmácia e do Medicamento (INFARMED).

Finland: Lääkelaitos/Läkemedelsverket (National Agency for Medicines).

Sweden: Läkemedelsverket-Medical Products Agency.

United Kingdom: For human use and veterinary (non-immunologicals): Medicines Control Agency. For veterinary immunologicals: Veterinary Medicines Directorate.

European Community: Commission of the European Communities. European Agency for the Evaluation of Medicinal Products (EMEA).

APPENDIX C TO SUBPART A OF PART 26—INDICATIVE LIST OF PRODUCTS COVERED BY SUBPART A

Recognizing that precise definition of medicinal products and drugs are to be found in

the legislation referred to above, an indicative list of products covered by this arrangement is given below:

—human medicinal products including prescription and nonprescription drugs;
—human biologicals including vaccines, and immunologicals;
—veterinary pharmaceuticals, including prescription and nonprescription drugs, with the exclusion of veterinary immunologicals (Under 9 CFR 101.2 ''veterinary immunologicals'' are referred to as ''veterinary biologicals'');
—premixes for the preparation of veterinary medicated feeds (EC), Type A medicated articles for the preparation of veterinary medicated feeds (United States);
—intermediate products and active pharmaceutical ingredients or bulk pharmaceuticals (United States)/starting materials (EC).

APPENDIX D TO SUBPART A OF PART 26—CRITERIA FOR ASSESSING EQUIVALENCE FOR POST- AND PREAPPROVAL

I. Legal/Regulatory authority and structures and procedures providing for post- and preapproval:

A. Appropriate statutory mandate and jurisdiction.
B. Ability to issue and update binding requirements on GMP's and guidance documents.
C. Authority to make inspections, review and copy documents, and to take samples and collect other evidence.
D. Ability to enforce requirements and to remove products found in violation of such requirements from the market.
E. Substantive current good manufacturing requirements.
F. Accountability of the regulatory authority.
G. Inventory of current products and manufacturers.
H. System for maintaining or accessing inspection reports, samples and other analytical data, and other firm/product information relating to matters covered by subpart A of this part.

II. Mechanisms in place to assure appropriate professional standards and avoidance of conflicts of interest.

III. Administration of the regulatory authority:

A. Standards of education/qualification and training.
B. Effective quality assurance systems measures to ensure adequate job performance.
C. Appropriate staffing and resources to enforce laws and regulations.

IV. Conduct of inspections:

A. Adequate preinspection preparation, including appropriate expertise of investigator/team, review of firm/product and databases, and availability of appropriate inspection equipment.
B. Adequate conduct of inspection, including statutory access to facilities, effective response to refusals, depth and competence of evaluation of operations, systems and documentation; collection of evidence; appropriate duration of inspection and completeness of written report of observations to firm management.
C. Adequate postinspection activities, including completeness of inspectors' report, inspection report review where appropriate, and conduct of followup inspections and other activities where appropriate, assurance of preservation and retrieval of records.

V. Execution of regulatory enforcement actions to achieve corrections, designed to prevent future violations, and to remove products found in violation of requirements from the market.

VI. Effective use of surveillance systems:

A. Sampling and analysis.
B. Recall monitoring.
C. Product defect reporting system.
D. Routine surveillance inspections.
E. Verification of approved manufacturing process changes to marketing authorizations/approved applications.

VII. Additional specific criteria for preapproval inspections:

A. Satisfactory demonstration through a jointly developed and administered training program and joint inspections to assess the regulatory authorities' capabilities.
B. Preinspection preparation includes the review of appropriate records, including site plans and drug master file or similar documentation to enable adequate inspections.
C. Ability to verify chemistry, manufacturing, and control data supporting an application is authentic and complete.
D. Ability to assess and evaluate research and development data as scientifically sound, especially transfer technology of pilot, scale up and full scale production batches.
E. Ability to verify conformity of the onsite processes and procedures with those described in the application.
F. Review and evaluate equipment installation, operational and performance qualification data, and evaluate test method validation.

APPENDIX E TO SUBPART A OF PART 26—ELEMENTS TO BE CONSIDERED IN DEVELOPING A TWO-WAY ALERT SYSTEM

1. Documentation

—Definition of a crisis/emergency and under what circumstances an alert is required
—Standard Operating Procedures (SOP's)
—Mechanism of health hazards evaluation and classification
—Language of communication and transmission of information

2. Crisis Management System

—Crisis analysis and communication mechanisms
—Establishment of contact points
—Reporting mechanisms

3. Enforcement Procedures

—Followup mechanisms
—Corrective action procedures

4. Quality Assurance System

—Pharmacovigilance programme
—Surveillance/monitoring of implementation of corrective action

5. Contact Points

For the purpose of subpart A of this part, the contact points for the alert system will be:

A. For the European Community:

the Executive Director of the European Agency for the Evaluation of Medicinal Products, 7, Westferry Circus, Canary Wharf, UK - London E14 4HB, England. Telephone 44–171–418 8400, Fax 418–8416.

B. For the United States :

Biologics:Food and Drug Administration, Center for Biologics Evaluation and Research, Document Control Center, 10903 New Hampshire Ave., Bldg. 71, Rm. G112, Silver Spring, MD 20993–0002, telephone: 240–402–9153, FAX: 301–595–1302.
Human Drugs: Director, Office of Compliance, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, phone: 301–796–3100, fax: 301–847–8747.
Veterinary Drugs: Director, Office of Surveillance and Compliance (HFV–200), MPN II, 7500 Standish Pl., Rockville, MD 20855–2773, phone: 301–827–6644, fax: 301–594–1807.

[63 FR 60141, Nov. 6, 1998, as amended at 69 FR 48775, Aug. 11, 2004; 74 FR 13112, Mar. 26, 2009; 80 FR 18090, Apr. 3, 2015]

Subpart B—Specific Sector Provisions for Medical Devices

§ 26.31 Purpose.

(a) The purpose of this subpart is to specify the conditions under which a party will accept the results of quality system-related evaluations and inspections and premarket evaluations of the other party with regard to medical devices as conducted by listed conformity assessment bodies (CAB's) and to provide for other related cooperative activities.

(b) This subpart is intended to evolve as programs and policies of the parties evolve. The parties will review this subpart periodically, in order to assess progress and identify potential enhancements to this subpart as Food and Drug Administration (FDA) and European Community (EC) policies evolve over time.

§ 26.32 Scope.

(a) The provisions of this subpart shall apply to the exchange and, where appropriate, endorsement of the following types of reports from conformity assessment bodies (CAB's) assessed to be equivalent:

(1) Under the U.S. system, surveillance/postmarket and initial/preapproval inspection reports;

(2) Under the U.S. system, premarket (510(k)) product evaluation reports;

(3) Under the European Community (EC) system, quality system evaluation reports; and

(4) Under the EC system, EC type examination and verification reports.

(b) Appendix A of this subpart names the legislation, regulations, and related procedures under which:

(1) Products are regulated as medical devices by each party;

(2) CAB's are designated and confirmed; and

(3) These reports are prepared.

(c) For purposes of this subpart, equivalence means that: CAB's in the EC are capable of conducting product and quality systems evaluations against U.S. regulatory requirements in a manner equivalent to those conducted by FDA; and CAB's in the United States are capable of conducting product and quality systems

evaluations against EC regulatory requirements in a manner equivalent to those conducted by EC CAB's.

§ 26.33 Product coverage.

(a) There are three components to this subpart each covering a discrete range of products:

(1) *Quality System Evaluations.* U.S.-type surveillance/postmarket and initial/preapproval inspection reports and European Community (EC)-type quality system evaluation reports will be exchanged with regard to all products regulated under both U.S. and EC law as medical devices.

(2) *Product Evaluation.* U.S.-type premarket (510(k)) product evaluation reports and EC-type-testing reports will be exchanged only with regard to those products classified under the U.S. system as Class I/Class II-Tier 2 medical devices which are listed in appendix B of this subpart.

(3) *Postmarket Vigilance Reports.* Postmarket vigilance reports will be exchanged with regard to all products regulated under both U.S. and EC law as medical devices.

(b) Additional products and procedures may be made subject to this subpart by agreement of the parties.

§ 26.34 Regulatory authorities.

The regulatory authorities shall have the responsibility of implementing the provisions of this subpart, including the designation and monitoring of conformity assessment bodies (CAB's). Regulatory authorities will be specified in appendix C of this subpart. Each party will promptly notify the other party in writing of any change in the regulatory authority for a country.

§ 26.35 Length and purpose of transition period.

There will be a 3-year transition period immediately following the date described in § 26.80(a). During the transition period, the parties will engage in confidence-building activities for the purpose of obtaining sufficient evidence to make determinations concerning the equivalence of conformity assessment bodies (CAB's) of the other party with respect to the ability to perform quality system and product evaluations or other reviews resulting in reports to be exchanged under this subpart.

§ 26.36 Listing of CAB's.

Each party shall designate conformity assessment bodies (CAB's) to participate in confidence building activities by transmitting to the other party a list of CAB's which meet the criteria for technical competence and independence, as identified in appendix A of this subpart. The list shall be accompanied by supporting evidence. Designated CAB's will be listed in appendix D of this subpart for participation in the confidence building activities once confirmed by the importing party. Nonconfirmation would have to be justified based on documented evidence.

§ 26.37 Confidence building activities.

(a) At the beginning of the transitional period, the Joint Sectoral Group will establish a joint confidence building program calculated to provide sufficient evidence of the capabilities of the designated conformity assessment bodies (CAB's) to perform quality system or product evaluations to the specifications of the parties.

(b) The joint confidence building program should include the following actions and activities:

(1) Seminars designed to inform the parties and CAB's about each party's regulatory system, procedures, and requirements;

(2) Workshops designed to provide the parties with information regarding requirements and procedures for the designation and surveillance of CAB's;

(3) Exchange of information about reports prepared during the transition period;

(4) Joint training exercises; and

(5) Observed inspections.

(c) During the transition period, any significant problem that is identified with a CAB may be the subject of cooperative activities, as resources allow and as agreed to by the regulatory authorities, aimed at resolving the problem.

(d) Both parties will exercise good faith efforts to complete the confidence building activities as expeditiously as possible to the extent that the resources of the parties allow.

(e) Both the parties will each prepare annual progress reports which will describe the confidence building activities undertaken during each year of the transition period. The form and content of the reports will be determined by the parties through the Joint Sectoral Committee.

§ 26.38 Other transition period activities.

(a) During the transition period, the parties will jointly determine the necessary information which must be present in quality system and product evaluation reports.

(b) The parties will jointly develop a notification and alert system to be used in case of defects, recalls, and other problems concerning product quality that could necessitate additional actions (e.g., inspections by the parties of the importing country) or suspension of the distribution of the product.

§ 26.39 Equivalence assessment.

(a) In the final 6 months of the transition period, the parties shall proceed to a joint assessment of the equivalence of the conformity assessment bodies (CAB's) that participated in the confidence building activities. CAB's will be determined to be equivalent provided they have demonstrated proficiency through the submission of a sufficient number of adequate reports. CAB's may be determined to be equivalent with regard to the ability to perform any type of quality system or product evaluation covered by this subpart and with regard to any type of product covered by this subpart. The parties shall develop a list contained in appendix E of this subpart of CAB's determined to be equivalent, which shall contain a full explanation of the scope of the equivalency determination, including any appropriate limitations, with regard to performing any type of quality system or product evaluation.

(b) The parties shall allow CAB's not listed for participation in this subpart, or listed for participation only as to certain types of evaluations, to apply for participation in this subpart once the necessary measures have been taken or sufficient experience has been gained, in accordance with § 26.46.

(c) Decisions concerning the equivalence of CAB's must be agreed to by both parties.

§ 26.40 Start of the operational period.

(a) The operational period will start at the end of the transition period after the parties have developed the list of conformity assessment bodies (CAB's) found to be equivalent. The provisions of §§ 26.40, 26.41, 26.42, 26.43, 26.44, 26.45, and 26.46 will apply only with regard to listed CAB's and only to the extent of any specifications and limitations contained on the list with regard to a CAB.

(b) The operational period will apply to quality system evaluation reports and product evaluation reports generated by CAB's listed in accordance with this subpart for the evaluations performed in the respective territories of the parties, except if the parties agree otherwise.

§ 26.41 Exchange and endorsement of quality system evaluation reports.

(a) Listed European Community (EC) conformity assessment bodies (CAB's) will provide FDA with reports of quality system evaluations, as follows:

(1) For preapproval quality system evaluations, EC CAB's will provide full reports; and

(2) For surveillance quality system evaluations, EC CAB's will provide abbreviated reports.

(b) Listed U.S. CAB's will provide to the EC Notified Body of the manufacturer's choice:

(1) Full reports of initial quality system evaluations;

(2) Abbreviated reports of quality systems surveillance audits.

(c) If the abbreviated reports do not provide sufficient information, the importing party may request additional clarification from the CAB.

(d) Based on the determination of equivalence in light of the experience gained, the quality system evaluation reports prepared by the CAB's listed as equivalent will normally be endorsed by the importing party, except under specific and delineated circumstances. Examples of such circumstances include indications of material inconsistencies or inadequacies in a report, quality defects identified in

postmarket surveillance or other specific evidence of serious concern in relation to product quality or consumer safety. In such cases, the importing party may request clarification from the exporting party which may lead to a request for reinspection. The parties will endeavor to respond to requests for clarification in a timely manner. Where divergence is not clarified in this process, the importing party may carry out the quality system evaluation.

§ 26.42 Exchange and endorsement of product evaluation reports.

(a) European Community (EC) conformity assessment bodies (CAB's) listed for this purpose will, subject to the specifications and limitations on the list, provide to FDA 510(k) premarket notification assessment reports prepared to U.S. medical device requirements.

(b) U.S. CAB's will, subject to the specifications and limitations on the list, provide to the EC Notified Body of the manufacturer's choice, type examination, and verification reports prepared to EC medical device requirements.

(c) Based on the determination of equivalence in light of the experience gained, the product evaluation reports prepared by the CAB's listed as equivalent will normally be endorsed by the importing party, except under specific and delineated circumstances. Examples of such circumstances include indications of material inconsistencies, inadequacies, or incompleteness in a product evaluation report, or other specific evidence of serious concern in relation to product safety, performance, or quality. In such cases, the importing party may request clarification from the exporting party which may lead to a request for a reevaluation. The parties will endeavor to respond to requests for clarification in a timely manner. Endorsement remains the responsibility of the importing party.

§ 26.43 Transmission of quality system evaluation reports.

Quality system evaluation reports covered by § 26.41 concerning products covered by this subpart shall be transmitted to the importing party within 60-calendar days of a request by the importing party. Should a new inspection be requested, the time period shall be extended by an additional 30-calendar days. A party may request a new inspection, for cause, identified to the other party. If the exporting party cannot perform an inspection within a specified period of time, the importing party may perform an inspection on its own.

§ 26.44 Transmission of product evaluation reports.

Transmission of product evaluation reports will take place according to the importing party's specified procedures.

§ 26.45 Monitoring continued equivalence.

Monitoring activities will be carried out in accordance with § 26.69.

§ 26.46 Listing of additional CAB's.

(a) During the operational period, additional conformity assessment bodies (CAB's) will be considered for equivalence using the procedures and criteria described in §§ 26.36, 26.37, and 26.39, taking into account the level of confidence gained in the overall regulatory system of the other party.

(b) Once a designating authority considers that such CAB's, having undergone the procedures of §§ 26.36, 26.37, and 26.39, may be determined to be equivalent, it will then designate those bodies on an annual basis. Such procedures satisfy the procedures of § 26.66(a) and (b).

(c) Following such annual designations, the procedures for confirmation of CAB's under § 26.66(c) and (d) shall apply.

§ 26.47 Role and composition of the Joint Sectoral Committee.

(a) The Joint Sectoral Committee for this subpart is set up to monitor the activities under both the transitional and operational phases of this subpart.

(b) The Joint Sectoral Committee will be cochaired by a representative of the Food and Drug Administration (FDA) for the United States and a representative of the European Community (EC) who will each have one vote. Decisions will be taken by unanimous consent.

(c) The Joint Sectoral Committee's functions will include:

(1) Making a joint assessment of the equivalence of conformity assessment bodies (CAB's);

(2) Developing and maintaining the list of equivalent CAB's, including any limitation in terms of their scope of activities and communicating the list to all authorities and the Joint Committee described in subpart C of this part;

(3) Providing a forum to discuss issues relating to this subpart, including concerns that a CAB may no longer be equivalent and opportunity to review product coverage; and

(4) Consideration of the issue of suspension.

§ 26.48 Harmonization.

During both the transitional and operational phases of this subpart, both parties intend to continue to participate in the activities of the Global Harmonization Task Force (GHTF) and utilize the results of those activities to the extent possible. Such participation involves developing and reviewing documents developed by the GHTF and jointly determining whether they are applicable to the implementation of this subpart.

§ 26.49 Regulatory cooperation.

(a) The parties and authorities shall inform and consult with one another, as permitted by law, of proposals to introduce new controls or to change existing technical regulations or inspection procedures and to provide the opportunity to comment on such proposals.

(b) The parties shall notify each other in writing of any changes to appendix A of this subpart.

§ 26.50 Alert system and exchange of postmarket vigilance reports.

(a) An alert system will be set up during the transition period and maintained thereafter by which the parties will notify each other when there is an immediate danger to public health. Elements of such a system will be described in an appendix F of this subpart. As part of that system, each party shall notify the other party of any confirmed problem reports, corrective actions, or recalls. These reports are regarded as part of ongoing investigations.

(b) Contact points will be agreed between both parties to permit authorities to be made aware with the appropriate speed in case of quality defect, batch recalls, counterfeiting and other problems concerning quality, which could necessitate additional controls or suspension of the distribution of the product.

APPENDIX A TO SUBPART B OF PART 26—RELEVANT LEGISLATION, REGULATIONS, AND PROCEDURES.

1. For the European Community (EC) the following legislation applies to § 26.42(a) of this subpart:

[Copies of EC documents may be obtained from the European Document Research, 1100 17th St. NW., suite 301, Washington, DC 20036.]

a. Council Directive 90/385/EEC of 20 June 1990 on active implantable medical devices

OJ No. L 189, 20.7. 1990, p. 17. Conformity assessment procedures.

Annex 2 (with the exception of section 4)

Annex 4

Annex 5

b. Council Directive 93/42/EEC of 14 June 1993 on Medical Devices OJ No. L 169,12.7.1993, p.1. Conformity assessment procedures.

Annex 2 (with the exception of section 4)

Annex 3

Annex 4

Annex 5

Annex 6

2. For the United States, the following legislation applies to § 26.32(a):

[Copies of FDA documents may be obtained from the Government Printing Office, 1510 H St. NW., Washington, DC 20005. FDA documents may be viewed on FDA's Internet web site at *http://www.fda.gov*.]

a. The Federal Food, Drug and Cosmetic Act, 21 U.S.C. 321 *et seq*.

b. The Public Health Service Act, 42 U.S.C. 201 *et seq*.

c. Regulations of the United States Food and Drug Administration found at 21 CFR, in particular, Parts 800 to 1299.

d. Medical Devices; Third Party Review of Selected Premarket Notifications; Pilot Program, 61 FR 14789–14796 (April 3, 1996).

e. Draft Guidance Document on Accredited Persons Program, 63 FR 28392 (May 22, 1998).

f. Draft Guidance for Staff, Industry and Third Parties, Third Party Programs under the Sectoral Annex on Medical Devices to the Agreement on Mutual Recognition Between the United States of America and the

European Community (MRA), 63 FR 36240 (July 2, 1998).

g. Guidance Document on Use of Standards, 63 FR 9561 (February 25, 1998).

APPENDIX B TO SUBPART B OF PART 26—SCOPE OF PRODUCT COVERAGE

1. Initial Coverage of the Transition Period

Upon entry into force of this subpart as described in §26.80 (it is understood that the date of entry into force will not occur prior to June 1, 1998, unless the parties decide otherwise), products qualifying for the transitional arrangements under this subpart include:

a. All Class I products requiring premarket evaluations in the United States—see Table 1.

b. Those Class II products listed in Table 2.

2. During the Transition Period

The parties will jointly identify additional product groups, including their related accessories, in line with their respective priorities as follows:

a. Those for which review may be based primarily on written guidance which the parties will use their best efforts to prepare expeditiously; and

b. Those for which review may be based primarily on international standards, in order for the parties to gain the requisite experience.

The corresponding additional product lists will be phased in on an annual basis. The parties may consult with industry and other interested parties in determining which products will be added.

3. Commencement of the Operational Period

a. At the commencement of the operational period, product coverage shall extend to all Class I/II products covered during the transition period.

b. FDA will expand the program to categories of Class II devices as is consistent with the results of the pilot, and with FDA's ability to write guidance documents if the device pilot for the third party review of medical devices is successful. The MRA will cover to the maximum extent feasible all Class II devices listed in Table 3 for which FDA-accredited third party review is available in the United States.

4. Unless explicitly included by joint decision of the parties, this part does not cover any U.S. Class II-tier 3 or any Class III product under either system.

[The lists of medical devices included in these tables are subject to change as a result of the Food and Drug Administration Modernization Act of 1997.]

TABLE 1—CLASS I PRODUCTS REQUIRING PREMARKET EVALUATIONS IN THE UNITED STATES, INCLUDED IN SCOPE OF PRODUCT COVERAGE AT BEGINNING OF TRANSITION PERIOD [1]

21 CFR Section No.	Regulation Name Product Code—Device Name
Anesthesiology Panel (21 CFR part 868)	
868.1910	Esophageal Stethoscope BZW—Stethoscope, Esophageal
868.5620	Breathing Mouthpiece BYP—Mouthpiece, Breathing
868.5640	Medicinal Nonventilatory Nebulizer (Atomizer) CCQ—Nebulizer, Medicinal, Nonventilatory (Atomizer)
868.5675	Rebreathing Device BYW—Device, Rebreathing
868.5700	Nonpowered Oxygen Tent FOG—Hood, Oxygen, Infant BYL—Tent, Oxygen
868.6810	Tracheobronchial Suction Catheter BSY—Catheters, Suction, Tracheobronchial
Cardiovascular Panel	
(None).	
Dental Panel (21 CFR part 872)	
872.3400	Karaya and Sodium Borate With or Without Acacia Denture Adhesive KOM—Adhesive, Denture, Acacia and Karaya With Sodium Borate
872.3700	Dental Mercury (U.S.P.) ELY—Mercury
872.4200	Dental Handpiece and Accessories EBW—Controller, Food, Handpiece and Cord EFB—Handpiece, Air-Powered, Dental EFA—Handpiece, Belt and/or Gear Driven, Dental EGS—Handpiece, Contra- and Right-Angle Attachment, Dental EKX—Handpiece, Direct Drive, AC-Powered EKY—Handpiece, Water-Powered
872.6640	Dental Operative Unit and Accessories

TABLE 1—CLASS I PRODUCTS REQUIRING PREMARKET EVALUATIONS IN THE UNITED STATES, INCLUDED IN SCOPE OF PRODUCT COVERAGE AT BEGINNING OF TRANSITION PERIOD [1]—Continued

21 CFR Section No.	Regulation Name
	Product Code—Device Name
	EIA—Unit, Operative Dental
Ear, Nose, and Throat Panel (21 CFR Part 874)	
874.1070	Short Increment Sensitivity Index (SISI) Adapter
	ETR—Adapter, Short Increment Sensitivity Index (SISI)
874.1500	Gustometer
	ETM—Gustometer
874.1800	Air or Water Caloric Stimulator
	KHH—Stimulator, Caloric-Air
	ETP—Stimulator, Caloric-Water
874.1925	Toynbee Diagnostic Tube
	ETK—Tube, Toynbee Diagnostic
874.3300	Hearing Aid
	LRB—Face Plate Hearing-Aid
	ESD—Hearing-aid, Air-Conduction
874.4100	Epistaxis Balloon
	EMX—Balloon, Epistaxis
874.5300	ENT Examination and Treatment Unit
	ETF—Unit, Examining/Treatment, ENT
874.5550	Powered Nasal Irrigator
	KMA—Irrigator, Powered Nasal
874.5840	Antistammering Device
	KTH—Device, Anti-Stammering
Gastroenterology—Urology Panel (21 CFR Part 876)	
876.5160	Urological Clamp for Males
	FHA—Clamp, Penile
876.5210	Enema Kit
	FCE—Kit, Enema, (for Cleaning Purpose)
876.5250	Urine Collector and Accessories
	FAQ—Bag, Urine Collection, Leg, for External Use
General Hospital Panel (21 CFR Part 880)	
880.5270	Neonatal Eye Pad
	FOK—Pad, Neonatal Eye
880.5420	Pressure Infusor for an I.V. Bag
	KZD—Infusor, Pressure, for I.V. Bags
880.5680	Pediatric Position Holder
	FRP—Holder, Infant Position
880.6250	Patient Examination Glove
	LZB—Finger Cot
	FMC—Glove, Patient Examination
	LYY—Glove, Patient Examination, Latex
	LZA—Glove, Patient Examination, Poly
	LZC—Glove, Patient Examination, Speciality
	LYZ—Glove, Patient Examination, Vinyl
880.6375	Patient Lubricant
	KMJ—Lubricant, Patient
880.6760	Protective Restraint
	BRT—Restraint, Patient, Conductive
	FMQ—Restraint, Protective
Neurology Panel (21 CFR Part 882)	
882.1030	Ataxiagraph
	GWW—Ataxiagraph
882.1420	Electroencephalogram (EEG) Signal Spectrum Analyzer
	GWS—Analyzer, Spectrum, Electroencephalogram Signal
882.4060	Ventricular Cannula
	HCD—Cannula, Ventricular
882.4545	Shunt System Implantation Instrument
	GYK—Instrument, Shunt System Implantation
882.4650	Neurosurgical Suture Needle
	HAS—Needle, Neurosurgical Suture
882.4750	Skull Punch
	GXJ—Punch, Skull
Obstetrics and Gynecology Panel	
(None).	
Ophthalmology Panel (21 CFR Part 886)	
886.1780	Retinoscope
	HKM—Retinoscope, Battery-Powered
886.1940	Tonometer Sterilizer

TABLE 1—CLASS I PRODUCTS REQUIRING PREMARKET EVALUATIONS IN THE UNITED STATES, INCLUDED IN SCOPE OF PRODUCT COVERAGE AT BEGINNING OF TRANSITION PERIOD [1]—Continued

21 CFR Section No.	Regulation Name
	Product Code—Device Name
	HKZ—Sterilizer, Tonometer
886.4070	Powered Corneal Burr
	HQS—Burr, Corneal, AC-Powered
	HOG—Burr, Corneal, Battery-Powered
	HRG—Engine, Trephine, Accessories, AC-Powered
	HFR—Engine, Trephine, Accessories, Battery-Powered
	HLD—Engine, Trephine, Accessories, Gas-Powered
886.4370	Keratome
	HNO—Keratome, AC-Powered
	HMY—Keratome, Battery-Powered
886.5850	Sunglasses (Nonprescription)
	HQY—Sunglasses (Nonprescription Including Photosensitive)
Orthopedic Panel (21 CFR Part 888)	
888.1500	Goniometer
	KQX—Goniometer, AC-Powered
888.4150	Calipers for Clinical Use
	KTZ—Caliper
Physical Medicine Panel (21 CFR Part 890)	
890.3850	Mechanical Wheelchair
	LBE—Stroller, Adaptive
	IOR—Wheelchair, Mechanical
890.5180	Manual Patient Rotation Bed
	INY—Bed, Patient Rotation, Manual
890.5710	Hot or Cold Disposable Pack
	IMD—Pack, Hot or Cold, Disposable
Radiology Panel (21 CFR Part 892)	
892.1100	Scintillation (Gamma) Camera
	IYX—Camera, Scintillation (Gamma)
892.1110	Positron Camera
	IZC—Camera, Positron
892.1300	Nuclear Rectilinear Scanner
	IYW—Scanner, Rectilinear, Nuclear
892.1320	Nuclear Uptake Probe
	IZD—Probe, Uptake, Nuclear
892.1330	Nuclear Whole Body Scanner
	JAM—Scanner, Whole Body, Nuclear
892.1410	Nuclear Electrocardiograph Synchronizer
	IVY—Synchronizer, Electrocardiograph, Nuclear
892.1890	Radiographic Film Illuminator
	IXC—Illuminator, Radiographic-Film
	JAG—Illuminator, Radiographic-Film, Explosion-Proof
892.1910	Radiographic Grid
	IXJ—Grid, Radiographic
892.1960	Radiographic Intensifying Screen
	EAM—Screen, Intensifying, Radiographic
892.1970	Radiographic ECG/Respirator Synchronizer
	IXO—Synchronizer, ECG/Respirator, Radiographic
892.5650	Manual Radionuclide Applicator System
	IWG—System, Applicator, Radionuclide, Manual
General and Plastic Surgery Panel (21 CFR Part 878)	
878.4200	Introduction/Drainage Catheter and Accessories
	KGZ—Accessories, Catheter
	GCE—Adaptor, Catheter
	FGY—Cannula, Injection
	GBA—Catheter, Balloon Type
	GBZ—Catheter, Cholangiography
	GBQ—Catheter, Continuous Irrigation
	GBY—Catheter, Eustachian, General & Plastic Surgery
	JCY—Catheter, Infusion
	GBX—Catheter, Irrigation
	GBP—Catheter, Multiple Lumen
	GBO—Catheter, Nephrostomy, General & Plastic Surgery
	GBN—Catheter, Pediatric, General & Plastic Surgery
	GBW—Catheter, Peritoneal
	GBS—Catheter, Ventricular, General & Plastic Surgery
	GCD—Connector, Catheter
	GCC—Dilator, Catheter
	GCB—Needle, Catheter
878.4320	Removable Skin Clip

TABLE 1—CLASS I PRODUCTS REQUIRING PREMARKET EVALUATIONS IN THE UNITED STATES, INCLUDED IN SCOPE OF PRODUCT COVERAGE AT BEGINNING OF TRANSITION PERIOD [1]—Continued

21 CFR Section No.	Regulation Name
	Product Code—Device Name
	FZQ—Clip, Removable (Skin)
878.4460	Surgeon's Gloves
	KGO—Surgeon's Gloves
878.4680	Nonpowered, Single Patient, Portable Suction Apparatus
	GCY—Apparatus, Suction, Single Patient Use, Portable, Nonpowered
878.4760	Removable Skin Staple
	GDT—Staple, Removable (Skin)
878.4820	AC-Powered, Battery-Powered, and Pneumatically Powered Surgical Instrument Motors and Accessories/Attachments
	GFG—Bit, Surgical
	GFA—Blade, Saw, General & Plastic Surgery
	DWH—Blade, Saw, Surgical, Cardiovascular
	BRZ—Board, Arm (With Cover)
	GFE—Brush, Dermabrasion
	GFF—Bur, Surgical, General & Plastic Surgery
	KDG—Chisel (Osteotome)
	GFD—Dermatome
	GFC—Driver, Surgical, Pin
	GFB—Head, Surgical, Hammer
	GEY—Motor, Surgical Instrument, AC-Powered
	GET—Motor, Surgical Instrument, Pneumatic Powered
	DWI—Saw, Electrically Powered
	KFK—Saw, Pneumatically Powered
	HAB—Saw, Powered, and Accessories
878.4960	Air or AC-Powered Operating Table and Air or AC-Powered Operating Chair & Accessories
	GBB—Chair, Surgical, AC-Powered
	FQO—Table, Operating-Room, AC-Powered
	GDC—Table, Operating-Room, Electrical
	FWW—Table, Operating-Room, Pneumatic
	JEA—Table, Surgical with Orthopedic Accessories, AC-Powered
880.5090	Liquid Bandage
	KMF—Bandage, Liquid

[1]Descriptive information on product codes, panel codes, and other medical device identifiers may be viewed on FDA's Internet Web Site at *http://www.fda.gov/cdrh/prodcode.html.*

TABLE 2—CLASS II MEDICAL DEVICES INCLUDED IN SCOPE OF PRODUCT COVERAGE AT BEGINNING OF TRANSITION PERIOD (UNITED STATES TO DEVELOP GUIDANCE DOCUMENTS IDENTIFYING U.S. REQUIREMENTS AND EUROPEAN COMMUNITY (EC) TO IDENTIFY STANDARDS NEEDED TO MEET EC REQUIREMENTS) [1]

Panel	21 CFR Section No.	Regulation Name
		Product Code—Device Name
RA	892.1000	Magnetic Resonance Diagnostic Device
		MOS—COIL, Magnetic Resonance, Specialty
		LNH—System, Nuclear Magnetic Resonance Imaging
		LNI—System, Nuclear Magnetic Resonance Spectroscopic
Diagnostic Ultrasound:		
RA	892.1540	Nonfetal Ultrasonic Monitor
		JAF—Monitor, Ultrasonic, Nonfetal
RA	892.1550	Ultrasonic Pulsed Doppler Imaging System
		IYN—System, Imaging, Pulsed Doppler, Ultrasonic
RA	892.1560	Ultrasonic Pulsed Echo Imaging System
		IYO—System, Imaging, Pulsed Echo, Ultrasonic
RA	892.1570	Diagnostic Ultrasonic Transducer
		ITX—Transducer, Ultrasonic, Diagnostic
Diagnostic X-Ray Imaging Devices (except mammographic x-ray systems):		
RA	892.1600	Angiographic X-Ray System
		IZI—System, X-Ray, Angiographic
RA	892.1650	Image-Intensified Fluoroscopic X-Ray System
		MQB—Solid State X-Ray Imager (Flat Panel/Digital Imager)
		JAA—System, X-Ray, Fluoroscopic, Image-Intensified
RA	892.1680	Stationary X-Ray System

TABLE 2—CLASS II MEDICAL DEVICES INCLUDED IN SCOPE OF PRODUCT COVERAGE AT BEGINNING OF TRANSITION PERIOD (UNITED STATES TO DEVELOP GUIDANCE DOCUMENTS IDENTIFYING U.S. REQUIREMENTS AND EUROPEAN COMMUNITY (EC) TO IDENTIFY STANDARDS NEEDED TO MEET EC REQUIREMENTS) [1]—Continued

Panel	21 CFR Section No.	Regulation Name
		Product Code—Device Name
		KPR—System, X-Ray, Stationary
RA	892.1720	Mobile X-Ray System
		IZL—System, X-Ray, Mobile
RA	892.1740	Tomographic X-Ray System
		IZF—System, X-Ray, Tomographic
RA	892.1750	Computed Tomography X-Ray System
		JAK—System, X-Ray, Tomography, Computed
ECG-Related Devices:		
CV	870.2340	Electrocardiograph
		DPS—Electrocardiograph
		MLC—Monitor, ST Segment
CV	870.2350	Electrocardiograph Lead Switching Adaptor
		DRW—Adaptor, Lead Switching, Electrocardiograph
CV	870.2360	Electrocardiograph Electrode
		DRX—Electrode, Electrocardiograph
CV	870.2370	Electrocardiograph Surface Electrode Tester
		KRC—Tester, Electrode, Surface, Electrocardiographic
NE	882.1400	Electroencephalograph
		GWQ—Electroencephalograph
HO	880.5725	Infusion Pump (external only)
		MRZ—Accessories, Pump, Infusion
		FRN—Pump, Infusion
		LZF—Pump, Infusion, Analytical Sampling
		MEB—Pump, Infusion, Elastomeric
		LZH—Pump, Infusion, Enteral
		MHD—Pump, Infusion, Gallstone Dissolution
		LZG—Pump, Infusion, Insulin
		MEA—Pump, Infusion, PCA
Ophthalmic Instruments:		
OP	886.1570	Ophthalmoscope
		HLI—Ophthalmoscope, AC-Powered
		HLJ—Ophthalmoscope, Battery-Powered
OP	886.1780	Retinoscope
		HKL—Retinoscope, AC-Powered
OP	886.1850	AC-Powered Slit-Lamp Biomicroscope
		HJO—Biomicroscope, Slit-Lamp, AC-Powered
OP	886.4150	Vitreous Aspiration and Cutting Instrument
		MMC—Dilator, Expansive Iris (Accessory)
		HQE—Instrument, Vitreous Aspiration and Cutting, AC-Powered
		HKP—Instrument, Vitreous Aspiration and Cutting, Battery-Powered
		MLZ—Vitrectomy, Instrument Cutter
OP	886.4670	Phacofragmentation System
		HQC—Unit, Phacofragmentation
SU	878.4580	Surgical Lamp
		HBI—Illuminator, Fiberoptic, Surgical Field
		FTF—Illuminator, Nonremote
		FTG—Illuminator, Remote
		HJE—Lamp, Fluorescein, AC-Powered
		FQP—Lamp, Operating-Room
		FTD—Lamp, Surgical
		GBC—Lamp, Surgical, Incandescent
		FTA—Light, Surgical, Accessories
		FSZ—Light, Surgical, Carrier
		FSY—Light, Surgical, Ceiling Mounted
		FSX—Light, Surgical, Connector
		FSW—Light, Surgical, Endoscopic
		FST—Light, Surgical, Fiberoptic
		FSS—Light, Surgical, Floor Standing
		FSQ—Light, Surgical, Instrument
NE	882.5890	Transcutaneous Electrical Nerve Stimulator for Pain Relief
		GZJ—Stimulator, Nerve, Transcutaneous, For Pain Relief
		Noninvasive Blood Pressure Measurement Devices:
CV	870.1120	Blood Pressure Cuff
		DXQ—Cuff, Blood-Pressure
CV	870.1130	Noninvasive Blood Pressure Measurement System (except nonoscillometric)

TABLE 2—CLASS II MEDICAL DEVICES INCLUDED IN SCOPE OF PRODUCT COVERAGE AT BEGINNING OF TRANSITION PERIOD (UNITED STATES TO DEVELOP GUIDANCE DOCUMENTS IDENTIFYING U.S. REQUIREMENTS AND EUROPEAN COMMUNITY (EC) TO IDENTIFY STANDARDS NEEDED TO MEET EC REQUIREMENTS) [1]—Continued

Panel	21 CFR Section No.	Regulation Name
		Product Code—Device Name
		DXN—System, Measurement, Blood-Pressure, Noninvasive
HO	880.6880	Steam Sterilizer (greater than 2 cubic feet)
		FLE—Sterilizer, Steam
Clinical Thermometers:		
HO	880.2910	Clinical Electronic Thermometer (except tympanic or pacifier)
		FLL—Thermometer, Electronic, Clinical
AN	868.5630	Nebulizer
		CAF—Nebulizer (Direct Patient Interface)
Hypodermic Needles and Syringes (except antistick and self-destruct):		
HO	880.5570	Hypodermic Single Lumen Needle
		MMK—Container, Sharpes
		FMI—Needle, Hypodermic, Single Lumen
		MHC—Port, Intraosseous, Implanted
HO	880.5860	Piston Syringe
		FMF—Syringe, Piston
Selected Dental Materials:		
DE	872.3060	Gold-Based Alloys and Precious Metal Alloys for Clinical Use
		EJT—Alloy, Gold Based, For Clinical Use
		EJS—Alloy, Precious Metal, For Clinical Use
DE	872.3200	Resin Tooth Bonding Agent
		KLE—Agent, Tooth Bonding, Resin
DE	872.3275	Dental Cement
		EMA—Cement, Dental
		EMB—Zinc Oxide Eugenol
DE	872.3660	Impression Material
		ELW—Material, Impression
DE	872.3690	Tooth Shade Resin Material
		EBF—Material, Tooth Shade, Resin
DE	872.3710	Base Metal Alloy
		EJH—Metal, Base
Latex Condoms:		
OB	884.5300	Condom
		HIS—Condom

[1]Descriptive information on product codes, panel codes, and other medical device identifiers may be viewed on FDA's Internet Web Site at *http://www.fda.gov/cdrh/prodcode.html.*

TABLE 3—MEDICAL DEVICES FOR POSSIBLE INCLUSION IN SCOPE OF PRODUCT COVERAGE DURING OPERATIONAL PERIOD [1]

Product Family	21 CFR Section No	Device Name	Tier
Anesthesiology Panel			
Anesthesia Devices	868.5160	Gas machine for anesthesia or analgesia	2
	868.5270	Breathing system heater	2
	868.5440	Portable oxygen generator	2
	868.5450	Respiratory gas humidifier	2
	868.5630	Nebulizer	2
	868.5710	Electrically powered oxygen tent	2
	868.5880	Anesthetic vaporizer	2
Gas Analyser	868.1040	Powered Algesimeter	2
	868.1075	Argon gas analyzer	2
	868.1400	Carbon dioxide gas analyzer	2
	868.1430	Carbon monoxide gas analyzer	2
	868.1500	Enflurane gas analyzer	2
	868.1620	Halothane gas analyzer	2
	868.1640	Helium gas analyzer	2
	868.1670	Neon gas analyzer	2
	868.1690	Nitrogen gas analyzer	2
	868.1700	Nitrous oxide gas analyzer	2
	868.1720	Oxygen gas analyzer	2
	868.1730	Oxygen uptake computer	2
Peripheral Nerve Stimulators	868.2775	Electrical peripheral nerve stimulator	2

TABLE 3—MEDICAL DEVICES FOR POSSIBLE INCLUSION IN SCOPE OF PRODUCT COVERAGE DURING OPERATIONAL PERIOD [1]—Continued

Product Family	21 CFR Section No	Device Name	Tier
Respiratory Monitoring	868.1750	Pressure plethysmograph	2
	868.1760	Volume plethysmograph	2
	868.1780	Inspiratory airway pressure meter	2
	868.1800	Rhinoanemometer	2
	868.1840	Diagnostic spirometer	2
	868.1850	Monitoring spirometer	2
	868.1860	Peak-flow meter for spirometry	2
	868.1880	Pulmonary-function data calculator	2
	868.1890	Predictive pulmonary-function value calculator	2
	868.1900	Diagnostic pulmonary-function interpretation calculator	2
	868.2025	Ultrasonic air embolism monitor	2
	868.2375	Breathing frequency monitor (except apnea detectors)	2
	868.2480	Cutaneous carbon dioxide ($PcCO_2$) monitor	2
	868.2500	Cutaneous oxygen monitor (for an infant not under gas anesthesia).	2
	868.2550	Pneumotachomometer	2
	868.2600	Airway pressure monitor	2
	868.5665	Powered percussor	2
	868.5690	Incentive spirometer	2
Ventilator	868.5905	Noncontinuous ventilator (IPPB)	2
	868.5925	Powered emergency ventilator	2
	868.5935	External negative pressure ventilator	2
	868.5895	Continuous ventilator	2
	868.5955	Intermittent mandatory ventilation attachment	2
	868.6250	Portable air compressor	2
Cardiovascular Panel			
Cardiovascular Diagnostic	870.1425	Programmable diagnostic computer	2
	870.1450	Densitometer	2
	870.2310	Apex cardiograph (vibrocardiograph)	2
	870.2320	Ballistocardiograph	2
	870.2340	Electrocardiograph	2
	870.2350	Electrocardiograph lead switching adaptor	1
	870.2360	Electrocardiograph electrode	2
	870.2370	Electrocardiograph surface electrode tester	2
	870.2400	Vectorcardiograph	1
	870.2450	Medical cathode-ray tube display	1
	870.2675	Oscillometer	2
	870.2840	Apex cardiographic transducer	2
	870.2860	Heart sound transducer	2
Cardiovascular Monitoring		Valve, pressure relief, cardiopulmonary bypass.	

TABLE 3—MEDICAL DEVICES FOR POSSIBLE INCLUSION IN SCOPE OF PRODUCT COVERAGE DURING OPERATIONAL PERIOD [1]—Continued

Product Family	21 CFR Section No	Device Name	Tier
	870.1100	Blood pressure alarm	2
	870.1110	Blood pressure computer	2
	870.1120	Blood pressure cuff	2
	870.1130	Noninvasive blood pressure measurement system	2
	870.1140	Venous blood pressure manometer	2
	870.1220	Electrode recording catheter or electrode recording probe	2
	870.1270	Intracavitary phonocatheter system	2
	870.1875	Stethoscope (electronic)	2
	870.2050	Biopotential amplifier and signal conditioner	2
	870.2060	Transducer signal amplifier and conditioner	2
	870.2100	Cardiovascular blood flow-meter	2
	870.2120	Extravascular blood flow probe	2
	870.2300	Cardiac monitor (including cardiotachometer and rate alarm).	2
	870.2700	Oximeter	2
	870.2710	Ear oximeter	2
	870.2750	Impedance phlebograph	2
	870.2770	Impedance plethysmograph	2
	870.2780	Hydraulic, pneumatic, or photoelectric plethysmographs	2
	870.2850	Extravascular blood pressure transducer	2
	870.2870	Catheter tip pressure transducer	2
	870.2880	Ultrasonic transducer	2
	870.2890	Vessel occlusion transducer	2
	870.2900	Patient transducer and electrode cable (including connector).	2
	870.2910	Radiofrequency physiological signal transmitter and receiver.	2
	870.2920	Telephone electrocardiograph transmitter and receiver	2
	870.4205	Cardiopulmonary bypass bubble detector	2
	870.4220	Cardiopulmonary bypass heart-lung machine console	2
	870.4240	Cardiovascular bypass heat exchanger	2
	870.4250	Cardiopulmonary bypass temperature controller	2
	870.4300	Cardiopulmonary bypass gas control unit	2
	870.4310	Cardiopulmonary bypass coronary pressure gauge	2
	870.4330	Cardiopulmonary bypass on-line blood gas monitor	2
	870.4340	Cardiopulmonary bypass level sensing monitor and/or control.	2
	870.4370	Roller-type cardiopulmonary bypass blood pump	2
	870.4380	Cardiopulmonary bypass pump speed control	2
	870.4410	Cardiopulmonary bypass in-line blood gas sensor	2
Cardiovascular Therapeutic	870.5050	Patient care suction apparatus	2
	870.5900	Thermal regulation system	2
Defibrillator	870.5300	DC-defibrillator (including paddles)	2
	870.5325	Defibrillator tester	2
Echocardiograph	870.2330	Echocardiograph	2
Pacemaker & Accessories	870.1750	External programmable pacemaker pulse generator	2
	870.3630	Pacemaker generator function analyzer	2
	870.3640	Indirect pacemaker generator function analyzer	2
	870.3720	Pacemaker electrode function tester	2
Miscellaneous	870.1800	Withdrawal-infusion pump	2
	870.2800	Medical magnetic tape recorder	2
	None	Batteries, rechargeable, class II devices.	
Dental Panel			
Dental Equipment	872.1720	Pulp tester	2
	872.1740	Caries detection device	2
	872.4120	Bone cutting instrument and accessories	2
	872.4465	Gas-powered jet injector	2
	872.4475	Spring-powered jet injector	2
	872.4600	Intraoral ligature and wire lock	2
	872.4840	Rotary scaler	2
	872.4850	Ultrasonic scaler	2
	872.4920	Dental electrosurgical unit and accessories	2
	872.6070	Ultraviolet activator for polymerization	2
	872.6350	Ultraviolet detector	2
Dental Material	872.3050	Amalgam alloy	2

TABLE 3—MEDICAL DEVICES FOR POSSIBLE INCLUSION IN SCOPE OF PRODUCT COVERAGE DURING OPERATIONAL PERIOD [1]—Continued

Product Family	21 CFR Section No	Device Name	Tier
	872.3060	Gold-based alloys and precious metal alloys for clinical use	2
	872.3200	Resin tooth bonding agent	2
	872.3250	Calcium hydroxide cavity liner	2
	872.3260	Cavity varnish	2
	872.3275	Dental cement (other than zinc oxide-eugenol)	2
	872.3300	Hydrophilic resin coating for dentures	2
	872.3310	Coating material for resin fillings	2
	872.3590	Preformed plastic denture tooth	2
	872.3660	Impression material	2
	872.3690	Tooth shade resin material	2
	872.3710	Base metal alloy	2
	872.3750	Bracket adhesive resin and tooth conditioner	2
	872.3760	Denture relining, repairing, or rebasing resin	2
	872.3765	Pit and fissure sealant and conditioner	2
	872.3770	Temporary crown and bridge resin	2
	872.3820	Root canal filling resin (other than chloroform use)	2
	872.3920	Porcelain tooth	2
Dental X-ray	872.1800	Extraoral source x-ray system	2
	872.1810	Intraoral source x-ray system	2
Dental Implants	872.4880	Intraosseous fixation screw or wire	2
	872.3890	Endodontic stabilizing splint	2
Orthodontic	872.5470	Orthodontic plastic bracket	2
Ear/Nose/Throat Panel			
Diagnostic Equipment	874.1050	Audiometer	2
	874.1090	Auditory impedance tester	2
	874.1120	Electronic noise generator for audiometric testing	2
	874.1325	Electroglottograph	2
	874.1820	Surgical nerve stimulator/locator	2
Hearing Aids	874.3300	Hearing aid (for bone-conduction)	2
	874.3310	Hearing aid calibrator and analysis system	2
	874.3320	Group hearing aid or group auditory trainer	2
	874.3330	Master hearing aid	2
Surgical Equipment	874.4250	Ear, nose, and throat electric or pneumatic surgical drill	1
	874.4490	Argon laser for otology, rhinology, and laryngology	2
	874.4500	Ear, nose, and throat microsurgical carbon dioxide laser	2
Gastroenterology/Urology Panel			
Endoscope (including angioscopes, laparscopes, ophthalmic endoscopes).	876.1500	Endoscope and accessories	2
	876.4300	Endoscopic electrosurgical unit and accessories	2
Gastroenterology	876.1725	Gastrointestinal motility monitoring system	1
Hemodialysis	876.5600	Sorbent regenerated dialysate delivery system for hemodialysis.	2
	876.5630	Peritoneal dialysis system and accessories	2
	876.5665	Water purification system for hemodialysis	2
	876.5820	Hemodialysis system and accessories	2
	876.5830	Hemodialyzer with disposable insert (kiil-type)	2
Lithotriptor	876.4500	Mechanical lithotriptor	2
Urology Equipment	876.1620	Urodynamics measurement system	2
	876.5320	Nonimplanted electrical continence device	2
	876.5880	Isolated kidney perfusion and transport system and accessories.	2
General Hospital Panel			
Infusion Pumps and Systems	880.2420	Electronic monitor for gravity flow infusion systems	2
	880.2460	Electrically powered spinal fluid pressure monitor	2
	880.5430	Nonelectrically powered fluid injector	2
	880.5725	Infusion pump	2
Neonatal Incubators	880.5400	Neonatal incubator	2
	880.5410	Neonatal transport incubator	2
	880.5700	Neonatal phototherapy unit	2
Piston Syringes	880.5570	Hypodermic single lumen needle	1
	880.5860	Piston syringe (except antistick)	1
	880.6920	Syringe needle introducer	2
Miscellaneous	880.2910	Clinical electronic thermometer	2
	880.2920	Clinical mercury thermometer	2
	880.5100	AC-powered adjustable hospital bed	1
	880.5500	AC-powered patient lift	2
	880.6880	Steam sterilizer (greater than 2 cubic feet)	2
Neurology Panel			
	882.1020	Rigidity analyzer	2
	882.1610	Alpha monitor	2
Neuro-Diagnostic	882.1320	Cutaneous electrode	2

TABLE 3—MEDICAL DEVICES FOR POSSIBLE INCLUSION IN SCOPE OF PRODUCT COVERAGE DURING OPERATIONAL PERIOD [1]—Continued

Product Family	21 CFR Section No	Device Name	Tier
	882.1340	Nasopharyngeal electrode	2
	882.1350	Needle electrode	2
	882.1400	Electroencephalograph	2
	882.1460	Nystagmograph	2
	882.1480	Neurological endoscope	2
	882.1540	Galvanic skin response measurement device	2
	882.1550	Nerve conduction velocity measurement device	2
	882.1560	Skin potential measurement device	2
	882.1570	Powered direct-contact temperature measurement device	2
	882.1620	Intracranial pressure monitoring device	2
	882.1835	Physiological signal amplifier	2
	882.1845	Physiological signal conditioner	2
	882.1855	Electroencephalogram (EEG) telemetry system	2
	882.5050	Biofeedback device	2
Echoencephalography	882.1240	Echoencephalograph	2
RPG	882.4400	Radiofrequency lesion generator	2
Neuro Surgery	none	Electrode, spinal epidural	2
	882.4305	Powered compound cranial drills, burrs, trephines, and their accessories.	2
	882.4310	Powered simple cranial drills burrs, trephines, and their accessories.	2
	882.4360	Electric cranial drill motor	2
	882.4370	Pneumatic cranial drill motor	2
	882.4560	Stereotaxic instrument	2
	882.4725	Radiofrequency lesion probe	2
	882.4845	Powered rongeur	2
	882.5500	Lesion temperature monitor	2
Stimulators	882.1870	Evoked response electrical stimulator	2
	882.1880	Evoked response mechanical stimulator	2
	882.1890	Evoked response photic stimulator	2
	882.1900	Evoked response auditory stimulator	2
	882.1950	Tremor transducer	2
	882.5890	Transcutaneous electrical nerve stimulator for pain relief	2
Obstetrics/Gynecology Panel			
Fetal Monitoring	884.1660	Transcervical endoscope (amnioscope) and accessories	2
	884.1690	Hysteroscope and accessories (for performance standards)	2
	884.2225	Obstetric-gynecologic ultrasonic imager	2
	884.2600	Fetal cardiac monitor	2
	884.2640	Fetal phonocardiographic monitor and accessories	2
	884.2660	Fetal ultrasonic monitor and accessories	2
	884.2675	Fetal scalp circular (spiral) electrode and applicator	1
	884.2700	Intrauterine pressure monitor and accessories	2
	884.2720	External uterine contraction monitor and accessories	2
	884.2740	Perinatal monitoring system and accessories	2
	884.2960	Obstetric ultrasonic transducer and accessories	2
Gynecological Surgery Equipment.	884.1720	Gynecologic laparoscope and accessories	2
	884.4160	Unipolar endoscopic coagulator-cutter and accessories	2
	884.4550	Gynecologic surgical laser	2
	884.4120	Gynecologic electrocautery and accessories	2
	884.5300	Condom	2
Ophthalmic Implants	886.3320	Eye sphere implant	2
Contact Lens	886.1385	Polymethylmethacrylate (PMMA) diagnostic contact lens	2
	886.5916	Rigid gas permeable contact lens (daily wear only)	2
Diagnostic Equipment	886.1120	Opthalmic camera	1
	886.1220	Corneal electrode	1
	886.1250	Euthyscope (AC-powered)	1
	886.1360	Visual field laser instrument	1
	886.1510	Eye movement monitor	1
	886.1570	Ophthalmoscope	1
	886.1630	AC-powered photostimulator	1
	886.1640	Ophthalmic preamplifier	1
	886.1670	Ophthalmic isotope uptake probe	2
	886.1780	Retinoscope (AC-powered device)	1
	886.1850	AC-powered slit lamp biomicroscope	1
	886.1930	Tonometer and accessories	2
	886.1945	Transilluminator (AC-powered device)	1
	886.3130	Ophthalmic conformer	2
(Diagnostic/Surgery Equipment)	886.4670	Phacofragmentation system	2
Ophthalmic Implants	886.3340	Extraocular orbital implant	2
	886.3800	Scleral shell	2
Surgical Equipment	880.5725	Infusion pump (performance standards)	2

TABLE 3—MEDICAL DEVICES FOR POSSIBLE INCLUSION IN SCOPE OF PRODUCT COVERAGE DURING OPERATIONAL PERIOD [1]—Continued

Product Family	21 CFR Section No	Device Name	Tier
	886.3100	Ophthalmic tantalum clip	2
	886.3300	Absorbable implant (scleral buckling method)	2
	886.4100	Radiofrequency electrosurgical cautery apparatus	2
	886.4115	Thermal cautery unit	2
	886.4150	Vitreous aspiration and cutting instrument	2
	886.4170	Cryophthalmic unit	2
	886.4250	Ophthalmic electrolysis unit (AC-powered device)	1
	886.4335	Operating headlamp (AC-powered device)	1
	886.4390	Ophthalmic laser	2
	886.4392	Nd:YAG laser for posterior capsulotomy	2
	886.4400	Electronic metal locator	1
	886.4440	AC-powered magnet	1
	886.4610	Ocular pressure applicator	2
	886.4690	Ophthalmic photocoagulator	2
	886.4790	Ophthalmic sponge	2
	886.5100	Ophthalmic beta radiation source	2
	none	Ophthalmoscopes, replacement batteries, hand-held	1
Orthopedic Panel			
Implants	888.3010	Bone fixation cerclage	2
	888.3020	Intramedullary fixation rod	2
	888.3030	Single/multiple component metallic bone fixation appliances and accessories.	2
	888.3040	Smooth or threaded metallic bone fixation fastener	2
	888.3050	Spinal interlaminal fixation orthosis	2
	888.3060	Spinal intervertebral body fixation orthosis	2
Surgical Equipment	888.1240	AC-powered dynamometer	2
	888.4580	Sonic surgical instrument and accessories/attachments	2
	none	Accessories, fixation, spinal interlaminal	2
	none	Accessories, fixation, spinal intervertebral body	2
	none	Monitor, pressure, intracompartmental	1
	none	Orthosis, fixation, spinal intervertebral fusion	2
	none	Orthosis, spinal pedicle fixation.	
	none	System, cement removal extraction	1
Physical Medicine Panel			
Diagnostic Equipment or (Therapy) Therapeutic Equipment.	890.1225	Chronaximeter	2
	890.1375	Diagnostic electromyograph	2
	890.1385	Diagnostic electromyograph needle electrode	2
	890.1450	Powered reflex hammer	2
	890.1850	Diagnostic muscle stimulator	2
or (Therapy)	890.5850	Powered muscle stimulator	2
Therapeutic Equipment	890.5100	Immersion hydrobath	2
	890.5110	Paraffin bath	2
	890.5500	Infrared lamp	2
	890.5720	Water circulating hot or cold pack	2
	890.5740	Powered heating pad	2
Radiology Panel			
MRI	892.1000	Magnetic resonance diagnostic device	2
Ultrasound Diagnostic	884.2660	Fetal ultrasonic monitor and accessories	2
	892.1540	Nonfetal ultrasonic monitor.	
	892.1560	Ultrasonic pulsed echo imaging system	2
	892.1570	Diagnostic ultrasonic transducer	2
	892.1550	Ultrasonic pulsed doppler imaging system.	
Angiographic	892.1600	Angiographic x-ray system	2
Diagnostic X-Ray	892.1610	Diagnostic x-ray beam-limiting device	2
	892.1620	Cine or spot fluorographic x-ray camera	2
	892.1630	Electrostatic x-ray imaging system	2
	892.1650	Image-intensified fluoroscopic x-ray system	2
	892.1670	Spot film device	2
	892.1680	Stationary x-ray system	2
	892.1710	Mammographic x-ray system	2
	892.1720	Mobile x-ray system	2
	892.1740	Tomographic x-ray system	1
	892.1820	Pneumoencephalographic chair	2
	892.1850	Radiographic film cassette	1
	892.1860	Radiographic film/cassette changer	1
	892.1870	Radiographic film/cassette changer programmer	2
	892.1900	Automatic radiographic film processor	2
	892.1980	Radiologic table	1
CT Scanner	892.1750	Computed tomography x-ray system	2
Radiation Therapy	892.5050	Medical charged-particle radiation therapy system	2

TABLE 3—MEDICAL DEVICES FOR POSSIBLE INCLUSION IN SCOPE OF PRODUCT COVERAGE DURING OPERATIONAL PERIOD [1]—Continued

Product Family	21 CFR Section No	Device Name	Tier
	892.5300	Medical neutron radiation therapy system	2
	892.5700	Remote controlled radionuclide applicator system	2
	892.5710	Radiation therapy beam-shaping block	2
	892.5730	Radionuclide brachytherapy source	2
	892.5750	Radionuclide radiation therapy system	2
	892.5770	Powered radiation therapy patient support assembly	2
	892.5840	Radiation therapy simulation system	2
	892.5930	Therapeutic x-ray tube housing assembly	1
Nuclear Medicine	892.1170	Bone densitometer	2
	892.1200	Emission computed tomography system	2
	892.1310	Nuclear tomography system	1
	892.1390	Radionuclide rebreathing system	2
General/Plastic Surgery Panel			
Surgical Lamps	878.4630	Ultraviolet lamp for dermatologic disorders	2
	890.5500	Infrared lamp	2
	878.4580	Surgical lamp	2
Electrosurgical Cutting Equipment.	878.4810	Laser surgical instrument for use in general and plastic surgery and in dermatology.	2
	878.4400	Electrosurgical cutting and coagulation device and accessories.	2
Miscellaneous	878.4780	Powered suction pump	2

[1]Descriptive information on product codes, panel codes, and other medical device identifiers may be viewed on FDA's Internet Web Site at *http://www.fda.gov/cdrh/prodcode.html.*

[63 FR 60141, Nov. 6, 1998; 64 FR 16348, Apr. 5, 1999]

APPENDIXES C–F TO SUBPART B OF PART 26 [RESERVED]

Subpart C—"Framework" Provisions

§ 26.60 Definitions.

(a) The following terms and definitions shall apply to this subpart only:

(1) *Designating Authority* means a body with power to designate, monitor, suspend, remove suspension of, or withdraw conformity assessment bodies as specified under this part.

(2) *Designation* means the identification by a designating authority of a conformity assessment body to perform conformity assessment procedures under this part.

(3) *Regulatory Authority* means a government agency or entity that exercises a legal right to control the use or sale of products within a party's jurisdiction and may take enforcement action to ensure that products marketed within its jurisdiction comply with legal requirements.

(b) Other terms concerning conformity assessment used in this part shall have the meaning given elsewhere in this part or in the definitions contained in "Guide 2: Standardization and Related Activities—General Vocabulary of the International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC)" (ISO/IEC Guide 2) (1996 edition), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the International Organization for Standardization, 1, rue de Varembé, Case postale 56, CH–1211 Genève 20, Switzerland, or on the Internet at *http://www.iso.ch* or may be examined at the Food and Drug Administration's Medical Library, 5600 Fishers Lane, rm. 11B–40, Rockville, MD 20857, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*. In the event of an inconsistency between the ISO/IEC Guide 2 and definitions in this part, the definitions in this part shall prevail.

§ 26.61 Purpose of this part.

This part specifies the conditions by which each party will accept or recognize results of conformity assessment

procedures, produced by the other party's conformity assessment bodies (CAB's) or authorities, in assessing conformity to the importing party's requirements, as specified on a sector-specific basis in subparts A and B of this part, and to provide for other related cooperative activities. The objective of such mutual recognition is to provide effective market access throughout the territories of the parties with regard to conformity assessment for all products covered under this part. If any obstacles to such access arise, consultations will promptly be held. In the absence of a satisfactory outcome of such consultations, the party alleging its market access has been denied may, within 90 days of such consultation, invoke its right to terminate the ''Agreement on Mutual Recognition Between the United States of America and the European Community,'' from which this part is derived, in accordance with § 26.80.

§ 26.62 General obligations.

(a) The United States shall, as specified in subparts A and B of this part, accept or recognize results of specified procedures, used in assessing conformity to specified legislative, regulatory, and administrative provisions of the United States, produced by the other party's conformity assessment bodies (CAB's) and/or authorities.

(b) The European Community (EC) and its Member States shall, as specified in subparts A and B of this part, accept or recognize results of specified procedures, used in assessing conformity to specified legislative, regulatory, and administrative provisions of the EC and its Member States, produced by the other party's CAB's and/or authorities.

(c) Where sectoral transition arrangements have been specified in subparts A and B of this part, the obligations in paragraphs (a) and (b) of this section will apply following the successful completion of those sectoral transition arrangements, with the understanding that the conformity assessment procedures utilized assure conformity to the satisfaction of the receiving party, with applicable legislative, regulatory, and administrative provisions of that party, equivalent to the assurance offered by the receiving party's own procedures.

§ 26.63 General coverage of this part.

(a) This part applies to conformity assessment procedures for products and/or processes and to other related cooperative activities as described in this part.

(b) Subparts A and B of this part may include:

(1) A description of the relevant legislative, regulatory, and administrative provisions pertaining to the conformity assessment procedures and technical regulations;

(2) A statement on the product scope and coverage;

(3) A list of designating authorities;

(4) A list of agreed conformity assessment bodies (CAB's) or authorities or a source from which to obtain a list of such bodies or authorities and a statement of the scope of the conformity assessment procedures for which each has been agreed;

(5) The procedures and criteria for designating the CAB's;

(6) A description of the mutual recognition obligations;

(7) A sectoral transition arrangement;

(8) The identity of a sectoral contact point in each party's territory; and

(9) A statement regarding the establishment of a Joint Sectoral Committee.

(c) This part shall not be construed to entail mutual acceptance of standards or technical regulations of the parties and, unless otherwise specified in subpart A or B of this part, shall not entail the mutual recognition of the equivalence of standards or technical regulations.

§ 26.64 Transitional arrangements.

The parties agree to implement the transitional commitments on confidence building as specified in subparts A and B of this part.

(a) The parties agree that each sectoral transitional arrangement shall specify a time period for completion.

(b) The parties may amend any transitional arrangement by mutual agreement.

(c) Passage from the transitional phase to the operational phase shall

proceed as specified in subparts A and B of this part, unless either party documents that the conditions provided in such subpart for a successful transition are not met.

§ 26.65 Designating authorities.

The parties shall ensure that the designating authorities specified in subpart B of this part have the power and competence in their respective territories to carry out decisions under this part to designate, monitor, suspend, remove suspension of, or withdraw conformity assessment bodies (CAB's).

§ 26.66 Designation and listing procedures.

The following procedures shall apply with regard to the designation of conformity assessment bodies (CAB's) and the inclusion of such bodies in the list of CAB's in subpart B of this part:

(a) The designating authority identified in subpart B of this part shall designate CAB's in accordance with the procedures and criteria set forth in subpart B of this part;

(b) A party proposing to add a CAB to the list of such bodies in subpart B of this part shall forward its proposal of one or more designated CAB's in writing to the other party with a view to a decision by the Joint Committee;

(c) Within 60 days following receipt of the proposal, the other party shall indicate its position regarding either its confirmation or its opposition. Upon confirmation, the inclusion in subpart B of this part of the proposed CAB or CAB's shall take effect; and

(d) In the event that the other party contests on the basis of documented evidence the technical competence or compliance of a proposed CAB, or indicates in writing that it requires an additional 30 days to more fully verify such evidence, such CAB shall not be included on the list of CAB's in subpart B of this part. In this instance, the Joint Committee may decide that the body concerned be verified. After the completion of such verification, the proposal to list the CAB in subpart B may be resubmitted to the other party.

§ 26.67 Suspension of listed conformity assessment bodies.

The following procedures shall apply with regard to the suspension of a conformity assessment body (CAB) listed in subpart B of this part.

(a) A party shall notify the other party of its contestation of the technical competence or compliance of a CAB listed in subpart B of this part and the contesting party's intent to suspend such CAB. Such contestation shall be exercised when justified in an objective and reasoned manner in writing to the other party;

(b) The CAB shall be given prompt notice by the other party and an opportunity to present information in order to refute the contestation or to correct the deficiencies which form the basis of the contestation;

(c) Any such contestation shall be discussed between the parties in the Joint Sectoral Committee described in subpart B of this part. If there is no Joint Sectoral Committee, the contesting party shall refer the matter directly to the Joint Committee. If agreement to suspend is reached by the Joint Sectoral Committee or, if there is no Joint Sectoral Committee, by the Joint Committee, the CAB shall be suspended;

(d) Where the Joint Sectoral Committee or Joint Committee decides that verification of technical competence or compliance is required, it shall normally be carried out in a timely manner by the party in whose territory the body in question is located, but may be carried out jointly by the parties in justified cases;

(e) If the matter has not been resolved by the Joint Sectoral Committee within 10 days of the notice of contestation, the matter shall be referred to the Joint Committee for a decision. If there is no Joint Sectoral Committee, the matter shall be referred directly to the Joint Committee. If no decision is reached by the Joint Committee within 10 days of the referral to it, the CAB shall be suspended upon the request of the contesting party;

(f) Upon the suspension of a CAB listed in subpart B of this part, a party is

no longer obligated to accept or recognize the results of conformity assessment procedures performed by that CAB subsequent to suspension. A party shall continue to accept the results of conformity assessment procedures performed by that CAB prior to suspension, unless a regulatory authority of the party decides otherwise based on health, safety or environmental considerations or failure to satisfy other requirements within the scope of subpart B of this part; and

(g) The suspension shall remain in effect until agreement has been reached by the parties upon the future status of that body.

§ 26.68 Withdrawal of listed conformity assessment bodies.

The following procedures shall apply with regard to the withdrawal from subpart B of this part of a conformity assessment body (CAB):

(a) A party proposing to withdraw a CAB listed in subpart B of this part shall forward its proposal in writing to the other party;

(b) Such CAB shall be promptly notified by the other party and shall be provided a period of at least 30 days from receipt to provide information in order to refute or to correct the deficiencies which form the basis of the proposed withdrawal;

(c) Within 60 days following receipt of the proposal, the other party shall indicate its position regarding either its confirmation or its opposition. Upon confirmation, the withdrawal from the list in subpart B of this part of the CAB shall take effect;

(d) In the event the other party opposes the proposal to withdraw by supporting the technical competence and compliance of the CAB, the CAB shall not at that time be withdrawn from the list of CAB's in subpart B of this part. In this instance, the Joint Sectoral Committee or the Joint Committee may decide to carry out a joint verification of the body concerned. After the completion of such verification, the proposal for withdrawal of the CAB may be resubmitted to the other party; and

(e) Subsequent to the withdrawal of a CAB listed in subpart B of this part, a party shall continue to accept the results of conformity assessment procedures performed by that CAB prior to withdrawal, unless a regulatory authority of the party decides otherwise based on health, safety, and environmental considerations or failure to satisfy other requirements within the scope of subpart B of this part.

§ 26.69 Monitoring of conformity assessment bodies.

The following shall apply with regard to the monitoring of conformity assessment bodies (CAB's) listed in subpart B of this part:

(a) Designating authorities shall assure that their CAB's listed in subpart B of this part are capable and remain capable of properly assessing conformity of products or processes, as applicable, and as covered in subpart B of this part. In this regard, designating authorities shall maintain, or cause to maintain, ongoing surveillance over their CAB's by means of regular audit or assessment;

(b) The parties undertake to compare methods used to verify that the CAB's listed in subpart B of this part comply with the relevant requirements of subpart B of this part. Existing systems for the evaluation of CAB's may be used as part of such comparison procedures;

(c) Designating authorities shall consult as necessary with their counterparts, to ensure the maintenance of confidence in conformity assessment procedures. With the consent of both parties, this consultation may include joint participation in audits/inspections related to conformity assessment activities or other assessments of CAB's listed in subpart B of this part; and

(d) Designating authorities shall consult, as necessary, with the relevant regulatory authorities of the other party to ensure that all technical requirements are identified and are satisfactorily addressed.

§ 26.70 Conformity assessment bodies.

Each party recognizes that the conformity assessment bodies (CAB's) listed in subpart B of this part fulfill the conditions of eligibility to assess conformity in relation to its requirements as specified in subpart B of this part.

The parties shall specify the scope of the conformity assessment procedures for which such bodies are listed.

§ 26.71 Exchange of information.

(a) The parties shall exchange information concerning the implementation of the legislative, regulatory, and administrative provisions identified in subparts A and B of this part.

(b) Each party shall notify the other party of legislative, regulatory, and administrative changes related to the subject matter of this part at least 60 days before their entry into force. Where considerations of safety, health or environmental protection require more urgent action, a party shall notify the other party as soon as practicable.

(c) Each party shall promptly notify the other party of any changes to its designating authorities and/or conformity assessment bodies (CAB's).

(d) The parties shall exchange information concerning the procedures used to ensure that the listed CAB's under their responsibility comply with the legislative, regulatory, and administrative provisions outlined in subpart B of this part.

(e) Regulatory authorities identified in subparts A and B of this part shall consult as necessary with their counterparts, to ensure the maintenance of confidence in conformity assessment procedures and to ensure that all technical requirements are identified and are satisfactorily addressed.

§ 26.72 Sectoral contact points.

Each party shall appoint and confirm in writing contact points to be responsible for activities under subparts A and B of this part.

§ 26.73 Joint Committee.

(a) A Joint Committee consisting of representatives of the United States and the European Community (EC) will be established. The Joint Committee shall be responsible for the effective functioning of the ''Agreement on Mutual Recognition Between the United States of America and the European Community,'' from which this part is derived.

(b) The Joint Committee may establish Joint Sectoral Committees comprised of appropriate regulatory authorities and others deemed necessary.

(c) The United States and the EC shall each have one vote in the Joint Committee. The Joint Committee shall make its decisions by unanimous consent. The Joint Committee shall determine its own rules and procedures.

(d) The Joint Committee may consider any matter relating to the effective functioning of that agreement. In particular it shall be responsible for:

(1) Listing, suspension, withdrawal and verification of conformity assessment bodies (CAB's) in accordance with that agreement;

(2) Amending transitional arrangements in the sectoral annexes to that agreement;

(3) Resolving any questions relating to the application of that agreement not otherwise resolved in the respective Joint Sectoral Committees;

(4) Providing a forum for discussion of issues that may arise concerning the implementation of that agreement;

(5) Considering ways to enhance the operation of that agreement;

(6) Coordinating the negotiation of additional sectoral annexes to that agreement; and

(7) Considering whether to amend that agreement in accordance with § 26.80.

(e) When a party introduces new or additional conformity assessment procedures affecting a sectoral annex to that agreement, the parties shall discuss the matter in the Joint Committee with a view to bringing such new or additional procedures within the scope of that agreement and the relevant sectoral annex.

§ 26.74 Preservation of regulatory authority.

(a) Nothing in this part shall be construed to limit the authority of a party to determine, through its legislative, regulatory, and administrative measures, the level of protection it considers appropriate for safety; for protection of human, animal, or plant life or health; for the environment; for consumers; and otherwise with regard to risks within the scope of the applicable subpart A or B of this part.

(b) Nothing in this part shall be construed to limit the authority of a regulatory authority to take all appropriate and immediate measures whenever it ascertains that a product may:

(1) Compromise the health or safety of persons in its territory;

(2) Not meet the legislative, regulatory, or administrative provisions within the scope of the applicable subpart A or B of this part; or

(3) Otherwise fail to satisfy a requirement within the scope of the applicable subpart A or B of this part. Such measures may include withdrawing the products from the market, prohibiting their placement on the market, restricting their free movement, initiating a product recall, and preventing the recurrence of such problems, including through a prohibition on imports. If the regulatory authority takes such action, it shall inform its counterpart authority and the other party within 15 days of taking such action, providing its reasons.

§ 26.75 Suspension of recognition obligations.

Either party may suspend its obligations under subpart A or B of this part, in whole or in part, if:

(a) A party suffers a loss of market access for the party's products within the scope of subpart A or B of this part as a result of the failure of the other party to fulfill its obligations under this part;

(b) The adoption of new or additional conformity assessment requirements as referenced in § 26.73(e) results in a loss of market access for the party's products within the scope of subpart B of this part because conformity assessment bodies (CAB's) designated by the party in order to meet such requirements have not been recognized by the party implementing the requirements; or

(c) The other party fails to maintain legal and regulatory authorities capable of implementing the provisions of this part.

§ 26.76 Confidentiality.

(a) Each party agrees to maintain, to the extent required under its laws, the confidentiality of information exchanged under this part.

(b) In particular, neither party shall disclose to the public, nor permit a conformity assessment body (CAB) to disclose to the public, information exchanged under this part that constitutes trade secrets, confidential commercial or financial information, or information that relates to an ongoing investigation.

(c) A party or a CAB may, upon exchanging information with the other party or with a CAB of the other party, designate the portions of the information that it considers to be exempt from disclosure.

(d) Each party shall take all precautions reasonably necessary to protect information exchanged under this part from unauthorized disclosure.

§ 26.77 Fees.

Each party shall endeavor to ensure that fees imposed for services under this part shall be commensurate with the services provided. Each party shall ensure that, for the sectors and conformity assessment procedures covered under this part, it shall charge no fees with respect to conformity assessment services provided by the other party.

§ 26.78 Agreements with other countries.

Except where there is written agreement between the parties, obligations contained in mutual recognition agreements concluded by either party with a party not a party to the agreement from which this part is derived (a third party) shall have no force and effect with regard to the other party in terms of acceptance of the results of conformity assessment procedures in the third party.

§ 26.79 Territorial application.

The agreement from which this part is derived shall apply, on the one hand, to the territories in which the Treaty establishing the European Community (EC) is applied, and under the conditions laid down in that Treaty and, on the other hand, to the territory of the United States.

§ 26.80 Entry into force, amendment, and termination.

(a) The ''Agreement on Mutual Recognition Between the United States of

America and the European Community,'' from which this part is derived, including its sectoral annexes on telecommunication equipment, electromagnetic compatibility, electrical safety, recreational craft, pharmaceutical Good Manufacturing Practices (GMP) inspections, and medical devices shall enter into force on the first day of the second month following the date on which the parties have exchanged letters confirming the completion of their respective procedures for the entry into force of that agreement.

(b) That agreement including any sectoral annex may, through the Joint Committee, be amended in writing by the parties to that agreement. Those parties may add a sectoral annex upon the exchange of letters. Such annex shall enter into force 30 days following the date on which those parties have exchanged letters confirming the completion of their respective procedures for the entry into force of the sectoral annex.

(c) Either party to that agreement may terminate that agreement in its entirety or any individual sectoral annex thereof by giving the other party to that agreement 6-months notice in writing. In the case of termination of one or more sectoral annexes, the parties to that agreement will seek to achieve by consensus to amend that agreement, with a view to preserving the remaining Sectoral Annexes, in accordance with the procedures in this section. Failing such consensus, that agreement shall terminate at the end of 6 months from the date of notice.

(d) Following termination of that agreement in its entirety or any individual sectoral annex thereof, a party to that agreement shall continue to accept the results of conformity assessment procedures performed by conformity assessment bodies under that agreement prior to termination, unless a regulatory authority in the party decides otherwise based on health, safety and environmental considerations or failure to satisfy other requirements within the scope of the applicable sectoral annex.

§ 26.81 Final provisions.

(a) The sectoral annexes referred to in § 26.80(a), as well as any new sectoral annexes added pursuant to § 26.80(b), shall form an integral part of the ''Agreement on Mutual Recognition Between the United States of America and the European Community,'' from which this part is derived.

(b) For a given product or sector, the provisions contained in subparts A and B of this part shall apply in the first place, and the provisions of subpart C of this part in addition to those provisions. In the case of any inconsistency between the provisions of subpart A or B of this part and subpart C of this part, subpart A or B shall prevail, to the extent of that inconsistency.

(c) The agreement from which this part is derived shall not affect the rights and obligations of the parties under any other international agreement.

(d) In the case of subpart B of this part, the parties shall review the status of such subpart at the end of 3 years from the date described in § 26.80(a).

PART 50—PROTECTION OF HUMAN SUBJECTS

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AUTHORITY: 21 U.S.C 321, 343, 346, 346a, 348, 350a, 350b, 352, 353, 355, 360, 360c–360f, 360h–360j, 371, 379e, 381; 42 U.S.C. 216, 241, 262, 263b–263n.

SOURCE: 45 FR 36390, May 30, 1980, unless otherwise noted.

Subpart A—General Provisions

§ 50.1 Scope.

(a) This part applies to all clinical investigations regulated by the Food and Drug Administration under sections 505(i) and 520(g) of the Federal Food, Drug, and Cosmetic Act, as well as clinical investigations that support applications for research or marketing permits for products regulated by the Food and Drug Administration, including foods, including dietary supplements, that bear a nutrient content claim or a health claim, infant formulas, food and color additives, drugs for human use, medical devices for human use, biological products for human use, and electronic products. Additional specific obligations and commitments of, and standards of conduct for, persons who sponsor or monitor clinical investigations involving particular test articles may also be found in other parts (e.g., parts 312 and 812). Compliance with these parts is intended to protect the rights and safety of subjects involved in investigations filed with the Food and Drug Administration pursuant to sections 403, 406, 409, 412, 413, 502, 503, 505, 510, 513–516, 518–520, 721, and 801 of the Federal Food, Drug, and Cosmetic Act and sections 351 and 354–360F of the Public Health Service Act.

(b) References in this part to regulatory sections of the Code of Federal Regulations are to chapter I of title 21, unless otherwise noted.

[45 FR 36390, May 30, 1980; 46 FR 8979, Jan. 27, 1981, as amended at 63 FR 26697, May 13, 1998; 64 FR 399, Jan. 5, 1999; 66 FR 20597, Apr. 24, 2001]

§ 50.3 Definitions.

As used in this part:

(a) *Act* means the Federal Food, Drug, and Cosmetic Act, as amended (secs. 201–902, 52 Stat. 1040 *et seq.* as amended (21 U.S.C. 321–392)).

(b) *Application for research or marketing permit* includes:

(1) A color additive petition, described in part 71.

(2) A food additive petition, described in parts 171 and 571.

(3) Data and information about a substance submitted as part of the procedures for establishing that the substance is generally recognized as safe for use that results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food, described in §§ 170.30 and 570.30.

(4) Data and information about a food additive submitted as part of the procedures for food additives permitted to be used on an interim basis pending additional study, described in § 180.1.

(5) Data and information about a substance submitted as part of the procedures for establishing a tolerance for unavoidable contaminants in food and food-packaging materials, described in section 406 of the act.

(6) An investigational new drug application, described in part 312 of this chapter.

(7) A new drug application, described in part 314.

(8) Data and information about the bioavailability or bioequivalence of drugs for human use submitted as part of the procedures for issuing, amending, or repealing a bioequivalence requirement, described in part 320.

(9) Data and information about an over-the-counter drug for human use submitted as part of the procedures for classifying these drugs as generally recognized as safe and effective and not misbranded, described in part 330.

(10) Data and information about a prescription drug for human use submitted as part of the procedures for classifying these drugs as generally recognized as safe and effective and not misbranded, described in this chapter.

(11) [Reserved]

(12) An application for a biologics license, described in part 601 of this chapter.

(13) Data and information about a biological product submitted as part of the procedures for determining that licensed biological products are safe and effective and not misbranded, described in part 601.

(14) Data and information about an in vitro diagnostic product submitted as part of the procedures for establishing, amending, or repealing a standard for these products, described in part 809.

(15) An *Application for an Investigational Device Exemption*, described in part 812.

(16) Data and information about a medical device submitted as part of the procedures for classifying these devices, described in section 513.

(17) Data and information about a medical device submitted as part of the procedures for establishing, amending, or repealing a standard for these devices, described in section 514.

(18) An application for premarket approval of a medical device, described in section 515.

(19) A product development protocol for a medical device, described in section 515.

(20) Data and information about an electronic product submitted as part of the procedures for establishing, amending, or repealing a standard for these products, described in section 358 of the Public Health Service Act.

(21) Data and information about an electronic product submitted as part of the procedures for obtaining a variance from any electronic product performance standard, as described in § 1010.4.

(22) Data and information about an electronic product submitted as part of the procedures for granting, amending, or extending an exemption from a radiation safety performance standard, as described in § 1010.5.

(23) Data and information about a clinical study of an infant formula when submitted as part of an infant formula notification under section 412(c) of the Federal Food, Drug, and Cosmetic Act.

(24) Data and information submitted in a petition for a nutrient content claim, described in § 101.69 of this chapter, or for a health claim, described in § 101.70 of this chapter.

(25) Data and information from investigations involving children submitted in a new dietary ingredient notification, described in § 190.6 of this chapter.

(c) *Clinical investigation* means any experiment that involves a test article and one or more human subjects and that either is subject to requirements for prior submission to the Food and Drug Administration under section 505(i) or 520(g) of the act, or is not subject to requirements for prior submission to the Food and Drug Administration under these sections of the act, but the results of which are intended to be submitted later to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit. The term does not include experiments that are subject to the provisions of part 58 of this chapter, regarding nonclinical laboratory studies.

(d) *Investigator* means an individual who actually conducts a clinical investigation, i.e., under whose immediate direction the test article is administered or dispensed to, or used involving, a subject, or, in the event of an investigation conducted by a team of individuals, is the responsible leader of that team.

(e) *Sponsor* means a person who initiates a clinical investigation, but who does not actually conduct the investigation, i.e., the test article is administered or dispensed to or used involving, a subject under the immediate direction of another individual. A person other than an individual (e.g., corporation or agency) that uses one or more of its own employees to conduct a clinical investigation it has initiated is considered to be a sponsor (not a sponsor-investigator), and the employees are considered to be investigators.

(f) *Sponsor-investigator* means an individual who both initiates and actually

conducts, alone or with others, a clinical investigation, i.e., under whose immediate direction the test article is administered or dispensed to, or used involving, a subject. The term does not include any person other than an individual, e.g., corporation or agency.

(g) *Human subject* means an individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy human or a patient.

(h) *Institution* means any public or private entity or agency (including Federal, State, and other agencies). The word *facility* as used in section 520(g) of the act is deemed to be synonymous with the term *institution* for purposes of this part.

(i) *Institutional review board* (IRB) means any board, committee, or other group formally designated by an institution to review biomedical research involving humans as subjects, to approve the initiation of and conduct periodic review of such research. The term has the same meaning as the phrase *institutional review committee* as used in section 520(g) of the act.

(j) *Test article* means any drug (including a biological product for human use), medical device for human use, human food additive, color additive, electronic product, or any other article subject to regulation under the act or under sections 351 and 354–360F of the Public Health Service Act (42 U.S.C. 262 and 263b–263n).

(k) *Minimal risk* means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

(l) *Legally authorized representative* means an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's particpation in the procedure(s) involved in the research.

(m) *Family member* means any one of the following legally competent persons: Spouse; parents; children (including adopted children); brothers, sisters, and spouses of brothers and sisters; and any individual related by blood or affinity whose close association with the subject is the equivalent of a family relationship.

(n) *Assent* means a child's affirmative agreement to participate in a clinical investigation. Mere failure to object should not, absent affirmative agreement, be construed as assent.

(o) *Children* means persons who have not attained the legal age for consent to treatments or procedures involved in clinical investigations, under the applicable law of the jurisdiction in which the clinical investigation will be conducted.

(p) *Parent* means a child's biological or adoptive parent.

(q) *Ward* means a child who is placed in the legal custody of the State or other agency, institution, or entity, consistent with applicable Federal, State, or local law.

(r) *Permission* means the agreement of parent(s) or guardian to the participation of their child or ward in a clinical investigation.

(s) *Guardian* means an individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care.

[45 FR 36390, May 30, 1980, as amended at 46 FR 8950, Jan. 27, 1981; 54 FR 9038, Mar. 3, 1989; 56 FR 28028, June 18, 1991; 61 FR 51528, Oct. 2, 1996; 62 FR 39440, July 23, 1997; 64 FR 399, Jan. 5, 1999; 64 FR 56448, Oct. 20, 1999; 66 FR 20597, Apr. 24, 2001; 78 FR 12950, Feb. 26, 2013]

Subpart B—Informed Consent of Human Subjects

SOURCE: 46 FR 8951, Jan. 27, 1981, unless otherwise noted.

§ 50.20 General requirements for informed consent.

Except as provided in §§ 50.23 and 50.24, no investigator may involve a human being as a subject in research covered by these regulations unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize

the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.

[46 FR 8951, Jan. 27, 1981, as amended at 64 FR 10942, Mar. 8, 1999]

§ 50.23 Exception from general requirements.

(a) The obtaining of informed consent shall be deemed feasible unless, before use of the test article (except as provided in paragraph (b) of this section), both the investigator and a physician who is not otherwise participating in the clinical investigation certify in writing all of the following:

(1) The human subject is confronted by a life-threatening situation necessitating the use of the test article.

(2) Informed consent cannot be obtained from the subject because of an inability to communicate with, or obtain legally effective consent from, the subject.

(3) Time is not sufficient to obtain consent from the subject's legal representative.

(4) There is available no alternative method of approved or generally recognized therapy that provides an equal or greater likelihood of saving the life of the subject.

(b) If immediate use of the test article is, in the investigator's opinion, required to preserve the life of the subject, and time is not sufficient to obtain the independent determination required in paragraph (a) of this section in advance of using the test article, the determinations of the clinical investigator shall be made and, within 5 working days after the use of the article, be reviewed and evaluated in writing by a physician who is not participating in the clinical investigation.

(c) The documentation required in paragraph (a) or (b) of this section shall be submitted to the IRB within 5 working days after the use of the test article.

(d)(1) Under 10 U.S.C. 1107(f) the President may waive the prior consent requirement for the administration of an investigational new drug to a member of the armed forces in connection with the member's participation in a particular military operation. The statute specifies that only the President may waive informed consent in this connection and the President may grant such a waiver only if the President determines in writing that obtaining consent: Is not feasible; is contrary to the best interests of the military member; or is not in the interests of national security. The statute further provides that in making a determination to waive prior informed consent on the ground that it is not feasible or the ground that it is contrary to the best interests of the military members involved, the President shall apply the standards and criteria that are set forth in the relevant FDA regulations for a waiver of the prior informed consent requirements of section 505(i)(4) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)(4)). Before such a determination may be made that obtaining informed consent from military personnel prior to the use of an investigational drug (including an antibiotic or biological product) in a specific protocol under an investigational new drug application (IND) sponsored by the Department of Defense (DOD) and limited to specific military personnel involved in a particular military operation is not feasible or is contrary to the best interests of the military members involved the Secretary of Defense must first request such a determination from the President, and certify and document to the President that the following standards and criteria contained in paragraphs (d)(1) through (d)(4) of this section have been met.

(i) The extent and strength of evidence of the safety and effectiveness of the investigational new drug in relation to the medical risk that could be encountered during the military operation supports the drug's administration under an IND.

(ii) The military operation presents a substantial risk that military personnel may be subject to a chemical, biological, nuclear, or other exposure likely to produce death or serious or life-threatening injury or illness.

(iii) There is no available satisfactory alternative therapeutic or preventive treatment in relation to the intended use of the investigational new drug.

(iv) Conditioning use of the investigational new drug on the voluntary participation of each member could significantly risk the safety and health of any individual member who would decline its use, the safety of other military personnel, and the accomplishment of the military mission.

(v) A duly constituted institutional review board (IRB) established and operated in accordance with the requirements of paragraphs (d)(2) and (d)(3) of this section, responsible for review of the study, has reviewed and approved the investigational new drug protocol and the administration of the investigational new drug without informed consent. DOD's request is to include the documentation required by § 56.115(a)(2) of this chapter.

(vi) DOD has explained:

(A) The context in which the investigational drug will be administered, e.g., the setting or whether it will be self-administered or it will be administered by a health professional;

(B) The nature of the disease or condition for which the preventive or therapeutic treatment is intended; and

(C) To the extent there are existing data or information available, information on conditions that could alter the effects of the investigational drug.

(vii) DOD's recordkeeping system is capable of tracking and will be used to track the proposed treatment from supplier to the individual recipient.

(viii) Each member involved in the military operation will be given, prior to the administration of the investigational new drug, a specific written information sheet (including information required by 10 U.S.C. 1107(d)) concerning the investigational new drug, the risks and benefits of its use, potential side effects, and other pertinent information about the appropriate use of the product.

(ix) Medical records of members involved in the military operation will accurately document the receipt by members of the notification required by paragraph (d)(1)(viii) of this section.

(x) Medical records of members involved in the military operation will accurately document the receipt by members of any investigational new drugs in accordance with FDA regulations including part 312 of this chapter.

(xi) DOD will provide adequate followup to assess whether there are beneficial or adverse health consequences that result from the use of the investigational product.

(xii) DOD is pursuing drug development, including a time line, and marketing approval with due diligence.

(xiii) FDA has concluded that the investigational new drug protocol may proceed subject to a decision by the President on the informed consent waiver request.

(xiv) DOD will provide training to the appropriate medical personnel and potential recipients on the specific investigational new drug to be administered prior to its use.

(xv) DOD has stated and justified the time period for which the waiver is needed, not to exceed one year, unless separately renewed under these standards and criteria.

(xvi) DOD shall have a continuing obligation to report to the FDA and to the President any changed circumstances relating to these standards and criteria (including the time period referred to in paragraph (d)(1)(xv) of this section) or that otherwise might affect the determination to use an investigational new drug without informed consent.

(xvii) DOD is to provide public notice as soon as practicable and consistent with classification requirements through notice in the FEDERAL REGISTER describing each waiver of informed consent determination, a summary of the most updated scientific information on the products used, and other pertinent information.

(xviii) Use of the investigational drug without informed consent otherwise conforms with applicable law.

(2) The duly constituted institutional review board, described in paragraph (d)(1)(v) of this section, must include at

least 3 nonaffiliated members who shall not be employees or officers of the Federal Government (other than for purposes of membership on the IRB) and shall be required to obtain any necessary security clearances. This IRB shall review the proposed IND protocol at a convened meeting at which a majority of the members are present including at least one member whose primary concerns are in nonscientific areas and, if feasible, including a majority of the nonaffiliated members. The information required by § 56.115(a)(2) of this chapter is to be provided to the Secretary of Defense for further review.

(3) The duly constituted institutional review board, described in paragraph (d)(1)(v) of this section, must review and approve:

(i) The required information sheet;

(ii) The adequacy of the plan to disseminate information, including distribution of the information sheet to potential recipients, on the investigational product (e.g., in forms other than written);

(iii) The adequacy of the information and plans for its dissemination to health care providers, including potential side effects, contraindications, potential interactions, and other pertinent considerations; and

(iv) An informed consent form as required by part 50 of this chapter, in those circumstances in which DOD determines that informed consent may be obtained from some or all personnel involved.

(4) DOD is to submit to FDA summaries of institutional review board meetings at which the proposed protocol has been reviewed.

(5) Nothing in these criteria or standards is intended to preempt or limit FDA's and DOD's authority or obligations under applicable statutes and regulations.

(e)(1) Obtaining informed consent for investigational in vitro diagnostic devices used to identify chemical, biological, radiological, or nuclear agents will be deemed feasible unless, before use of the test article, both the investigator (e.g., clinical laboratory director or other responsible individual) and a physician who is not otherwise participating in the clinical investigation make the determinations and later certify in writing all of the following:

(i) The human subject is confronted by a life-threatening situation necessitating the use of the investigational in vitro diagnostic device to identify a chemical, biological, radiological, or nuclear agent that would suggest a terrorism event or other public health emergency.

(ii) Informed consent cannot be obtained from the subject because:

(A) There was no reasonable way for the person directing that the specimen be collected to know, at the time the specimen was collected, that there would be a need to use the investigational in vitro diagnostic device on that subject's specimen; and

(B) Time is not sufficient to obtain consent from the subject without risking the life of the subject.

(iii) Time is not sufficient to obtain consent from the subject's legally authorized representative.

(iv) There is no cleared or approved available alternative method of diagnosis, to identify the chemical, biological, radiological, or nuclear agent that provides an equal or greater likelihood of saving the life of the subject.

(2) If use of the investigational device is, in the opinion of the investigator (e.g., clinical laboratory director or other responsible person), required to preserve the life of the subject, and time is not sufficient to obtain the independent determination required in paragraph (e)(1) of this section in advance of using the investigational device, the determinations of the investigator shall be made and, within 5 working days after the use of the device, be reviewed and evaluated in writing by a physician who is not participating in the clinical investigation.

(3) The investigator must submit the written certification of the determinations made by the investigator and an independent physician required in paragraph (e)(1) or (e)(2) of this section to the IRB and FDA within 5 working days after the use of the device.

(4) An investigator must disclose the investigational status of the in vitro diagnostic device and what is known about the performance characteristics of the device in the report to the subject's health care provider and in any

report to public health authorities. The investigator must provide the IRB with the information required in § 50.25 (except for the information described in § 50.25(a)(8)) and the procedures that will be used to provide this information to each subject or the subject's legally authorized representative at the time the test results are provided to the subject's health care provider and public health authorities.

(5) The IRB is responsible for ensuring the adequacy of the information required in section 50.25 (except for the information described in § 50.25(a)(8)) and for ensuring that procedures are in place to provide this information to each subject or the subject's legally authorized representative.

(6) No State or political subdivision of a State may establish or continue in effect any law, rule, regulation or other requirement that informed consent be obtained before an investigational in vitro diagnostic device may be used to identify chemical, biological, radiological, or nuclear agent in suspected terrorism events and other potential public health emergencies that is different from, or in addition to, the requirements of this regulation.

[46 FR 8951, Jan. 27, 1981, as amended at 55 FR 52817, Dec. 21, 1990; 64 FR 399, Jan. 5, 1999; 64 FR 54188, Oct. 5, 1999; 71 FR 32833, June 7, 2006; 76 FR 36993, June 24, 2011]

§ 50.24 Exception from informed consent requirements for emergency research.

(a) The IRB responsible for the review, approval, and continuing review of the clinical investigation described in this section may approve that investigation without requiring that informed consent of all research subjects be obtained if the IRB (with the concurrence of a licensed physician who is a member of or consultant to the IRB and who is not otherwise participating in the clinical investigation) finds and documents each of the following:

(1) The human subjects are in a life-threatening situation, available treatments are unproven or unsatisfactory, and the collection of valid scientific evidence, which may include evidence obtained through randomized placebo-controlled investigations, is necessary to determine the safety and effectiveness of particular interventions.

(2) Obtaining informed consent is not feasible because:

(i) The subjects will not be able to give their informed consent as a result of their medical condition;

(ii) The intervention under investigation must be administered before consent from the subjects' legally authorized representatives is feasible; and

(iii) There is no reasonable way to identify prospectively the individuals likely to become eligible for participation in the clinical investigation.

(3) Participation in the research holds out the prospect of direct benefit to the subjects because:

(i) Subjects are facing a life-threatening situation that necessitates intervention;

(ii) Appropriate animal and other preclinical studies have been conducted, and the information derived from those studies and related evidence support the potential for the intervention to provide a direct benefit to the individual subjects; and

(iii) Risks associated with the investigation are reasonable in relation to what is known about the medical condition of the potential class of subjects, the risks and benefits of standard therapy, if any, and what is known about the risks and benefits of the proposed intervention or activity.

(4) The clinical investigation could not practicably be carried out without the waiver.

(5) The proposed investigational plan defines the length of the potential therapeutic window based on scientific evidence, and the investigator has committed to attempting to contact a legally authorized representative for each subject within that window of time and, if feasible, to asking the legally authorized representative contacted for consent within that window rather than proceeding without consent. The investigator will summarize efforts made to contact legally authorized representatives and make this information available to the IRB at the time of continuing review.

(6) The IRB has reviewed and approved informed consent procedures and an informed consent document

consistent with § 50.25. These procedures and the informed consent document are to be used with subjects or their legally authorized representatives in situations where use of such procedures and documents is feasible. The IRB has reviewed and approved procedures and information to be used when providing an opportunity for a family member to object to a subject's participation in the clinical investigation consistent with paragraph (a)(7)(v) of this section.

(7) Additional protections of the rights and welfare of the subjects will be provided, including, at least:

(i) Consultation (including, where appropriate, consultation carried out by the IRB) with representatives of the communities in which the clinical investigation will be conducted and from which the subjects will be drawn;

(ii) Public disclosure to the communities in which the clinical investigation will be conducted and from which the subjects will be drawn, prior to initiation of the clinical investigation, of plans for the investigation and its risks and expected benefits;

(iii) Public disclosure of sufficient information following completion of the clinical investigation to apprise the community and researchers of the study, including the demographic characteristics of the research population, and its results;

(iv) Establishment of an independent data monitoring committee to exercise oversight of the clinical investigation; and

(v) If obtaining informed consent is not feasible and a legally authorized representative is not reasonably available, the investigator has committed, if feasible, to attempting to contact within the therapeutic window the subject's family member who is not a legally authorized representative, and asking whether he or she objects to the subject's participation in the clinical investigation. The investigator will summarize efforts made to contact family members and make this information available to the IRB at the time of continuing review.

(b) The IRB is responsible for ensuring that procedures are in place to inform, at the earliest feasible opportunity, each subject, or if the subject remains incapacitated, a legally authorized representative of the subject, or if such a representative is not reasonably available, a family member, of the subject's inclusion in the clinical investigation, the details of the investigation and other information contained in the informed consent document. The IRB shall also ensure that there is a procedure to inform the subject, or if the subject remains incapacitated, a legally authorized representative of the subject, or if such a representative is not reasonably available, a family member, that he or she may discontinue the subject's participation at any time without penalty or loss of benefits to which the subject is otherwise entitled. If a legally authorized representative or family member is told about the clinical investigation and the subject's condition improves, the subject is also to be informed as soon as feasible. If a subject is entered into a clinical investigation with waived consent and the subject dies before a legally authorized representative or family member can be contacted, information about the clinical investigation is to be provided to the subject's legally authorized representative or family member, if feasible.

(c) The IRB determinations required by paragraph (a) of this section and the documentation required by paragraph (e) of this section are to be retained by the IRB for at least 3 years after completion of the clinical investigation, and the records shall be accessible for inspection and copying by FDA in accordance with § 56.115(b) of this chapter.

(d) Protocols involving an exception to the informed consent requirement under this section must be performed under a separate investigational new drug application (IND) or investigational device exemption (IDE) that clearly identifies such protocols as protocols that may include subjects who are unable to consent. The submission of those protocols in a separate IND/IDE is required even if an IND for the same drug product or an IDE for the same device already exists. Applications for investigations under this section may not be submitted as amendments under §§ 312.30 or 812.35 of this chapter.

(e) If an IRB determines that it cannot approve a clinical investigation because the investigation does not meet the criteria in the exception provided under paragraph (a) of this section or because of other relevant ethical concerns, the IRB must document its findings and provide these findings promptly in writing to the clinical investigator and to the sponsor of the clinical investigation. The sponsor of the clinical investigation must promptly disclose this information to FDA and to the sponsor's clinical investigators who are participating or are asked to participate in this or a substantially equivalent clinical investigation of the sponsor, and to other IRB's that have been, or are, asked to review this or a substantially equivalent investigation by that sponsor.

[61 FR 51528, Oct. 2, 1996]

§ 50.25 Elements of informed consent.

(a) *Basic elements of informed consent.* In seeking informed consent, the following information shall be provided to each subject:

(1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental.

(2) A description of any reasonably foreseeable risks or discomforts to the subject.

(3) A description of any benefits to the subject or to others which may reasonably be expected from the research.

(4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.

(5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained and that notes the possibility that the Food and Drug Administration may inspect the records.

(6) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained.

(7) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject.

(8) A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

(b) *Additional elements of informed consent.* When appropriate, one or more of the following elements of information shall also be provided to each subject:

(1) A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable.

(2) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent.

(3) Any additional costs to the subject that may result from participation in the research.

(4) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject.

(5) A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject.

(6) The approximate number of subjects involved in the study.

(c) When seeking informed consent for applicable clinical trials, as defined in 42 U.S.C. 282(j)(1)(A), the following statement shall be provided to each clinical trial subject in informed consent documents and processes. This will notify the clinical trial subject that clinical trial information has been or will be submitted for inclusion in the clinical trial registry databank under paragraph (j) of section 402 of the Public Health Service Act. The statement is: ''A description of this clinical

trial will be available on *http://www.ClinicalTrials.gov*, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.''

(d) The informed consent requirements in these regulations are not intended to preempt any applicable Federal, State, or local laws which require additional information to be disclosed for informed consent to be legally effective.

(e) Nothing in these regulations is intended to limit the authority of a physician to provide emergency medical care to the extent the physician is permitted to do so under applicable Federal, State, or local law.

[46 FR 8951, Jan. 27, 1981, as amended at 76 FR 270, Jan. 4, 2011]

§ 50.27 Documentation of informed consent.

(a) Except as provided in § 56.109(c), informed consent shall be documented by the use of a written consent form approved by the IRB and signed and dated by the subject or the subject's legally authorized representative at the time of consent. A copy shall be given to the person signing the form.

(b) Except as provided in § 56.109(c), the consent form may be either of the following:

(1) A written consent document that embodies the elements of informed consent required by § 50.25. This form may be read to the subject or the subject's legally authorized representative, but, in any event, the investigator shall give either the subject or the representative adequate opportunity to read it before it is signed.

(2) A *short form* written consent document stating that the elements of informed consent required by § 50.25 have been presented orally to the subject or the subject's legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Also, the IRB shall approve a written summary of what is to be said to the subject or the representative. Only the short form itself is to be signed by the subject or the representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining the consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the representative in addition to a copy of the short form.

[46 FR 8951, Jan. 27, 1981, as amended at 61 FR 57280, Nov. 5, 1996]

Subpart C [Reserved]

Subpart D—Additional Safeguards for Children in Clinical Investigations

SOURCE: 66 FR 20598, Apr. 24, 2001, unless otherwise noted.

§ 50.50 IRB duties.

In addition to other responsibilities assigned to IRBs under this part and part 56 of this chapter, each IRB must review clinical investigations involving children as subjects covered by this subpart D and approve only those clinical investigations that satisfy the criteria described in § 50.51, § 50.52, or § 50.53 and the conditions of all other applicable sections of this subpart D.

§ 50.51 Clinical investigations not involving greater than minimal risk.

Any clinical investigation within the scope described in §§ 50.1 and 56.101 of this chapter in which no greater than minimal risk to children is presented may involve children as subjects only if the IRB finds that:

(a) No greater than minimal risk to children is presented; and

(b) Adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians as set forth in § 50.55.

[78 FR 12951, Feb. 26, 2013]

§ 50.52 Clinical investigations involving greater than minimal risk but presenting the prospect of direct benefit to individual subjects.

Any clinical investigation within the scope described in §§ 50.1 and 56.101 of this chapter in which more than minimal risk to children is presented by an intervention or procedure that holds out the prospect of direct benefit for

the individual subject, or by a monitoring procedure that is likely to contribute to the subject's well-being, may involve children as subjects only if the IRB finds that:

(a) The risk is justified by the anticipated benefit to the subjects;

(b) The relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches; and

(c) Adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians as set forth in § 50.55.

[66 FR 20598, Apr. 24, 2001, as amended at 78 FR 12951, Feb. 26, 2013]

§ 50.53 Clinical investigations involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subjects' disorder or condition.

Any clinical investigation within the scope described in §§ 50.1 and 56.101 of this chapter in which more than minimal risk to children is presented by an intervention or procedure that does not hold out the prospect of direct benefit for the individual subject, or by a monitoring procedure that is not likely to contribute to the well-being of the subject, may involve children as subjects only if the IRB finds that:

(a) The risk represents a minor increase over minimal risk;

(b) The intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations;

(c) The intervention or procedure is likely to yield generalizable knowledge about the subjects' disorder or condition that is of vital importance for the understanding or amelioration of the subjects' disorder or condition; and

(d) Adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians as set forth in § 50.55.

[66 FR 20598, Apr. 24, 2001, as amended at 78 FR 12951, Feb. 26, 2013]

§ 50.54 Clinical investigations not otherwise approvable that present an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children.

If an IRB does not believe that a clinical investigation within the scope described in §§ 50.1 and 56.101 of this chapter and involving children as subjects meets the requirements of § 50.51, § 50.52, or § 50.53, the clinical investigation may proceed only if:

(a) The IRB finds that the clinical investigation presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children; and

(b) The Commissioner of Food and Drugs, after consultation with a panel of experts in pertinent disciplines (for example: science, medicine, education, ethics, law) and following opportunity for public review and comment, determines either:

(1) That the clinical investigation in fact satisfies the conditions of § 50.51, § 50.52, or § 50.53, as applicable, or

(2) That the following conditions are met:

(i) The clinical investigation presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children;

(ii) The clinical investigation will be conducted in accordance with sound ethical principles; and

(iii) Adequate provisions are made for soliciting the assent of children and the permission of their parents or guardians as set forth in § 50.55.

[66 FR 20598, Apr. 24, 2001, as amended at 78 FR 12951, Feb. 26, 2013]

§ 50.55 Requirements for permission by parents or guardians and for assent by children.

(a) In addition to the determinations required under other applicable sections of this subpart D, the IRB must determine that adequate provisions are made for soliciting the assent of the children when in the judgment of the IRB the children are capable of providing assent.

(b) In determining whether children are capable of providing assent, the

IRB must take into account the ages, maturity, and psychological state of the children involved. This judgment may be made for all children to be involved in clinical investigations under a particular protocol, or for each child, as the IRB deems appropriate.

(c) The assent of the children is not a necessary condition for proceeding with the clinical investigation if the IRB determines:

(1) That the capability of some or all of the children is so limited that they cannot reasonably be consulted, or

(2) That the intervention or procedure involved in the clinical investigation holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the clinical investigation.

(d) Even where the IRB determines that the subjects are capable of assenting, the IRB may still waive the assent requirement if it finds and documents that:

(1) The clinical investigation involves no more than minimal risk to the subjects;

(2) The waiver will not adversely affect the rights and welfare of the subjects;

(3) The clinical investigation could not practicably be carried out without the waiver; and

(4) Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

(e) In addition to the determinations required under other applicable sections of this subpart D, the IRB must determine, in accordance with and to the extent that consent is required under part 50, that the permission of each child's parents or guardian is granted.

(1) Where parental permission is to be obtained, the IRB may find that the permission of one parent is sufficient for clinical investigations to be conducted under § 50.51 or § 50.52.

(2) Where clinical investigations are covered by § 50.53 or § 50.54 and permission is to be obtained from parents, both parents must give their permission unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.

(f) Permission by parents or guardians must be documented in accordance with and to the extent required by § 50.27.

(g) When the IRB determines that assent is required, it must also determine whether and how assent must be documented.

[66 FR 20598, Apr. 24, 2001, as amended at 78 FR 12951, Feb. 26, 2013]

§ 50.56 Wards.

(a) Children who are wards of the State or any other agency, institution, or entity can be included in clinical investigations approved under § 50.53 or § 50.54 only if such clinical investigations are:

(1) Related to their status as wards; or

(2) Conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as subjects are not wards.

(b) If the clinical investigation is approved under paragraph (a) of this section, the IRB must require appointment of an advocate for each child who is a ward.

(1) The advocate will serve in addition to any other individual acting on behalf of the child as guardian or in loco parentis.

(2) One individual may serve as advocate for more than one child.

(3) The advocate must be an individual who has the background and experience to act in, and agrees to act in, the best interest of the child for the duration of the child's participation in the clinical investigation.

(4) The advocate must not be associated in any way (except in the role as advocate or member of the IRB) with the clinical investigation, the investigator(s), or the guardian organization.

PART 54—FINANCIAL DISCLOSURE BY CLINICAL INVESTIGATORS

Sec.

54.1 Purpose.
54.2 Definitions.
54.3 Scope.
54.4 Certification and disclosure requirements.

54.5 Agency evaluation of financial interests.
54.6 Recordkeeping and record retention.

AUTHORITY: 21 U.S.C. 321, 331, 351, 352, 353, 355, 360, 360c–360j, 371, 372, 373, 374, 375, 376, 379; 42 U.S.C. 262.

SOURCE: 63 FR 5250, Feb. 2, 1998, unless otherwise noted.

§ 54.1 Purpose.

(a) The Food and Drug Administration (FDA) evaluates clinical studies submitted in marketing applications, required by law, for new human drugs and biological products and marketing applications and reclassification petitions for medical devices.

(b) The agency reviews data generated in these clinical studies to determine whether the applications are approvable under the statutory requirements. FDA may consider clinical studies inadequate and the data inadequate if, among other things, appropriate steps have not been taken in the design, conduct, reporting, and analysis of the studies to minimize bias. One potential source of bias in clinical studies is a financial interest of the clinical investigator in the outcome of the study because of the way payment is arranged (e.g., a royalty) or because the investigator has a proprietary interest in the product (e.g., a patent) or because the investigator has an equity interest in the sponsor of the covered study. This section and conforming regulations require an applicant whose submission relies in part on clinical data to disclose certain financial arrangements between sponsor(s) of the covered studies and the clinical investigators and certain interests of the clinical investigators in the product under study or in the sponsor of the covered studies. FDA will use this information, in conjunction with information about the design and purpose of the study, as well as information obtained through on-site inspections, in the agency's assessment of the reliability of the data.

§ 54.2 Definitions.

For the purposes of this part:

(a) *Compensation affected by the outcome of clinical studies* means compensation that could be higher for a favorable outcome than for an unfavorable outcome, such as compensation that is explicitly greater for a favorable result or compensation to the investigator in the form of an equity interest in the sponsor of a covered study or in the form of compensation tied to sales of the product, such as a royalty interest.

(b) *Significant equity interest in the sponsor of a covered study* means any ownership interest, stock options, or other financial interest whose value cannot be readily determined through reference to public prices (generally, interests in a nonpublicly traded corporation), or any equity interest in a publicly traded corporation that exceeds $50,000 during the time the clinical investigator is carrying out the study and for 1 year following completion of the study.

(c) *Proprietary interest in the tested product* means property or other financial interest in the product including, but not limited to, a patent, trademark, copyright or licensing agreement.

(d) *Clinical investigator* means only a listed or identified investigator or subinvestigator who is directly involved in the treatment or evaluation of research subjects. The term also includes the spouse and each dependent child of the investigator.

(e) *Covered clinical study* means any study of a drug or device in humans submitted in a marketing application or reclassification petition subject to this part that the applicant or FDA relies on to establish that the product is effective (including studies that show equivalence to an effective product) or any study in which a single investigator makes a significant contribution to the demonstration of safety. This would, in general, not include phase 1 tolerance studies or pharmacokinetic studies, most clinical pharmacology studies (unless they are critical to an efficacy determination), large open safety studies conducted at multiple sites, treatment protocols, and parallel track protocols. An applicant may consult with FDA as to which clinical studies constitute ''covered clinical studies'' for purposes of complying with financial disclosure requirements.

(f) *Significant payments of other sorts* means payments made by the sponsor of a covered study to the investigator

or the institution to support activities of the investigator that have a monetary value of more than $25,000, exclusive of the costs of conducting the clinical study or other clinical studies, (e.g., a grant to fund ongoing research, compensation in the form of equipment or retainers for ongoing consultation or honoraria) during the time the clinical investigator is carrying out the study and for 1 year following the completion of the study.

(g) *Applicant* means the party who submits a marketing application to FDA for approval of a drug, device, or biologic product. The applicant is responsible for submitting the appropriate certification and disclosure statements required in this part.

(h) *Sponsor of the covered clinical study* means the party supporting a particular study at the time it was carried out.

[63 FR 5250, Feb. 2, 1998, as amended at 63 FR 72181, Dec. 31, 1998]

§ 54.3 Scope.

The requirements in this part apply to any applicant who submits a marketing application for a human drug, biological product, or device and who submits covered clinical studies. The applicant is responsible for making the appropriate certification or disclosure statement where the applicant either contracted with one or more clinical investigators to conduct the studies or submitted studies conducted by others not under contract to the applicant.

§ 54.4 Certification and disclosure requirements.

For purposes of this part, an applicant must submit a list of all clinical investigators who conducted covered clinical studies to determine whether the applicant's product meets FDA's marketing requirements, identifying those clinical investigators who are full-time or part-time employees of the sponsor of each covered study. The applicant must also completely and accurately disclose or certify information concerning the financial interests of a clinical investigator who is not a full-time or part-time employee of the sponsor for each covered clinical study. Clinical investigators subject to investigational new drug or investigational device exemption regulations must provide the sponsor of the study with sufficient accurate information needed to allow subsequent disclosure or certification. The applicant is required to submit for each clinical investigator who participates in a covered study, either a certification that none of the financial arrangements described in § 54.2 exist, or disclose the nature of those arrangements to the agency. Where the applicant acts with due diligence to obtain the information required in this section but is unable to do so, the applicant shall certify that despite the applicant's due diligence in attempting to obtain the information, the applicant was unable to obtain the information and shall include the reason.

(a) The applicant (of an application submitted under sections 505, 506, 510(k), 513, or 515 of the Federal Food, Drug, and Cosmetic Act, or section 351 of the Public Health Service Act) that relies in whole or in part on clinical studies shall submit, for each clinical investigator who participated in a covered clinical study, either a certification described in paragraph (a)(1) of this section or a disclosure statement described in paragraph (a)(3) of this section.

(1) Certification: The applicant covered by this section shall submit for all clinical investigators (as defined in § 54.2(d)), to whom the certification applies, a completed Form FDA 3454 attesting to the absence of financial interests and arrangements described in paragraph (a)(3) of this section. The form shall be dated and signed by the chief financial officer or other responsible corporate official or representative.

(2) If the certification covers less than all covered clinical data in the application, the applicant shall include in the certification a list of the studies covered by this certification.

(3) Disclosure Statement: For any clinical investigator defined in § 54.2(d) for whom the applicant does not submit the certification described in paragraph (a)(1) of this section, the applicant shall submit a completed Form FDA 3455 disclosing completely and accurately the following:

(i) Any financial arrangement entered into between the sponsor of the

covered study and the clinical investigator involved in the conduct of a covered clinical trial, whereby the value of the compensation to the clinical investigator for conducting the study could be influenced by the outcome of the study;

(ii) Any significant payments of other sorts from the sponsor of the covered study, such as a grant to fund ongoing research, compensation in the form of equipment, retainer for ongoing consultation, or honoraria;

(iii) Any proprietary interest in the tested product held by any clinical investigator involved in a study;

(iv) Any significant equity interest in the sponsor of the covered study held by any clinical investigator involved in any clinical study; and

(v) Any steps taken to minimize the potential for bias resulting from any of the disclosed arrangements, interests, or payments.

(b) The clinical investigator shall provide to the sponsor of the covered study sufficient accurate financial information to allow the sponsor to submit complete and accurate certification or disclosure statements as required in paragraph (a) of this section. The investigator shall promptly update this information if any relevant changes occur in the course of the investigation or for 1 year following completion of the study.

(c) Refusal to file application. FDA may refuse to file any marketing application described in paragraph (a) of this section that does not contain the information required by this section or a certification by the applicant that the applicant has acted with due diligence to obtain the information but was unable to do so and stating the reason.

[63 FR 5250, Feb. 2, 1998; 63 FR 35134, June 29, 1998, as amended at 64 FR 399, Jan. 5, 1999]

§ 54.5 Agency evaluation of financial interests.

(a) *Evaluation of disclosure statement.* FDA will evaluate the information disclosed under § 54.4(a)(2) about each covered clinical study in an application to determine the impact of any disclosed financial interests on the reliability of the study. FDA may consider both the size and nature of a disclosed financial interest (including the potential increase in the value of the interest if the product is approved) and steps that have been taken to minimize the potential for bias.

(b) *Effect of study design.* In assessing the potential of an investigator's financial interests to bias a study, FDA will take into account the design and purpose of the study. Study designs that utilize such approaches as multiple investigators (most of whom do not have a disclosable interest), blinding, objective endpoints, or measurement of endpoints by someone other than the investigator may adequately protect against any bias created by a disclosable financial interest.

(c) *Agency actions to ensure reliability of data.* If FDA determines that the financial interests of any clinical investigator raise a serious question about the integrity of the data, FDA will take any action it deems necessary to ensure the reliability of the data including:

(1) Initiating agency audits of the data derived from the clinical investigator in question;

(2) Requesting that the applicant submit further analyses of data, e.g., to evaluate the effect of the clinical investigator's data on overall study outcome;

(3) Requesting that the applicant conduct additional independent studies to confirm the results of the questioned study; and

(4) Refusing to treat the covered clinical study as providing data that can be the basis for an agency action.

§ 54.6 Recordkeeping and record retention.

(a) *Financial records of clinical investigators to be retained.* An applicant who has submitted a marketing application containing covered clinical studies shall keep on file certain information pertaining to the financial interests of clinical investigators who conducted studies on which the application relies and who are not full or part-time employees of the applicant, as follows:

(1) Complete records showing any financial interest or arrangement as described in § 54.4(a)(3)(i) paid to such clinical investigators by the sponsor of the covered study.

(2) Complete records showing significant payments of other sorts, as described in § 54.4(a)(3)(ii), made by the sponsor of the covered clinical study to the clinical investigator.

(3) Complete records showing any financial interests held by clinical investigators as set forth in § 54.4(a)(3)(iii) and (a)(3)(iv).

(b) *Requirements for maintenance of clinical investigators' financial records.* (1) For any application submitted for a covered product, an applicant shall retain records as described in paragraph (a) of this section for 2 years after the date of approval of the application.

(2) The person maintaining these records shall, upon request from any properly authorized officer or employee of FDA, at reasonable times, permit such officer or employee to have access to and copy and verify these records.

PART 56—INSTITUTIONAL REVIEW BOARDS

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AUTHORITY: 21 U.S.C. 321, 343, 346, 346a, 348, 350a, 350b, 351, 352, 353, 355, 360, 360c–360f, 360h, 360i, 360j, 360hh–360ss, 371, 379e, 381; 42 U.S.C. 216, 241, 262.

SOURCE: 46 FR 8975, Jan. 27, 1981, unless otherwise noted.

Subpart A—General Provisions

§ 56.101 Scope.

(a) This part contains the general standards for the composition, operation, and responsibility of an Institutional Review Board (IRB) that reviews clinical investigations regulated by the Food and Drug Administration under sections 505(i) and 520(g) of the act, as well as clinical investigations that support applications for research or marketing permits for products regulated by the Food and Drug Administration, including foods, including dietary supplements, that bear a nutrient content claim or a health claim, infant formulas, food and color additives, drugs for human use, medical devices for human use, biological products for human use, and electronic products. Compliance with this part is intended to protect the rights and welfare of human subjects involved in such investigations.

(b) References in this part to regulatory sections of the Code of Federal Regulations are to chapter I of title 21, unless otherwise noted.

[46 FR 8975, Jan. 27, 1981, as amended at 64 FR 399, Jan. 5, 1999; 66 FR 20599, Apr. 24, 2001]

§ 56.102 Definitions.

As used in this part:

(a) *Act* means the Federal Food, Drug, and Cosmetic Act, as amended (secs. 201–902, 52 Stat. 1040 *et seq.*, as amended (21 U.S.C. 321–392)).

(b) *Application for research or marketing permit* includes:

(1) A color additive petition, described in part 71.

(2) Data and information regarding a substance submitted as part of the procedures for establishing that a substance is generally recognized as safe for a use which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food, described in § 170.35.

(3) A food additive petition, described in part 171.

(4) Data and information regarding a food additive submitted as part of the procedures regarding food additives permitted to be used on an interim basis pending additional study, described in § 180.1.

(5) Data and information regarding a substance submitted as part of the procedures for establishing a tolerance for unavoidable contaminants in food and food-packaging materials, described in section 406 of the act.

(6) An investigational new drug application, described in part 312 of this chapter.

(7) A new drug application, described in part 314.

(8) Data and information regarding the bioavailability or bioequivalence of drugs for human use submitted as part of the procedures for issuing, amending, or repealing a bioequivalence requirement, described in part 320.

(9) Data and information regarding an over-the-counter drug for human use submitted as part of the procedures for classifying such drugs as generally recognized as safe and effective and not misbranded, described in part 330.

(10) An application for a biologics license, described in part 601 of this chapter.

(11) Data and information regarding a biological product submitted as part of the procedures for determining that licensed biological products are safe and effective and not misbranded, as described in part 601 of this chapter.

(12) An Application for an Investigational Device Exemption, described in part 812.

(13) Data and information regarding a medical device for human use submitted as part of the procedures for classifying such devices, described in part 860.

(14) Data and information regarding a medical device for human use submitted as part of the procedures for establishing, amending, or repealing a standard for such device, described in part 861.

(15) An application for premarket approval of a medical device for human use, described in section 515 of the act.

(16) A product development protocol for a medical device for human use, described in section 515 of the act.

(17) Data and information regarding an electronic product submitted as part of the procedures for establishing, amending, or repealing a standard for such products, described in section 358 of the Public Health Service Act.

(18) Data and information regarding an electronic product submitted as part of the procedures for obtaining a variance from any electronic product performance standard, as described in § 1010.4.

(19) Data and information regarding an electronic product submitted as part of the procedures for granting, amending, or extending an exemption from a radiation safety performance standard, as described in § 1010.5.

(20) Data and information regarding an electronic product submitted as part of the procedures for obtaining an exemption from notification of a radiation safety defect or failure of compliance with a radiation safety performance standard, described in subpart D of part 1003.

(21) Data and information about a clinical study of an infant formula when submitted as part of an infant formula notification under section 412(c) of the Federal Food, Drug, and Cosmetic Act.

(22) Data and information submitted in a petition for a nutrient content claim, described in § 101.69 of this chapter, and for a health claim, described in § 101.70 of this chapter.

(23) Data and information from investigations involving children submitted in a new dietary ingredient notification, described in § 190.6 of this chapter.

(c) *Clinical investigation* means any experiment that involves a test article and one or more human subjects, and that either must meet the requirements for prior submission to the Food and Drug Administration under section

505(i) or 520(g) of the act, or need not meet the requirements for prior submission to the Food and Drug Administration under these sections of the act, but the results of which are intended to be later submitted to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit. The term does not include experiments that must meet the provisions of part 58, regarding nonclinical laboratory studies. The terms *research*, *clinical research*, *clinical study*, *study*, and *clinical investigation* are deemed to be synonymous for purposes of this part.

(d) *Emergency use* means the use of a test article on a human subject in a life-threatening situation in which no standard acceptable treatment is available, and in which there is not sufficient time to obtain IRB approval.

(e) *Human subject* means an individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy individual or a patient.

(f) *Institution* means any public or private entity or agency (including Federal, State, and other agencies). The term *facility* as used in section 520(g) of the act is deemed to be synonymous with the term *institution* for purposes of this part.

(g) *Institutional Review Board (IRB)* means any board, committee, or other group formally designated by an institution to review, to approve the initiation of, and to conduct periodic review of, biomedical research involving human subjects. The primary purpose of such review is to assure the protection of the rights and welfare of the human subjects. The term has the same meaning as the phrase *institutional review committee* as used in section 520(g) of the act.

(h) *Investigator* means an individual who actually conducts a clinical investigation (i.e., under whose immediate direction the test article is administered or dispensed to, or used involving, a subject) or, in the event of an investigation conducted by a team of individuals, is the responsible leader of that team.

(i) *Minimal risk* means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

(j) *Sponsor* means a person or other entity that initiates a clinical investigation, but that does not actually conduct the investigation, i.e., the test article is administered or dispensed to, or used involving, a subject under the immediate direction of another individual. A person other than an individual (e.g., a corporation or agency) that uses one or more of its own employees to conduct an investigation that it has initiated is considered to be a sponsor (not a sponsor-investigator), and the employees are considered to be investigators.

(k) *Sponsor-investigator* means an individual who both initiates and actually conducts, alone or with others, a clinical investigation, i.e., under whose immediate direction the test article is administered or dispensed to, or used involving, a subject. The term does not include any person other than an individual, e.g., it does not include a corporation or agency. The obligations of a sponsor-investigator under this part include both those of a sponsor and those of an investigator.

(l) *Test article* means any drug for human use, biological product for human use, medical device for human use, human food additive, color additive, electronic product, or any other article subject to regulation under the act or under sections 351 or 354–360F of the Public Health Service Act.

(m) *IRB approval* means the determination of the IRB that the clinical investigation has been reviewed and may be conducted at an institution within the constraints set forth by the IRB and by other institutional and Federal requirements.

[46 FR 8975, Jan. 27, 1981, as amended at 54 FR 9038, Mar. 3, 1989; 56 FR 28028, June 18, 1991; 64 FR 399, Jan. 5, 1999; 64 FR 56448, Oct. 20, 1999; 65 FR 52302, Aug. 29, 2000; 66 FR 20599, Apr. 24, 2001; 74 FR 2368, Jan. 15, 2009]

§ 56.103 Circumstances in which IRB review is required.

(a) Except as provided in §§ 56.104 and 56.105, any clinical investigation which

must meet the requirements for prior submission (as required in parts 312, 812, and 813) to the Food and Drug Administration shall not be initiated unless that investigation has been reviewed and approved by, and remains subject to continuing review by, an IRB meeting the requirements of this part.

(b) Except as provided in §§ 56.104 and 56.105, the Food and Drug Administration may decide not to consider in support of an application for a research or marketing permit any data or information that has been derived from a clinical investigation that has not been approved by, and that was not subject to initial and continuing review by, an IRB meeting the requirements of this part. The determination that a clinical investigation may not be considered in support of an application for a research or marketing permit does not, however, relieve the applicant for such a permit of any obligation under any other applicable regulations to submit the results of the investigation to the Food and Drug Administration.

(c) Compliance with these regulations will in no way render inapplicable pertinent Federal, State, or local laws or regulations.

[46 FR 8975, Jan. 27, 1981; 46 FR 14340, Feb. 27, 1981]

§ 56.104 Exemptions from IRB requirement.

The following categories of clinical investigations are exempt from the requirements of this part for IRB review:

(a) Any investigation which commenced before July 27, 1981 and was subject to requirements for IRB review under FDA regulations before that date, provided that the investigation remains subject to review of an IRB which meets the FDA requirements in effect before July 27, 1981.

(b) Any investigation commenced before July 27, 1981 and was not otherwise subject to requirements for IRB review under Food and Drug Administration regulations before that date.

(c) Emergency use of a test article, provided that such emergency use is reported to the IRB within 5 working days. Any subsequent use of the test article at the institution is subject to IRB review.

(d) Taste and food quality evaluations and consumer acceptance studies, if wholesome foods without additives are consumed or if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural, chemical, or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

[46 FR 8975, Jan. 27, 1981, as amended at 56 FR 28028, June 18, 1991]

§ 56.105 Waiver of IRB requirement.

On the application of a sponsor or sponsor-investigator, the Food and Drug Administration may waive any of the requirements contained in these regulations, including the requirements for IRB review, for specific research activities or for classes of research activities, otherwise covered by these regulations.

Subpart B—Organization and Personnel

§ 56.106 Registration.

(a) *Who must register?* Each IRB in the United States that reviews clinical investigations regulated by FDA under sections 505(i) or 520(g) of the act and each IRB in the United States that reviews clinical investigations that are intended to support applications for research or marketing permits for FDA-regulated products must register at a site maintained by the Department of Health and Human Services (HHS). (A research permit under section 505(i) of the act is usually known as an investigational new drug application (IND), while a research permit under section 520(g) of the act is usually known as an investigational device exemption (IDE).) An individual authorized to act on the IRB's behalf must submit the registration information. All other IRBs may register voluntarily.

(b) *What information must an IRB register?* Each IRB must provide the following information:

(1) The name, mailing address, and street address (if different from the

mailing address) of the institution operating the IRB and the name, mailing address, phone number, facsimile number, and electronic mail address of the senior officer of that institution who is responsible for overseeing activities performed by the IRB;

(2) The IRB's name, mailing address, street address (if different from the mailing address), phone number, facsimile number, and electronic mail address; each IRB chairperson's name, phone number, and electronic mail address; and the name, mailing address, phone number, facsimile number, and electronic mail address of the contact person providing the registration information.

(3) The approximate number of active protocols involving FDA-regulated products reviewed. For purposes of this rule, an ''active protocol'' is any protocol for which an IRB conducted an initial review or a continuing review at a convened meeting or under an expedited review procedure during the preceding 12 months; and

(4) A description of the types of FDA-regulated products (such as biological products, color additives, food additives, human drugs, or medical devices) involved in the protocols that the IRB reviews.

(c) *When must an IRB register?* Each IRB must submit an initial registration. The initial registration must occur before the IRB begins to review a clinical investigation described in paragraph (a) of this section. Each IRB must renew its registration every 3 years. IRB registration becomes effective after review and acceptance by HHS.

(d) *Where can an IRB register?* Each IRB may register electronically through *http://ohrp.cit.nih.gov/efile*. If an IRB lacks the ability to register electronically, it must send its registration information, in writing, to the Office of Good Clinical Practice, Office of Special Medical Programs, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5129, Silver Spring, MD 20993.

(e) *How does an IRB revise its registration information?* If an IRB's contact or chair person information changes, the IRB must revise its registration information by submitting any changes in that information within 90 days of the change. An IRB's decision to review new types of FDA-regulated products (such as a decision to review studies pertaining to food additives whereas the IRB previously reviewed studies pertaining to drug products), or to discontinue reviewing clinical investigations regulated by FDA is a change that must be reported within 30 days of the change. An IRB's decision to disband is a change that must be reported within 30 days of permanent cessation of the IRB's review of research. All other information changes may be reported when the IRB renews its registration. The revised information must be sent to FDA either electronically or in writing in accordance with paragraph (d) of this section.

[74 FR 2368, Jan. 15, 2009, as amended at 78 FR 16401, Mar. 15, 2013]

§ 56.107 IRB membership.

(a) Each IRB shall have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. The IRB shall be sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including consideration of race, gender, cultural backgrounds, and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. In addition to possessing the professional competence necessary to review the specific research activities, the IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. * * * The IRB shall therefore include persons knowledgeable in these areas. If an IRB regularly reviews research that involves a vulnerable category of subjects, such as children, prisoners, pregnant women, or handicapped or mentally disabled persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with those subjects.

(b) Every nondiscriminatory effort will be made to ensure that no IRB

consists entirely of men or entirely of women, including the instituton's consideration of qualified persons of both sexes, so long as no selection is made to the IRB on the basis of gender. No IRB may consist entirely of members of one profession.

(c) Each IRB shall include at least one member whose primary concerns are in the scientific area and at least one member whose primary concerns are in nonscientific areas.

(d) Each IRB shall include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.

(e) No IRB may have a member participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.

(f) An IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of complex issues which require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB.

[46 FR 8975, Jan. 27, 1981, as amended at 56 FR 28028, June 18, 1991; 56 FR 29756, June 28, 1991; 78 FR 16401, Mar. 15, 2013]

Subpart C—IRB Functions and Operations

§ 56.108 IRB functions and operations.

In order to fulfill the requirements of these regulations, each IRB shall:

(a) Follow written procedures: (1) For conducting its initial and continuing review of research and for reporting its findings and actions to the investigator and the institution; (2) for determining which projects require review more often than annually and which projects need verification from sources other than the investigator that no material changes have occurred since previous IRB review; (3) for ensuring prompt reporting to the IRB of changes in research activity; and (4) for ensuring that changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval except where necessary to eliminate apparent immediate hazards to the human subjects.

(b) Follow written procedures for ensuring prompt reporting to the IRB, appropriate institutional officials, and the Food and Drug Administration of: (1) Any unanticipated problems involving risks to human subjects or others; (2) any instance of serious or continuing noncompliance with these regulations or the requirements or determinations of the IRB; or (3) any suspension or termination of IRB approval.

(c) Except when an expedited review procedure is used (see § 56.110), review proposed research at convened meetings at which a majority of the members of the IRB are present, including at least one member whose primary concerns are in nonscientific areas. In order for the research to be approved, it shall receive the approval of a majority of those members present at the meeting.

[46 FR 8975, Jan. 27, 1981, as amended at 56 FR 28028, June 18, 1991; 67 FR 9585, Mar. 4, 2002]

§ 56.109 IRB review of research.

(a) An IRB shall review and have authority to approve, require modifications in (to secure approval), or disapprove all research activities covered by these regulations.

(b) An IRB shall require that information given to subjects as part of informed consent is in accordance with § 50.25. The IRB may require that information, in addition to that specifically mentioned in § 50.25, be given to the subjects when in the IRB's judgment the information would meaningfully add to the protection of the rights and welfare of subjects.

(c) An IRB shall require documentation of informed consent in accordance with § 50.27 of this chapter, except as follows:

(1) The IRB may, for some or all subjects, waive the requirement that the subject, or the subject's legally authorized representative, sign a written consent form if it finds that the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside the research context; or

(2) The IRB may, for some or all subjects, find that the requirements in § 50.24 of this chapter for an exception from informed consent for emergency research are met.

(d) In cases where the documentation requirement is waived under paragraph (c)(1) of this section, the IRB may require the investigator to provide subjects with a written statement regarding the research.

(e) An IRB shall notify investigators and the institution in writing of its decision to approve or disapprove the proposed research activity, or of modifications required to secure IRB approval of the research activity. If the IRB decides to disapprove a research activity, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing. For investigations involving an exception to informed consent under § 50.24 of this chapter, an IRB shall promptly notify in writing the investigator and the sponsor of the research when an IRB determines that it cannot approve the research because it does not meet the criteria in the exception provided under § 50.24(a) of this chapter or because of other relevant ethical concerns. The written notification shall include a statement of the reasons for the IRB's determination.

(f) An IRB shall conduct continuing review of research covered by these regulations at intervals appropriate to the degree of risk, but not less than once per year, and shall have authority to observe or have a third party observe the consent process and the research.

(g) An IRB shall provide in writing to the sponsor of research involving an exception to informed consent under § 50.24 of this chapter a copy of information that has been publicly disclosed under § 50.24(a)(7)(ii) and (a)(7)(iii) of this chapter. The IRB shall provide this information to the sponsor promptly so that the sponsor is aware that such disclosure has occurred. Upon receipt, the sponsor shall provide copies of the information disclosed to FDA.

(h) When some or all of the subjects in a study are children, an IRB must determine that the research study is in compliance with part 50, subpart D of this chapter, at the time of its initial review of the research. When some or all of the subjects in a study that was ongoing on April 30, 2001, are children, an IRB must conduct a review of the research to determine compliance with part 50, subpart D of this chapter, either at the time of continuing review or, at the discretion of the IRB, at an earlier date.

[46 FR 8975, Jan. 27, 1981, as amended at 61 FR 51529, Oct. 2, 1996; 66 FR 20599, Apr. 24, 2001; 78 FR 12951, Feb. 26, 2013]

§ 56.110 Expedited review procedures for certain kinds of research involving no more than minimal risk, and for minor changes in approved research.

(a) The Food and Drug Administration has established, and published in the FEDERAL REGISTER, a list of categories of research that may be reviewed by the IRB through an expedited review procedure. The list will be amended, as appropriate, through periodic republication in the FEDERAL REGISTER.

(b) An IRB may use the expedited review procedure to review either or both of the following: (1) Some or all of the research appearing on the list and found by the reviewer(s) to involve no more than minimal risk, (2) minor changes in previously approved research during the period (of 1 year or less) for which approval is authorized. Under an expedited review procedure, the review may be carried out by the IRB chairperson or by one or more experienced reviewers designated by the IRB chairperson from among the members of the IRB. In reviewing the research, the reviewers may exercise all of the authorities of the IRB except that the reviewers may not disapprove the research. A research activity may be disapproved only after review in accordance with the nonexpedited review procedure set forth in § 56.108(c).

(c) Each IRB which uses an expedited review procedure shall adopt a method for keeping all members advised of research proposals which have been approved under the procedure.

(d) The Food and Drug Administration may restrict, suspend, or terminate an institution's or IRB's use of

the expedited review procedure when necessary to protect the rights or welfare of subjects.

[46 FR 8975, Jan. 27, 1981, as amended at 56 FR 28029, June 18, 1991]

§ 56.111 Criteria for IRB approval of research.

(a) In order to approve research covered by these regulations the IRB shall determine that all of the following requirements are satisfied:

(1) Risks to subjects are minimized: (i) By using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

(2) Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies that subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

(3) Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, handicapped, or mentally disabled persons, or economically or educationally disadvantaged persons.

(4) Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with and to the extent required by part 50.

(5) Informed consent will be appropriately documented, in accordance with and to the extent required by § 50.27.

(6) Where appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

(7) Where appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

(b) When some or all of the subjects, such as children, prisoners, pregnant women, handicapped, or mentally disabled persons, or economically or educationally disadvantaged persons, are likely to be vulnerable to coercion or undue influence additional safeguards have been included in the study to protect the rights and welfare of these subjects.

(c) In order to approve research in which some or all of the subjects are children, an IRB must determine that all research is in compliance with part 50, subpart D of this chapter.

[46 FR 8975, Jan. 27, 1981, as amended at 56 FR 28029, June 18, 1991; 66 FR 20599, Apr. 24, 2001]

§ 56.112 Review by institution.

Research covered by these regulations that has been approved by an IRB may be subject to further appropriate review and approval or disapproval by officials of the institution. However, those officials may not approve the research if it has not been approved by an IRB.

§ 56.113 Suspension or termination of IRB approval of research.

An IRB shall have authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects. Any suspension or termination of approval shall include a statement of the reasons for the IRB's action and shall be reported promptly to the investigator, appropriate institutional officials, and the Food and Drug Administration.

§ 56.114 Cooperative research.

In complying with these regulations, institutions involved in multi-institutional studies may use joint review, reliance upon the review of another qualified IRB, or similar arrangements

aimed at avoidance of duplication of effort.

Subpart D—Records and Reports

§ 56.115 IRB records.

(a) An institution, or where appropriate an IRB, shall prepare and maintain adequate documentation of IRB activities, including the following:

(1) Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent documents, progress reports submitted by investigators, and reports of injuries to subjects.

(2) Minutes of IRB meetings which shall be in sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution.

(3) Records of continuing review activities.

(4) Copies of all correspondence between the IRB and the investigators.

(5) A list of IRB members identified by name; earned degrees; representative capacity; indications of experience such as board certifications, licenses, etc., sufficient to describe each member's chief anticipated contributions to IRB deliberations; and any employment or other relationship between each member and the institution; for example: full-time employee, part-time employee, a member of governing panel or board, stockholder, paid or unpaid consultant.

(6) Written procedures for the IRB as required by § 56.108 (a) and (b).

(7) Statements of significant new findings provided to subjects, as required by § 50.25.

(b) The records required by this regulation shall be retained for at least 3 years after completion of the research, and the records shall be accessible for inspection and copying by authorized representatives of the Food and Drug Administration at reasonable times and in a reasonable manner.

(c) The Food and Drug Administration may refuse to consider a clinical investigation in support of an application for a research or marketing permit if the institution or the IRB that reviewed the investigation refuses to allow an inspection under this section.

[46 FR 8975, Jan. 27, 1981, as amended at 56 FR 28029, June 18, 1991; 67 FR 9585, Mar. 4, 2002]

Subpart E—Administrative Actions for Noncompliance

§ 56.120 Lesser administrative actions.

(a) If apparent noncompliance with these regulations in the operation of an IRB is observed by an FDA investigator during an inspection, the inspector will present an oral or written summary of observations to an appropriate representative of the IRB. The Food and Drug Administration may subsequently send a letter describing the noncompliance to the IRB and to the parent institution. The agency will require that the IRB or the parent institution respond to this letter within a time period specified by FDA and describe the corrective actions that will be taken by the IRB, the institution, or both to achieve compliance with these regulations.

(b) On the basis of the IRB's or the institution's response, FDA may schedule a reinspection to confirm the adequacy of corrective actions. In addition, until the IRB or the parent institution takes appropriate corrective action, the Agency may require the IRB to:

(1) Withhold approval of new studies subject to the requirements of this part that are conducted at the institution or reviewed by the IRB;

(2) Direct that no new subjects be added to ongoing studies subject to this part; or

(3) Terminate ongoing studies subject to this part when doing so would not endanger the subjects.

(c) When the apparent noncompliance creates a significant threat to the rights and welfare of human subjects, FDA may notify relevant State and Federal regulatory agencies and other parties with a direct interest in the Agency's action of the deficiencies in the operation of the IRB.

(d) The parent institution is presumed to be responsible for the operation of an IRB, and the Food and Drug Administration will ordinarily direct any administrative action under this subpart against the institution. However, depending on the evidence of responsibility for deficiencies, determined during the investigation, the Food and Drug Administration may restrict its administrative actions to the IRB or to a component of the parent institution determined to be responsible for formal designation of the IRB.

[46 FR 8975, Jan. 27, 1981, as amended at 81 FR 19035, Apr. 4, 2016]

§ 56.121 Disqualification of an IRB or an institution.

(a) Whenever the IRB or the institution has failed to take adequate steps to correct the noncompliance stated in the letter sent by the agency under § 56.120(a), and the Commissioner of Food and Drugs determines that this noncompliance may justify the disqualification of the IRB or of the parent institution, the Commissioner will institute proceedings in accordance with the requirements for a regulatory hearing set forth in part 16.

(b) The Commissioner may disqualify an IRB or the parent institution if the Commissioner determines that:

(1) The IRB has refused or repeatedly failed to comply with any of the regulations set forth in this part, and

(2) The noncompliance adversely affects the rights or welfare of the human subjects in a clinical investigation.

(c) If the Commissioner determines that disqualification is appropriate, the Commissioner will issue an order that explains the basis for the determination and that prescribes any actions to be taken with regard to ongoing clinical research conducted under the review of the IRB. The Food and Drug Administration will send notice of the disqualification to the IRB and the parent institution. Other parties with a direct interest, such as sponsors and clinical investigators, may also be sent a notice of the disqualification. In addition, the agency may elect to publish a notice of its action in the FEDERAL REGISTER.

(d) The Food and Drug Administration will not approve an application for a research permit for a clinical investigation that is to be under the review of a disqualified IRB or that is to be conducted at a disqualified institution, and it may refuse to consider in support of a marketing permit the data from a clinical investigation that was reviewed by a disqualified IRB as conducted at a disqualified institution, unless the IRB or the parent institution is reinstated as provided in § 56.123.

§ 56.122 Public disclosure of information regarding revocation.

A determination that the Food and Drug Administration has disqualified an institution and the administrative record regarding that determination are disclosable to the public under part 20.

§ 56.123 Reinstatement of an IRB or an institution.

An IRB or an institution may be reinstated if the Commissioner determines, upon an evaluation of a written submission from the IRB or institution that explains the corrective action that the institution or IRB plans to take, that the IRB or institution has provided adequate assurance that it will operate in compliance with the standards set forth in this part. Notification of reinstatement shall be provided to all persons notified under § 56.121(c).

§ 56.124 Actions alternative or additional to disqualification.

Disqualification of an IRB or of an institution is independent of, and neither in lieu of nor a precondition to, other proceedings or actions authorized by the act. The Food and Drug Administration may, at any time, through the Department of Justice institute any appropriate judicial proceedings (civil or criminal) and any other appropriate regulatory action, in addition to or in lieu of, and before, at the time of, or after, disqualification. The agency may also refer pertinent matters to another Federal, State, or local government agency for any action that that agency determines to be appropriate.

PART 58—GOOD LABORATORY PRACTICE FOR NONCLINICAL LABORATORY STUDIES

Subpart A—General Provisions

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58.1 Scope.
58.3 Definitions.
58.10 Applicability to studies performed under grants and contracts.
58.15 Inspection of a testing facility.

Subpart B—Organization and Personnel

58.29 Personnel.
58.31 Testing facility management.
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AUTHORITY: 21 U.S.C. 342, 346, 346a, 348, 351, 352, 353, 355, 360, 360b–360f, 360h–360j, 371, 379e, 381; 42 U.S.C. 216, 262, 263b–263n.

SOURCE: 43 FR 60013, Dec. 22, 1978, unless otherwise noted.

Subpart A—General Provisions

§ 58.1 Scope.

(a) This part prescribes good laboratory practices for conducting nonclinical laboratory studies that support or are intended to support applications for research or marketing permits for products regulated by the Food and Drug Administration, including food and color additives, animal food additives, human and animal drugs, medical devices for human use, biological products, and electronic products. Compliance with this part is intended to assure the quality and integrity of the safety data filed pursuant to sections 406, 408, 409, 502, 503, 505, 506, 510, 512–516, 518–520, 721, and 801 of the Federal Food, Drug, and Cosmetic Act and sections 351 and 354–360F of the Public Health Service Act.

(b) References in this part to regulatory sections of the Code of Federal Regulations are to chapter I of title 21, unless otherwise noted.

[43 FR 60013, Dec. 22, 1978, as amended at 52 FR 33779, Sept. 4, 1987; 64 FR 399, Jan. 5, 1999]

§ 58.3 Definitions.

As used in this part, the following terms shall have the meanings specified:

(a) *Act* means the Federal Food, Drug, and Cosmetic Act, as amended (secs. 201–902, 52 Stat. 1040 *et seq.*, as amended (21 U.S.C. 321–392)).

(b) *Test article* means any food additive, color additive, drug, biological product, electronic product, medical device for human use, or any other article subject to regulation under the act or under sections 351 and 354–360F of the Public Health Service Act.

(c) *Control article* means any food additive, color additive, drug, biological product, electronic product, medical device for human use, or any article other than a test article, feed, or water that is administered to the test system in the course of a nonclinical laboratory study for the purpose of establishing a basis for comparison with the test article.

(d) *Nonclinical laboratory study* means in vivo or in vitro experiments in which test articles are studied prospectively in test systems under laboratory conditions to determine their safety. The term does not include studies utilizing human subjects or clinical studies or field trials in animals. The term does not include basic exploratory studies carried out to determine whether a test article has any potential utility or to determine physical or chemical characteristics of a test article.

(e) *Application for research or marketing permit* includes:

(1) A color additive petition, described in part 71.

(2) A food additive petition, described in parts 171 and 571.

(3) Data and information regarding a substance submitted as part of the procedures for establishing that a substance is generally recognized as safe for use, which use results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food, described in §§ 170.35 and 570.35.

(4) Data and information regarding a food additive submitted as part of the procedures regarding food additives permitted to be used on an interim basis pending additional study, described in § 180.1.

(5) An *investigational new drug application*, described in part 312 of this chapter.

(6) A *new drug application*, described in part 314.

(7) Data and information regarding an over-the-counter drug for human use, submitted as part of the procedures for classifying such drugs as generally recognized as safe and effective and not misbranded, described in part 330.

(8) Data and information about a substance submitted as part of the procedures for establishing a tolerance for unavoidable contaminants in food and food-packaging materials, described in parts 109 and 509.

(9) [Reserved]

(10) A *Notice of Claimed Investigational Exemption for a New Animal Drug*, described in part 511.

(11) A *new animal drug application*, described in part 514.

(12) [Reserved]

(13) An *application for a biologics license*, described in part 601 of this chapter.

(14) An *application for an investigational device exemption*, described in part 812.

(15) An *Application for Premarket Approval of a Medical Device*, described in section 515 of the act.

(16) A *Product Development Protocol for a Medical Device*, described in section 515 of the act.

(17) Data and information regarding a medical device submitted as part of the procedures for classifying such devices, described in part 860.

(18) Data and information regarding a medical device submitted as part of the procedures for establishing, amending, or repealing a performance standard for such devices, described in part 861.

(19) Data and information regarding an electronic product submitted as part of the procedures for obtaining an exemption from notification of a radiation safety defect or failure of compliance with a radiation safety performance standard, described in subpart D of part 1003.

(20) Data and information regarding an electronic product submitted as part of the procedures for establishing, amending, or repealing a standard for such product, described in section 358 of the Public Health Service Act.

(21) Data and information regarding an electronic product submitted as part of the procedures for obtaining a variance from any electronic product

performance standard as described in § 1010.4.

(22) Data and information regarding an electronic product submitted as part of the procedures for granting, amending, or extending an exemption from any electronic product performance standard, as described in § 1010.5.

(23) A premarket notification for a food contact substance, described in part 170, subpart D, of this chapter.

(f) *Sponsor* means:

(1) A person who initiates and supports, by provision of financial or other resources, a nonclinical laboratory study;

(2) A person who submits a nonclinical study to the Food and Drug Administration in support of an application for a research or marketing permit; or

(3) A testing facility, if it both initiates and actually conducts the study.

(g) *Testing facility* means a person who actually conducts a nonclinical laboratory study, i.e., actually uses the test article in a test system. *Testing facility* includes any establishment required to register under section 510 of the act that conducts nonclinical laboratory studies and any consulting laboratory described in section 704 of the act that conducts such studies. *Testing facility* encompasses only those operational units that are being or have been used to conduct nonclinical laboratory studies.

(h) *Person* includes an individual, partnership, corporation, association, scientific or academic establishment, government agency, or organizational unit thereof, and any other legal entity.

(i) *Test system* means any animal, plant, microorganism, or subparts thereof to which the test or control article is administered or added for study. *Test system* also includes appropriate groups or components of the system not treated with the test or control articles.

(j) *Specimen* means any material derived from a test system for examination or analysis.

(k) *Raw data* means any laboratory worksheets, records, memoranda, notes, or exact copies thereof, that are the result of original observations and activities of a nonclinical laboratory study and are necessary for the reconstruction and evaluation of the report of that study. In the event that exact transcripts of raw data have been prepared (e.g., tapes which have been transcribed verbatim, dated, and verified accurate by signature), the exact copy or exact transcript may be substituted for the original source as raw data. *Raw data* may include photographs, microfilm or microfiche copies, computer printouts, magnetic media, including dictated observations, and recorded data from automated instruments.

(l) *Quality assurance unit* means any person or organizational element, except the study director, designated by testing facility management to perform the duties relating to quality assurance of nonclinical laboratory studies.

(m) *Study director* means the individual responsible for the overall conduct of a nonclinical laboratory study.

(n) *Batch* means a specific quantity or lot of a test or control article that has been characterized according to § 58.105(a).

(o) *Study initiation date* means the date the protocol is signed by the study director.

(p) *Study completion date* means the date the final report is signed by the study director.

[43 FR 60013, Dec. 22, 1978, as amended at 52 FR 33779, Sept. 4, 1987; 54 FR 9039, Mar. 3, 1989; 64 FR 56448, Oct. 20, 1999; 67 FR 35729, May 21, 2002]

§ 58.10 Applicability to studies performed under grants and contracts.

When a sponsor conducting a nonclinical laboratory study intended to be submitted to or reviewed by the Food and Drug Administration utilizes the services of a consulting laboratory, contractor, or grantee to perform an analysis or other service, it shall notify the consulting laboratory, contractor, or grantee that the service is part of a nonclinical laboratory study that must be conducted in compliance with the provisions of this part.

§ 58.15 Inspection of a testing facility.

(a) A testing facility shall permit an authorized employee of the Food and Drug Administration, at reasonable

times and in a reasonable manner, to inspect the facility and to inspect (and in the case of records also to copy) all records and specimens required to be maintained regarding studies within the scope of this part. The records inspection and copying requirements shall not apply to quality assurance unit records of findings and problems, or to actions recommended and taken.

(b) The Food and Drug Administration will not consider a nonclinical laboratory study in support of an application for a research or marketing permit if the testing facility refuses to permit inspection. The determination that a nonclinical laboratory study will not be considered in support of an application for a research or marketing permit does not, however, relieve the applicant for such a permit of any obligation under any applicable statute or regulation to submit the results of the study to the Food and Drug Administration.

Subpart B—Organization and Personnel

§ 58.29 Personnel.

(a) Each individual engaged in the conduct of or responsible for the supervision of a nonclinical laboratory study shall have education, training, and experience, or combination thereof, to enable that individual to perform the assigned functions.

(b) Each testing facility shall maintain a current summary of training and experience and job description for each individual engaged in or supervising the conduct of a nonclinical laboratory study.

(c) There shall be a sufficient number of personnel for the timely and proper conduct of the study according to the protocol.

(d) Personnel shall take necessary personal sanitation and health precautions designed to avoid contamination of test and control articles and test systems.

(e) Personnel engaged in a nonclinical laboratory study shall wear clothing appropriate for the duties they perform. Such clothing shall be changed as often as necessary to prevent microbiological, radiological, or chemical contamination of test systems and test and control articles.

(f) Any individual found at any time to have an illness that may adversely affect the quality and integrity of the nonclinical laboratory study shall be excluded from direct contact with test systems, test and control articles and any other operation or function that may adversely affect the study until the condition is corrected. All personnel shall be instructed to report to their immediate supervisors any health or medical conditions that may reasonably be considered to have an adverse effect on a nonclinical laboratory study.

§ 58.31 Testing facility management.

For each nonclinical laboratory study, testing facility management shall:

(a) Designate a study director as described in § 58.33, before the study is initiated.

(b) Replace the study director promptly if it becomes necessary to do so during the conduct of a study.

(c) Assure that there is a quality assurance unit as described in § 58.35.

(d) Assure that test and control articles or mixtures have been appropriately tested for identity, strength, purity, stability, and uniformity, as applicable.

(e) Assure that personnel, resources, facilities, equipment, materials, and methodologies are available as scheduled.

(f) Assure that personnel clearly understand the functions they are to perform.

(g) Assure that any deviations from these regulations reported by the quality assurance unit are communicated to the study director and corrective actions are taken and documented.

[43 FR 60013, Dec. 22, 1978, as amended at 52 FR 33780, Sept. 4, 1987]

§ 58.33 Study director.

For each nonclinical laboratory study, a scientist or other professional of appropriate education, training, and experience, or combination thereof, shall be identified as the study director. The study director has overall responsibility for the technical conduct

of the study, as well as for the interpretation, analysis, documentation and reporting of results, and represents the single point of study control. The study director shall assure that:

(a) The protocol, including any change, is approved as provided by § 58.120 and is followed.

(b) All experimental data, including observations of unanticipated responses of the test system are accurately recorded and verified.

(c) Unforeseen circumstances that may affect the quality and integrity of the nonclinical laboratory study are noted when they occur, and corrective action is taken and documented.

(d) Test systems are as specified in the protocol.

(e) All applicable good laboratory practice regulations are followed.

(f) All raw data, documentation, protocols, specimens, and final reports are transferred to the archives during or at the close of the study.

[43 FR 60013, Dec. 22, 1978; 44 FR 17657, Mar. 23, 1979]

§ 58.35 Quality assurance unit.

(a) A testing facility shall have a quality assurance unit which shall be responsible for monitoring each study to assure management that the facilities, equipment, personnel, methods, practices, records, and controls are in conformance with the regulations in this part. For any given study, the quality assurance unit shall be entirely separate from and independent of the personnel engaged in the direction and conduct of that study.

(b) The quality assurance unit shall:

(1) Maintain a copy of a master schedule sheet of all nonclinical laboratory studies conducted at the testing facility indexed by test article and containing the test system, nature of study, date study was initiated, current status of each study, identity of the sponsor, and name of the study director.

(2) Maintain copies of all protocols pertaining to all nonclinical laboratory studies for which the unit is responsible.

(3) Inspect each nonclinical laboratory study at intervals adequate to assure the integrity of the study and maintain written and properly signed records of each periodic inspection showing the date of the inspection, the study inspected, the phase or segment of the study inspected, the person performing the inspection, findings and problems, action recommended and taken to resolve existing problems, and any scheduled date for reinspection. Any problems found during the course of an inspection which are likely to affect study integrity shall be brought to the attention of the study director and management immediately.

(4) Periodically submit to management and the study director written status reports on each study, noting any problems and the corrective actions taken.

(5) Determine that no deviations from approved protocols or standard operating procedures were made without proper authorization and documentation.

(6) Review the final study report to assure that such report accurately describes the methods and standard operating procedures, and that the reported results accurately reflect the raw data of the nonclinical laboratory study.

(7) Prepare and sign a statement to be included with the final study report which shall specify the dates inspections were made and findings reported to management and to the study director.

(c) The responsibilities and procedures applicable to the quality assurance unit, the records maintained by the quality assurance unit, and the method of indexing such records shall be in writing and shall be maintained. These items including inspection dates, the study inspected, the phase or segment of the study inspected, and the name of the individual performing the inspection shall be made available for inspection to authorized employees of the Food and Drug Administration.

(d) A designated representative of the Food and Drug Administration shall have access to the written procedures established for the inspection and may request testing facility management to certify that inspections are being implemented, performed, documented,

and followed-up in accordance with this paragraph.

[43 FR 60013, Dec. 22, 1978, as amended at 52 FR 33780, Sept. 4, 1987; 67 FR 9585, Mar. 4, 2002]

Subpart C—Facilities

§ 58.41 General.

Each testing facility shall be of suitable size and construction to facilitate the proper conduct of nonclinical laboratory studies. It shall be designed so that there is a degree of separation that will prevent any function or activity from having an adverse effect on the study.

[52 FR 33780, Sept. 4, 1987]

§ 58.43 Animal care facilities.

(a) A testing facility shall have a sufficient number of animal rooms or areas, as needed, to assure proper: (1) Separation of species or test systems, (2) isolation of individual projects, (3) quarantine of animals, and (4) routine or specialized housing of animals.

(b) A testing facility shall have a number of animal rooms or areas separate from those described in paragraph (a) of this section to ensure isolation of studies being done with test systems or test and control articles known to be biohazardous, including volatile substances, aerosols, radioactive materials, and infectious agents.

(c) Separate areas shall be provided, as appropriate, for the diagnosis, treatment, and control of laboratory animal diseases. These areas shall provide effective isolation for the housing of animals either known or suspected of being diseased, or of being carriers of disease, from other animals.

(d) When animals are housed, facilities shall exist for the collection and disposal of all animal waste and refuse or for safe sanitary storage of waste before removal from the testing facility. Disposal facilities shall be so provided and operated as to minimize vermin infestation, odors, disease hazards, and environmental contamination.

[43 FR 60013, Dec. 22, 1978, as amended at 52 FR 33780, Sept. 4, 1987]

§ 58.45 Animal supply facilities.

There shall be storage areas, as needed, for feed, bedding, supplies, and equipment. Storage areas for feed and bedding shall be separated from areas housing the test systems and shall be protected against infestation or contamination. Perishable supplies shall be preserved by appropriate means.

[43 FR 60013, Dec. 22, 1978, as amended at 52 FR 33780, Sept. 4, 1987]

§ 58.47 Facilities for handling test and control articles.

(a) As necessary to prevent contamination or mixups, there shall be separate areas for:

(1) Receipt and storage of the test and control articles.

(2) Mixing of the test and control articles with a carrier, e.g., feed.

(3) Storage of the test and control article mixtures.

(b) Storage areas for the test and/or control article and test and control mixtures shall be separate from areas housing the test systems and shall be adequate to preserve the identity, strength, purity, and stability of the articles and mixtures.

§ 58.49 Laboratory operation areas.

Separate laboratory space shall be provided, as needed, for the performance of the routine and specialized procedures required by nonclinical laboratory studies.

[52 FR 33780, Sept. 4, 1987]

§ 58.51 Specimen and data storage facilities.

Space shall be provided for archives, limited to access by authorized personnel only, for the storage and retrieval of all raw data and specimens from completed studies.

Subpart D—Equipment

§ 58.61 Equipment design.

Equipment used in the generation, measurement, or assessment of data and equipment used for facility environmental control shall be of appropriate design and adequate capacity to function according to the protocol and

shall be suitably located for operation, inspection, cleaning, and maintenance.

[52 FR 33780, Sept. 4, 1987]

§ 58.63 Maintenance and calibration of equipment.

(a) Equipment shall be adequately inspected, cleaned, and maintained. Equipment used for the generation, measurement, or assessment of data shall be adequately tested, calibrated and/or standardized.

(b) The written standard operating procedures required under § 58.81(b)(11) shall set forth in sufficient detail the methods, materials, and schedules to be used in the routine inspection, cleaning, maintenance, testing, calibration, and/or standardization of equipment, and shall specify, when appropriate, remedial action to be taken in the event of failure or malfunction of equipment. The written standard operating procedures shall designate the person responsible for the performance of each operation.

(c) Written records shall be maintained of all inspection, maintenance, testing, calibrating and/or standardizing operations. These records, containing the date of the operation, shall describe whether the maintenance operations were routine and followed the written standard operating procedures. Written records shall be kept of nonroutine repairs performed on equipment as a result of failure and malfunction. Such records shall document the nature of the defect, how and when the defect was discovered, and any remedial action taken in response to the defect.

[43 FR 60013, Dec. 22, 1978, as amended at 52 FR 33780, Sept. 4, 1987; 67 FR 9585, Mar. 4, 2002]

Subpart E—Testing Facilities Operation

§ 58.81 Standard operating procedures.

(a) A testing facility shall have standard operating procedures in writing setting forth nonclinical laboratory study methods that management is satisfied are adequate to insure the quality and integrity of the data generated in the course of a study. All deviations in a study from standard operating procedures shall be authorized by the study director and shall be documented in the raw data. Significant changes in established standard operating procedures shall be properly authorized in writing by management.

(b) Standard operating procedures shall be established for, but not limited to, the following:

(1) Animal room preparation.

(2) Animal care.

(3) Receipt, identification, storage, handling, mixing, and method of sampling of the test and control articles.

(4) Test system observations.

(5) Laboratory tests.

(6) Handling of animals found moribund or dead during study.

(7) Necropsy of animals or postmortem examination of animals.

(8) Collection and identification of specimens.

(9) Histopathology.

(10) Data handling, storage, and retrieval.

(11) Maintenance and calibration of equipment.

(12) Transfer, proper placement, and identification of animals.

(c) Each laboratory area shall have immediately available laboratory manuals and standard operating procedures relative to the laboratory procedures being performed. Published literature may be used as a supplement to standard operating procedures.

(d) A historical file of standard operating procedures, and all revisions thereof, including the dates of such revisions, shall be maintained.

[43 FR 60013, Dec. 22, 1978, as amended at 52 FR 33780, Sept. 4, 1987]

§ 58.83 Reagents and solutions.

All reagents and solutions in the laboratory areas shall be labeled to indicate identity, titer or concentration, storage requirements, and expiration date. Deteriorated or outdated reagents and solutions shall not be used.

§ 58.90 Animal care.

(a) There shall be standard operating procedures for the housing, feeding, handling, and care of animals.

(b) All newly received animals from outside sources shall be isolated and their health status shall be evaluated

in accordance with acceptable veterinary medical practice.

(c) At the initiation of a nonclinical laboratory study, animals shall be free of any disease or condition that might interfere with the purpose or conduct of the study. If, during the course of the study, the animals contract such a disease or condition, the diseased animals shall be isolated, if necessary. These animals may be treated for disease or signs of disease provided that such treatment does not interfere with the study. The diagnosis, authorizations of treatment, description of treatment, and each date of treatment shall be documented and shall be retained.

(d) Warm-blooded animals, excluding suckling rodents, used in laboratory procedures that require manipulations and observations over an extended period of time or in studies that require the animals to be removed from and returned to their home cages for any reason (e.g., cage cleaning, treatment, etc.), shall receive appropriate identification. All information needed to specifically identify each animal within an animal-housing unit shall appear on the outside of that unit.

(e) Animals of different species shall be housed in separate rooms when necessary. Animals of the same species, but used in different studies, should not ordinarily be housed in the same room when inadvertent exposure to control or test articles or animal mixup could affect the outcome of either study. If such mixed housing is necessary, adequate differentiation by space and identification shall be made.

(f) Animal cages, racks and accessory equipment shall be cleaned and sanitized at appropriate intervals.

(g) Feed and water used for the animals shall be analyzed periodically to ensure that contaminants known to be capable of interfering with the study and reasonably expected to be present in such feed or water are not present at levels above those specified in the protocol. Documentation of such analyses shall be maintained as raw data.

(h) Bedding used in animal cages or pens shall not interfere with the purpose or conduct of the study and shall be changed as often as necessary to keep the animals dry and clean.

(i) If any pest control materials are used, the use shall be documented. Cleaning and pest control materials that interfere with the study shall not be used.

[43 FR 60013, Dec. 22, 1978, as amended at 52 FR 33780, Sept. 4, 1987; 54 FR 15924, Apr. 20, 1989; 56 FR 32088, July 15, 1991; 67 FR 9585, Mar. 4, 2002]

Subpart F—Test and Control Articles

§ 58.105 Test and control article characterization.

(a) The identity, strength, purity, and composition or other characteristics which will appropriately define the test or control article shall be determined for each batch and shall be documented. Methods of synthesis, fabrication, or derivation of the test and control articles shall be documented by the sponsor or the testing facility. In those cases where marketed products are used as control articles, such products will be characterized by their labeling.

(b) The stability of each test or control article shall be determined by the testing facility or by the sponsor either: (1) Before study initiation, or (2) concomitantly according to written standard operating procedures, which provide for periodic analysis of each batch.

(c) Each storage container for a test or control article shall be labeled by name, chemical abstract number or code number, batch number, expiration date, if any, and, where appropriate, storage conditions necessary to maintain the identity, strength, purity, and composition of the test or control article. Storage containers shall be assigned to a particular test article for the duration of the study.

(d) For studies of more than 4 weeks' duration, reserve samples from each batch of test and control articles shall be retained for the period of time provided by § 58.195.

[43 FR 60013, Dec. 22, 1978, as amended at 52 FR 33781, Sept. 4, 1987; 67 FR 9585, Mar. 4, 2002]

§ 58.107 Test and control article handling.

Procedures shall be established for a system for the handling of the test and control articles to ensure that:

(a) There is proper storage.

(b) Distribution is made in a manner designed to preclude the possibility of contamination, deterioration, or damage.

(c) Proper identification is maintained throughout the distribution process.

(d) The receipt and distribution of each batch is documented. Such documentation shall include the date and quantity of each batch distributed or returned.

§ 58.113 Mixtures of articles with carriers.

(a) For each test or control article that is mixed with a carrier, tests by appropriate analytical methods shall be conducted:

(1) To determine the uniformity of the mixture and to determine, periodically, the concentration of the test or control article in the mixture.

(2) To determine the stability of the test and control articles in the mixture as required by the conditions of the study either:

(i) Before study initiation, or

(ii) Concomitantly according to written standard operating procedures which provide for periodic analysis of the test and control articles in the mixture.

(b) [Reserved]

(c) Where any of the components of the test or control article carrier mixture has an expiration date, that date shall be clearly shown on the container. If more than one component has an expiration date, the earliest date shall be shown.

[43 FR 60013, Dec. 22, 1978, as amended at 45 FR 24865, Apr. 11, 1980; 52 FR 33781, Sept. 4, 1987]

Subpart G—Protocol for and Conduct of a Nonclinical Laboratory Study

§ 58.120 Protocol.

(a) Each study shall have an approved written protocol that clearly indicates the objectives and all methods for the conduct of the study. The protocol shall contain, as applicable, the following information:

(1) A descriptive title and statement of the purpose of the study.

(2) Identification of the test and control articles by name, chemical abstract number, or code number.

(3) The name of the sponsor and the name and address of the testing facility at which the study is being conducted.

(4) The number, body weight range, sex, source of supply, species, strain, substrain, and age of the test system.

(5) The procedure for identification of the test system.

(6) A description of the experimental design, including the methods for the control of bias.

(7) A description and/or identification of the diet used in the study as well as solvents, emulsifiers, and/or other materials used to solubilize or suspend the test or control articles before mixing with the carrier. The description shall include specifications for acceptable levels of contaminants that are reasonably expected to be present in the dietary materials and are known to be capable of interfering with the purpose or conduct of the study if present at levels greater than established by the specifications.

(8) Each dosage level, expressed in milligrams per kilogram of body weight or other appropriate units, of the test or control article to be administered and the method and frequency of administration.

(9) The type and frequency of tests, analyses, and measurements to be made.

(10) The records to be maintained.

(11) The date of approval of the protocol by the sponsor and the dated signature of the study director.

(12) A statement of the proposed statistical methods to be used.

(b) All changes in or revisions of an approved protocol and the reasons therefore shall be documented, signed by the study director, dated, and maintained with the protocol.

[43 FR 60013, Dec. 22, 1978, as amended at 52 FR 33781, Sept. 4, 1987; 67 FR 9585, Mar. 4, 2002]

§ 58.130 Conduct of a nonclinical laboratory study.

(a) The nonclinical laboratory study shall be conducted in accordance with the protocol.

(b) The test systems shall be monitored in conformity with the protocol.

(c) Specimens shall be identified by test system, study, nature, and date of collection. This information shall be located on the specimen container or shall accompany the specimen in a manner that precludes error in the recording and storage of data.

(d) Records of gross findings for a specimen from postmortem observations should be available to a pathologist when examining that specimen histopathologically.

(e) All data generated during the conduct of a nonclinical laboratory study, except those that are generated by automated data collection systems, shall be recorded directly, promptly, and legibly in ink. All data entries shall be dated on the date of entry and signed or initialed by the person entering the data. Any change in entries shall be made so as not to obscure the original entry, shall indicate the reason for such change, and shall be dated and signed or identified at the time of the change. In automated data collection systems, the individual responsible for direct data input shall be identified at the time of data input. Any change in automated data entries shall be made so as not to obscure the original entry, shall indicate the reason for change, shall be dated, and the responsible individual shall be identified.

[43 FR 60013, Dec. 22, 1978, as amended at 52 FR 33781, Sept. 4, 1987; 67 FR 9585, Mar. 4, 2002]

Subparts H–I [Reserved]

Subpart J—Records and Reports

§ 58.185 Reporting of nonclinical laboratory study results.

(a) A final report shall be prepared for each nonclinical laboratory study and shall include, but not necessarily be limited to, the following:

(1) Name and address of the facility performing the study and the dates on which the study was initiated and completed.

(2) Objectives and procedures stated in the approved protocol, including any changes in the original protocol.

(3) Statistical methods employed for analyzing the data.

(4) The test and control articles identified by name, chemical abstracts number or code number, strength, purity, and composition or other appropriate characteristics.

(5) Stability of the test and control articles under the conditions of administration.

(6) A description of the methods used.

(7) A description of the test system used. Where applicable, the final report shall include the number of animals used, sex, body weight range, source of supply, species, strain and substrain, age, and procedure used for identification.

(8) A description of the dosage, dosage regimen, route of administration, and duration.

(9) A description of all circumstances that may have affected the quality or integrity of the data.

(10) The name of the study director, the names of other scientists or professionals, and the names of all supervisory personnel, involved in the study.

(11) A description of the transformations, calculations, or operations performed on the data, a summary and analysis of the data, and a statement of the conclusions drawn from the analysis.

(12) The signed and dated reports of each of the individual scientists or other professionals involved in the study.

(13) The locations where all specimens, raw data, and the final report are to be stored.

(14) The statement prepared and signed by the quality assurance unit as described in § 58.35(b)(7).

(b) The final report shall be signed and dated by the study director.

(c) Corrections or additions to a final report shall be in the form of an amendment by the study director. The amendment shall clearly identify that part of the final report that is being added to or corrected and the reasons for the correction or addition, and

shall be signed and dated by the person responsible.

[43 FR 60013, Dec. 22, 1978, as amended at 52 FR 33781, Sept. 4, 1987]

§ 58.190 Storage and retrieval of records and data.

(a) All raw data, documentation, protocols, final reports, and specimens (except those specimens obtained from mutagenicity tests and wet specimens of blood, urine, feces, and biological fluids) generated as a result of a nonclinical laboratory study shall be retained.

(b) There shall be archives for orderly storage and expedient retrieval of all raw data, documentation, protocols, specimens, and interim and final reports. Conditions of storage shall minimize deterioration of the documents or specimens in accordance with the requirements for the time period of their retention and the nature of the documents or specimens. A testing facility may contract with commercial archives to provide a repository for all material to be retained. Raw data and specimens may be retained elsewhere provided that the archives have specific reference to those other locations.

(c) An individual shall be identified as responsible for the archives.

(d) Only authorized personnel shall enter the archives.

(e) Material retained or referred to in the archives shall be indexed to permit expedient retrieval.

[43 FR 60013, Dec. 22, 1978, as amended at 52 FR 33781, Sept. 4, 1987; 67 FR 9585, Mar. 4, 2002]

§ 58.195 Retention of records.

(a) Record retention requirements set forth in this section do not supersede the record retention requirements of any other regulations in this chapter.

(b) Except as provided in paragraph (c) of this section, documentation records, raw data and specimens pertaining to a nonclinical laboratory study and required to be made by this part shall be retained in the archive(s) for whichever of the following periods is shortest:

(1) A period of at least 2 years following the date on which an application for a research or marketing permit, in support of which the results of the nonclinical laboratory study were submitted, is approved by the Food and Drug Administration. This requirement does not apply to studies supporting investigational new drug applications (IND's) or applications for investigational device exemptions (IDE's), records of which shall be governed by the provisions of paragraph (b)(2) of this section.

(2) A period of at least 5 years following the date on which the results of the nonclinical laboratory study are submitted to the Food and Drug Administration in support of an application for a research or marketing permit.

(3) In other situations (e.g., where the nonclinical laboratory study does not result in the submission of the study in support of an application for a research or marketing permit), a period of at least 2 years following the date on which the study is completed, terminated, or discontinued.

(c) Wet specimens (except those specimens obtained from mutagenicity tests and wet specimens of blood, urine, feces, and biological fluids), samples of test or control articles, and specially prepared material, which are relatively fragile and differ markedly in stability and quality during storage, shall be retained only as long as the quality of the preparation affords evaluation. In no case shall retention be required for longer periods than those set forth in paragraphs (a) and (b) of this section.

(d) The master schedule sheet, copies of protocols, and records of quality assurance inspections, as required by § 58.35(c) shall be maintained by the quality assurance unit as an easily accessible system of records for the period of time specified in paragraphs (a) and (b) of this section.

(e) Summaries of training and experience and job descriptions required to be maintained by § 58.29(b) may be retained along with all other testing facility employment records for the length of time specified in paragraphs (a) and (b) of this section.

(f) Records and reports of the maintenance and calibration and inspection of equipment, as required by § 58.63(b) and (c), shall be retained for the length of

time specified in paragraph (b) of this section.

(g) Records required by this part may be retained either as original records or as true copies such as photocopies, microfilm, microfiche, or other accurate reproductions of the original records.

(h) If a facility conducting nonclinical testing goes out of business, all raw data, documentation, and other material specified in this section shall be transferred to the archives of the sponsor of the study. The Food and Drug Administration shall be notified in writing of such a transfer.

[43 FR 60013, Dec. 22, 1978, as amended at 52 FR 33781, Sept. 4, 1987; 54 FR 9039, Mar. 3, 1989]

Subpart K—Disqualification of Testing Facilities

§ 58.200 Purpose.

(a) The purposes of disqualification are:

(1) To permit the exclusion from consideration of completed studies that were conducted by a testing facility which has failed to comply with the requirements of the good laboratory practice regulations until it can be adequately demonstrated that such noncompliance did not occur during, or did not affect the validity or acceptability of data generated by, a particular study; and

(2) To exclude from consideration all studies completed after the date of disqualification until the facility can satisfy the Commissioner that it will conduct studies in compliance with such regulations.

(b) The determination that a nonclinical laboratory study may not be considered in support of an application for a research or marketing permit does not, however, relieve the applicant for such a permit of any obligation under any other applicable regulation to submit the results of the study to the Food and Drug Administration.

§ 58.202 Grounds for disqualification.

The Commissioner may disqualify a testing facility upon finding all of the following:

(a) The testing facility failed to comply with one or more of the regulations set forth in this part (or any other regulations regarding such facilities in this chapter);

(b) The noncompliance adversely affected the validity of the nonclinical laboratory studies; and

(c) Other lesser regulatory actions (e.g., warnings or rejection of individual studies) have not been or will probably not be adequate to achieve compliance with the good laboratory practice regulations.

§ 58.204 Notice of and opportunity for hearing on proposed disqualification.

(a) Whenever the Commissioner has information indicating that grounds exist under § 58.202 which in his opinion justify disqualification of a testing facility, he may issue to the testing facility a written notice proposing that the facility be disqualified.

(b) A hearing on the disqualification shall be conducted in accordance with the requirements for a regulatory hearing set forth in part 16 of this chapter.

§ 58.206 Final order on disqualification.

(a) If the Commissioner, after the regulatory hearing, or after the time for requesting a hearing expires without a request being made, upon an evaluation of the administrative record of the disqualification proceeding, makes the findings required in § 58.202, he shall issue a final order disqualifying the facility. Such order shall include a statement of the basis for that determination. Upon issuing a final order, the Commissioner shall notify (with a copy of the order) the testing facility of the action.

(b) If the Commissioner, after a regulatory hearing or after the time for requesting a hearing expires without a request being made, upon an evaluation of the administrative record of the disqualification proceeding, does not make the findings required in § 58.202, he shall issue a final order terminating the disqualification proceeding. Such order shall include a statement of the basis for that determination. Upon issuing a final order the Commissioner

shall notify the testing facility and provide a copy of the order.

§ 58.210 Actions upon disqualification.

(a) Once a testing facility has been disqualified, each application for a research or marketing permit, whether approved or not, containing or relying upon any nonclinical laboratory study conducted by the disqualified testing facility may be examined to determine whether such study was or would be essential to a decision. If it is determined that a study was or would be essential, the Food and Drug Administration shall also determine whether the study is acceptable, notwithstanding the disqualification of the facility. Any study done by a testing facility before or after disqualification may be presumed to be unacceptable, and the person relying on the study may be required to establish that the study was not affected by the circumstances that led to the disqualification, e.g., by submitting validating information. If the study is then determined to be unacceptable, such data will be eliminated from consideration in support of the application; and such elimination may serve as new information justifying the termination or withdrawal of approval of the application.

(b) No nonclinical laboratory study begun by a testing facility after the date of the facility's disqualification shall be considered in support of any application for a research or marketing permit, unless the facility has been reinstated under § 58.219. The determination that a study may not be considered in support of an application for a research or marketing permit does not, however, relieve the applicant for such a permit of any obligation under any other applicable regulation to submit the results of the study to the Food and Drug Administration.

[43 FR 60013, Dec. 22, 1978, as amended at 59 FR 13200, Mar. 21, 1994]

§ 58.213 Public disclosure of information regarding disqualification.

(a) Upon issuance of a final order disqualifying a testing facility under § 58.206(a), the Commissioner may notify all or any interested persons. Such notice may be given at the discretion of the Commissioner whenever he believes that such disclosure would further the public interest or would promote compliance with the good laboratory practice regulations set forth in this part. Such notice, if given, shall include a copy of the final order issued under § 58.206(a) and shall state that the disqualification constitutes a determination by the Food and Drug Administration that nonclinical laboratory studies performed by the facility will not be considered by the Food and Drug Administration in support of any application for a research or marketing permit. If such notice is sent to another Federal Government agency, the Food and Drug Administration will recommend that the agency also consider whether or not it should accept nonclinical laboratory studies performed by the testing facility. If such notice is sent to any other person, it shall state that it is given because of the relationship between the testing facility and the person being notified and that the Food and Drug Administration is not advising or recommending that any action be taken by the person notified.

(b) A determination that a testing facility has been disqualified and the administrative record regarding such determination are disclosable to the public under part 20 of this chapter.

§ 58.215 Alternative or additional actions to disqualification.

(a) Disqualification of a testing facility under this subpart is independent of, and neither in lieu of nor a precondition to, other proceedings or actions authorized by the act. The Food and Drug Administration may, at any time, institute against a testing facility and/or against the sponsor of a nonclinical laboratory study that has been submitted to the Food and Drug Administration any appropriate judicial proceedings (civil or criminal) and any other appropriate regulatory action, in addition to or in lieu of, and prior to, simultaneously with, or subsequent to, disqualification. The Food and Drug Administration may also refer the matter to another Federal, State, or local government law enforcement or regulatory agency for such action as that agency deems appropriate.

(b) The Food and Drug Administration may refuse to consider any particular nonclinical laboratory study in support of an application for a research or marketing permit, if it finds that the study was not conducted in accordance with the good laboratory practice regulations set forth in this part, without disqualifying the testing facility that conducted the study or undertaking other regulatory action.

§ 58.217 Suspension or termination of a testing facility by a sponsor.

Termination of a testing facility by a sponsor is independent of, and neither in lieu of nor a precondition to, proceedings or actions authorized by this subpart. If a sponsor terminates or suspends a testing facility from further participation in a nonclinical laboratory study that is being conducted as part of any application for a research or marketing permit that has been submitted to any Center of the Food and Drug Administration (whether approved or not), it shall notify that Center in writing within 15 working days of the action; the notice shall include a statement of the reasons for such action. Suspension or termination of a testing facility by a sponsor does not relieve it of any obligation under any other applicable regulation to submit the results of the study to the Food and Drug Administration.

[43 FR 60013, Dec. 22, 1978, as amended at 50 FR 8995, Mar. 6, 1985]

§ 58.219 Reinstatement of a disqualified testing facility.

A testing facility that has been disqualified may be reinstated as an acceptable source of nonclinical laboratory studies to be submitted to the Food and Drug Administration if the Commissioner determines, upon an evaluation of the submission of the testing facility, that the facility can adequately assure that it will conduct future nonclinical laboratory studies in compliance with the good laboratory practice regulations set forth in this part and, if any studies are currently being conducted, that the quality and integrity of such studies have not been seriously compromised. A disqualified testing facility that wishes to be so reinstated shall present in writing to the Commissioner reasons why it believes it should be reinstated and a detailed description of the corrective actions it has taken or intends to take to assure that the acts or omissions which led to its disqualification will not recur. The Commissioner may condition reinstatement upon the testing facility being found in compliance with the good laboratory practice regulations upon an inspection. If a testing facility is reinstated, the Commissioner shall so notify the testing facility and all organizations and persons who were notified, under § 58.213 of the disqualification of the testing facility. A determination that a testing facility has been reinstated is disclosable to the public under part 20 of this chapter.

PART 60—PATENT TERM RESTORATION

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AUTHORITY: 21 U.S.C. 348, 355, 360e, 360j, 371, 379e; 35 U.S.C. 156; 42 U.S.C. 262.

SOURCE: 53 FR 7305, Mar. 7, 1988, unless otherwise noted.

EDITORIAL NOTE: Nomenclature changes to part 60 appear at 68 FR 24879, May 9, 2003.

Subpart A—General Provisions

§ 60.1 Scope.

(a) This part sets forth procedures and requirements for the Food and Drug Administration's review of applications for the extension of the term of certain patents under 35 U.S.C. 156. Patent term restoration is available for certain patents related to drug products (as defined in 35 U.S.C. 156(f)(2)), and to medical devices, food additives, or color additives subject to regulation under the Federal Food, Drug, and Cosmetic Act or the Public Health Service Act. Food and Drug Administration actions in this area include:

(1) Assisting the United States Patent and Trademark Office in determining eligibility for patent term restoration;

(2) Determining the length of a product's regulatory review period;

(3) If petitioned, reviewing and ruling on due diligence challenges to the Food and Drug Administration's regulatory review period determinations; and

(4) Conducting hearings to review initial Food and Drug Administration findings on due diligence challenges.

(b) References in this part to the Code of Federal Regulations are to chapter I of title 21, unless otherwise noted.

[53 FR 7305, Mar. 7, 1988, as amended at 57 FR 56261, Nov. 27, 1992]

§ 60.2 Purpose.

(a) The purpose of this part is to establish a thorough yet efficient process for the Food and Drug Administration review of patent term restoration applications. To achieve this purpose, the regulations are intended to:

(1) Facilitate determinations of patent term restoration eligibility and regulatory review period length, and

(2) Ensure that parties interested in due diligence challenges will have an opportunity to participate in that process, including informal hearings.

(b) The regulations are intended to complement those promulgated by the United States Patent and Trademark Office to implement those parts of the law which are under that agency's jurisdiction. These regulations shall be construed in light of these objectives.

§ 60.3 Definitions.

(a) The definitions contained in 35 U.S.C. 156 apply to those terms when used in this part.

(b) The following definitions of terms apply to this part:

(1) The term *Act* means the Federal Food, Drug, and Cosmetic Act (secs. 201–901, 52 Stat. 1040 *et seq.* as amended (21 U.S.C. 301–392)).

(2) *Active ingredient* means any component that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of man or of animals. The term includes those components that may undergo chemical change in the manufacture of the drug product and be present in the drug product in a modified form intended to furnish the specified activity or effect.

(3) *Applicant* means any person who submits an application or an amendment or supplement to an application under 35 U.S.C. 156 seeking patent term restoration.

(4) *Application* means an application for patent term restoration submitted under 35 U.S.C. 156.

(5) *Clinical investigation or study* means any experiment that involves a test article and one or more subjects and that is either subject to requirements for prior submission to the Food and Drug Administration under section 505(i), 512(j), or 520(g) of the Federal Food, Drug, and Cosmetic Act, or is not subject to the requirements for prior submission to FDA under those sections of the Federal Food, Drug, and Cosmetic Act, but the results of which are intended to be submitted later to, or held for inspection by, FDA as part of an application for a research or marketing permit. The term does not include experiments that are subject to the provisions of part 58 regarding nonclinical laboratory studies.

(6) *Color additive* means any substance that meets the definition in section 201(t) of the Act and which is subject to premarketing approval under section 721 of the Act.

(7) *Due diligence petition* means a petition submitted under § 60.30(a).

(8) *FDA* means the Food and Drug Administration.

(9) *Food additive* means any substance that meets the definition in section 201(s) of the Act and which is subject to premarketing approval under section 409 of the Act.

(10) *Human drug product* means the active ingredient of a new drug or human biologic product (as those terms are used in the Act and the Public Health Service Act), including any salt or ester of the active ingredient, as a single entity or in combination with another active ingredient.

(11) *Marketing applicant* means any person who submits an application for premarketing approval by FDA under:

(i) Section 505(b) of the Act or section 351 of the Public Health Service Act (human drug products);

(ii) Section 515 of the Act (medical devices);

(iii) Section 409 or 721 of the Act (food and color additives); or

(iv) Section 512 of the Act (animal drug products).

(12) *Marketing application* means an application for:

(i) Human drug products submitted under section 505(b) of the Act or section 351 of the Public Health Service Act;

(ii) Medical devices submitted under section 515 of the Act;

(iii) Food and color additives submitted under section 409 or 721 of the Act; or

(iv) Animal drug products submitted under section 512 of the Act.

(13) *Medical device* means any article that meets the definition in section 201(h) of the Act and which is subject to premarketing approval under section 515 of the Act.

(14) *Product* means a human drug product, animal drug product, medical device, food additive, or color additive, as those terms are defined in this section.

(15) *PTO* means the United States Patent and Trademark Office.

(16) *Animal drug product* means the active ingredient of a new animal drug (as that term is used in the Act) that is not primarily manufactured using recombinant deoxyribonucleic acid (DNA), recombinant ribonucleic acid (RNA), hybridoma technology, or other processes involving site-specific genetic manipulation techniques, including any salt or ester of the active ingredient, as a single entity or in combination with another active ingredient.

[53 FR 7305, Mar. 7, 1988, as amended at 57 FR 56261, Nov. 27, 1992; 64 FR 399, Jan. 5, 1999]

Subpart B—Eligibility Assistance

§ 60.10 FDA assistance on eligibility.

(a) Upon written request from the U.S. Patent and Trademark Office, FDA will assist the U.S. Patent and Trademark Office in determining whether a patent related to a product is eligible for patent term restoration as follows:

(1) Verifying whether the product was subject to a regulatory review period before its commercial marketing or use;

(2) For human drug products, food additives, color additives, and medical devices, determining whether the permission for commercial marketing or use of the product after the regulatory review period is the first permitted commercial marketing or use of the product either:

(i) Under the provision of law under which the regulatory review period occurred; or

(ii) Under the process claimed in the patent when the patent claims a method of manufacturing the product that primarily uses recombinant deoxyribonucleic acid (DNA) technology in the manufacture of the product;

(3) For animal drug products, determining whether the permission for commercial marketing or use of the product after the regulatory review period:

(i) Is the first permitted commercial marketing or use of the product; or

(ii) Is the first permitted commercial marketing or use of the product for administration to a food-producing animal, whichever is applicable, under the

provision of law under which the regulatory review period occurred;

(4) Informing the U.S. Patent and Trademark Office whether the patent term restoration application was submitted within 60 days after the product was approved for marketing or use, or, if the product is an animal drug approved for use in a food-producing animal, verifying whether the application was filed within 60 days of the first approval for marketing or use in a food-producing animal; and

(5) Providing the U.S. Patent and Trademark Office with any other information relevant to the U.S. Patent and Trademark Office's determination of whether a patent related to a product is eligible for patent term restoration.

(b) FDA will notify the U.S. Patent and Trademark Office of its findings in writing, send a copy of this notification to the applicant, and file a copy of the notification in the docket established for the application in FDA's Division of Dockets Management (HFA–305), 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

[57 FR 56261, Nov. 27, 1992]

Subpart C—Regulatory Review Period Determinations

§ 60.20 FDA action on regulatory review period determinations.

(a) FDA will consult its records and experts to verify the dates contained in the application and to determine the length of the product's regulatory review period under § 60.22. The application shall contain information relevant to the determination of the regulatory review period as stated in the ''Guidelines for Extension of Patent Term Under 35 U.S.C. 156'' published on October 9, 1984, in PTO's *Official Gazette* and as required by 37 CFR chapter I.

(b) After determining the length of the regulatory review period, FDA will notify PTO in writing of its determination, send a copy of this determination to the applicant, and file a copy of the determination in the docket established for the application in FDA's Division of Dockets Management (HFA–305), 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

(c) FDA will also publish the regulatory review period determination in the FEDERAL REGISTER. The notice will include the following:

(1) The name of the applicant;

(2) The trade name and generic name (if applicable) of the product;

(3) The number of the patent for which an extension of the term is sought;

(4) The approved indications or uses for the product;

(5) An explanation of any discrepancies between the dates in the application and FDA records;

(6) Where appropriate, an explanation that FDA has no record in which to review the date(s) contained in the application; and

(7) The regulatory review period determination, including a statement of the length of the testing and approval phases and the dates used in calculating each phase.

[53 FR 7305, Mar. 7, 1988, as amended at 59 FR 14364, Mar. 28, 1994]

§ 60.22 Regulatory review period determinations.

In determining a product's regulatory review period, which consists of the sum of the lengths of a testing phase and an approval phase, FDA will review the information in each application using the following definitions of the testing phase and the approval phase for that class of products.

(a) For human drugs:

(1) The testing phase begins on the date an exemption under section 505(i) of the Act becomes effective (or the date an exemption under former section 507(d) of the Act became effective) for the approved human drug product and ends on the date a marketing application under section 351 of the Public Health Service Act or section 505 of the act is initially submitted to FDA (or was initially submitted to FDA under former section 507 of the Act), and

(2) The approval phase begins on the date a marketing application under section 351 of the Public Health Service Act or section 505(b) of the Act is initially submitted to FDA (or was initially submitted under former section 507 of the Act) and ends on the date the application is approved.

(b) For food and color additives:

(1) The testing phase begins on the date a major health or environmental effects test is begun and ends on the date a petition relying on the test and requesting the issuance of a regulation for use of the additive under section 409 or 721 of the Act is initially submitted to FDA.

(2) The approval phase begins on the date a petition requesting the issuance of a regulation for use of the additive under section 409 or 721 of the Act is initially submitted to FDA and ends upon whichever of the following occurs last:

(i) The regulation for the additive becomes effective; or

(ii) Objections filed against the regulation that result in a stay of effectiveness are resolved and commercial marketing is permitted; or

(iii) Proceedings resulting from objections to the regulation, after commercial marketing has been permitted and later stayed pending resolution of the proceedings, are finally resolved and commercial marketing is permitted.

(c) For medical devices:

(1) The testing phase begins on the date a clinical investigation on humans is begun and ends on the date an application for premarket approval of the device or a notice of completion of a product development protocol is initially submitted under section 515 of the Act. For purposes of this part, a clinical investigation is considered to begin on whichever of the following dates applies:

(i) If an investigational device exemption (IDE) under section 520(g) of the Act is required, the effective date of the exemption.

(ii) If an IDE is not required, but institutional review board (IRB) approval under section 520(g)(3) of the Act is required, the IRB approval date.

(iii) If neither an IDE nor IRB approval is required, the date on which the device is first used with human subjects as part of a clinical investigation to be filed with FDA to secure premarket approval of the device.

(2) The approval phase either:

(i) Begins on the date an application for premarket approval of the device is initially submitted under section 515 of the Act and ends on the date the application is approved; or

(ii) Begins on the date a notice of completion of a product development protocol is initially submitted under section 515 of the Act and ends on the date the protocol is declared to be completed.

(d) For animal drugs:

(1) The testing phase begins on the date a major health or environmental effects test is begun or the date on which the agency acknowledges the filing of a notice of claimed investigational exemption for a new animal drug, whichever is earlier, and ends on the date a marketing application under section 512 of the Act is initially submitted to FDA.

(2) The approval phase begins on the date a marketing application under section 512 of the Act is initially submitted to FDA and ends on the date the application is approved.

(e) For purposes of this section, a ''major health or environmental effects test'' may be any test which:

(1) Is reasonably related to the evaluation of the product's health or environmental effects, or both:

(2) Produces data necessary for marketing approval; and

(3) Is conducted over a period of no less than 6 months duration, excluding time required to analyze or evaluate test results.

(f) For purposes of determining the regulatory review period for any product, a marketing application, a notice of completion of a product development protocol, or a petition is *initially submitted* on the date it contains sufficient information to allow FDA to commence review of the application. A marketing application, a notice of completion of a product development protocol, or a petition is *approved* on the date FDA sends the applicant a letter informing it of the approval or, by order declares a product development protocol to be completed, or, in the case of food and color additives, on the effective date of the final rule listing the additive for use as published in the FEDERAL REGISTER or, in the case of a new animal drug in a Category II Type A medicated article, on the date of publication in the FEDERAL REGISTER of the notice of approval pursuant to

section 512(i) of the Act. For purposes of this section, the regulatory review period for an animal drug shall mean either the regulatory review period relating the drug's approval for use in nonfood-producing animals or the regulatory review period relating to the drug's approval for use in food-producing animals, whichever is applicable.

[53 FR 7305, Mar. 7, 1988, as amended at 57 FR 56262, Nov. 27, 1992; 64 FR 400, Jan. 5, 1999]

§ 60.24 Revision of regulatory review period determinations.

(a) Any person may request a revision of the regulatory review period determination within 60 days after its initial publication in the FEDERAL REGISTER. The request shall be sent to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. The request shall specify the following:

(1) The type of action requested;

(2) The identity of the product;

(3) The identity of the applicant;

(4) The FDA docket number; and

(5) The basis for the request for revision, including any documentary evidence.

(b) Unless the applicant is the person requesting the revision, the applicant shall respond to the request within 15 days. In responding to the request, the applicant may submit information which is relevant to the events during the regulatory review period but which was not included in the original patent term restoration application. A request for a revision is not equivalent to a due diligence petition under § 60.30 or a request for a hearing under § 60.40. If no response is submitted, FDA will decide the matter on the basis of the information in the patent term restoration application, request for revision, and FDA records.

(c) FDA shall apply the provisions of § 60.22 in considering the request for a revision of the regulatory review period determination. If FDA revises its prior determination, FDA will notify PTO of the revision, send a copy of this notification to the applicant, and publish the revision in the FEDERAL REGISTER, including a statement giving the reasons for the revision.

[53 FR 7305, Mar. 7, 1988, as amended at 59 FR 14364, Mar. 28, 1994; 67 FR 9585, Mar. 4, 2002]

§ 60.26 Final action on regulatory review period determinations.

(a) FDA will consider a regulatory review period determination to be final upon expiration of the 180-day period for filing a due diligence petition under § 60.30 unless FDA receives:

(1) New information from PTO records, FDA records, or FDA centers that affects the regulatory review period determination;

(2) A request under § 60.24 for revision of the regulatory review period determination;

(3) A due diligence petition filed under § 60.30; or

(4) A request for a hearing filed under § 60.40.

(b) FDA will notify PTO that the regulatory review period determination is final upon:

(1) The expiration of the 180-day period for filing a due diligence petition; or

(2) If FDA has received a request for a revision, a due diligence petition, or a request for a hearing, upon resolution of the request for a revision, the petition, or the hearing, whichever is later. FDA will send a copy of the notification to the applicant and file a copy of the notification in the docket established for the application in FDA's Division of Dockets Management (HFA–305), 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

[53 FR 7305, Mar. 7, 1988, as amended at 59 FR 14364, Mar. 28, 1994]

§ 60.28 Time frame for determining regulatory review periods.

(a) FDA will determine the regulatory review period for a product within 30 days of the receipt of a written request from PTO for such a determination and a copy of the patent term restoration application.

(b) FDA may extend the 30-day period if:

(1) A related FDA action that may affect the regulatory review period determination is pending; or

(2) PTO requests that FDA temporarily suspend the determination process; or

(3) PTO or FDA receives new information about the product that warrants an extension of the time required for the determination of the regulatory review period.

(c) This section does not apply to applications withdrawn by the applicant or applications that PTO determines are ineligible for patent term restoration.

Subpart D—Due Diligence Petitions

§ 60.30 Filing, format, and content of petitions.

(a) Any person may file a petition with FDA, no later than 180 days after the publication of a regulatory review period determination under § 60.20, that challenges FDA's determination by alleging that the applicant for patent term restoration did not act with due diligence in seeking FDA approval of the product during the regulatory review period.

(b) The petition shall be filed in accordance with § 10.20, under the docket number of the FEDERAL REGISTER notice of the agency's regulatory review period determination, and shall be in the format specified in § 10.30. The petition shall contain the information specified in § 10.30 and any additional information required by this subpart. If any provision of § 10.20 or § 10.30 is inconsistent with any provision of this part, FDA will consider the petition in accordance with this part.

(c) The petition shall claim that the applicant did not act with due diligence during some part of the regulatory review period and shall set forth sufficient facts, including dates if possible, to merit an investigation by FDA of whether the applicant acted with due diligence.

(d) The petition shall contain a certification that the petitioner has served a true and complete copy of the petition upon the applicant by certified or registered mail (return receipt requested) or by personal delivery.

[53 FR 7305, Mar. 7, 1988, as amended at 67 FR 9585, Mar. 4, 2002]

§ 60.32 Applicant response to petition.

(a) The applicant shall file with FDA a written response to the petition no later than 30 days after the applicant's receipt of a copy of the petition.

(b) The applicant's response may present additional facts and circumstances to address the assertions in the petition, but shall be limited to the issue of whether the applicant acted with due diligence during the regulatory review period. The applicant's response may include documents that were not in the original patent extension application.

(c) If the applicant does not respond to the petition, FDA will decide the matter on the basis of the information submitted in the patent term restoration application, due diligence petition, and FDA records.

§ 60.34 FDA action on petitions.

(a) Within 90 days after FDA receives a petition filed under § 60.30(a), the agency will either deny the petition under paragraph (b) or (c) of this section or investigate and determine under § 60.36 whether the applicant acted with due diligence during the regulatory review period. FDA will publish its due diligence determination in the FEDERAL REGISTER, notify PTO of the due diligence determination in writing, and send copies of the notice to PTO, the applicant, and the petitioner.

(b) FDA may deny a due diligence petition without considering the merits of the petition if:

(1) The petition is not filed in accordance with § 60.30;

(2) The petition is not filed in accordance with § 10.20;

(3) The petition does not contain the information required by § 10.30;

(4) The petition fails to contain information or allegations upon which it may reasonably be determined that the applicant did not act with due diligence during the applicable regulatory review period; or

(5) The petition fails to allege a sufficient total amount of time during which the applicant did not exercise due diligence such that, even if the petition were granted, the petition would

not affect the maximum patent extension the applicant sought in the application.

§ 60.36 Standard of due diligence.

(a) In determining the due diligence of an applicant, FDA will examine the facts and circumstances of the applicant's actions during the regulatory review period to determine whether the applicant exhibited that degree of attention, continuous directed effort, and timeliness as may reasonably be expected from, and are ordinarily exercised by, a person during a regulatory review period. FDA will take into consideration all relevant factors, such as the amount of time between the approval of an investigational exemption or research permit and the commencement of a clinical investigation and the amount of time required to conduct a clinical investigation.

(b) For purposes of this part, the actions of the marketing applicant shall be imputed to the applicant for patent term restoration. The actions of an agent, attorney, contractor, employee, licensee, or predecessor in interest of the marketing applicant or applicant for patent term restoration shall be imputed to the applicant for patent term restoration.

Subpart E—Due Diligence Hearings

§ 60.40 Request for hearing.

(a) Any person may request, not later than 60 days after the publication under § 60.34(a) of FDA's due diligence determination, that FDA conduct an informal hearing on the due diligence determination.

(b) The request for a hearing under this section shall:

(1) Be sent by mail, personal delivery, or any other mode of written communication to the Division of Dockets Management and filed under the relevant product file;

(2) Specify the facts and the action that are the subject of the hearing;

(3) Provide the name and address of the person requesting the hearing; and

(4) Certify that the requesting party has served a true and complete copy of the request upon the petitioner and the applicant by certified or registered mail (return receipt requested) or by personal delivery.

(c) The request shall state whether the requesting party seeks a hearing within 30 days or 60 days of FDA's receipt of the request.

[53 FR 7305, Mar. 7, 1988, as amended at 67 FR 9585, Mar. 4, 2002]

§ 60.42 Notice of hearing.

Ten days before the hearing, FDA will notify the requesting party, the applicant, and the petitioner, orally or in writing, of the date, time, and location of the hearing. The agency will provide the requesting party, the applicant, and the petitioner with an opportunity to participate as a party in the hearing.

§ 60.44 Hearing procedures.

The due diligence hearing shall be conducted in accordance with this part, supplemented by the nonconflicting procedures in part 16. During the due diligence hearing, the applicant and the petitioner shall enjoy all the rights and privileges accorded a person requesting a hearing under part 16. The standard of due diligence set forth in § 60.36 will apply in the due diligence hearing. The party requesting the due diligence hearing shall have the burden of proof at the hearing.

§ 60.46 Administrative decision.

Within 30 days after the completion of the due diligence hearing, the Commissioner will affirm or revise the determination made under § 60.34(a) and will publish the due diligence redetermination in the FEDERAL REGISTER, notify PTO of the redetermination, and send copies of the notice to PTO and to the requesting party, the applicant, and the petitioner.

PART 70—COLOR ADDITIVES

Subpart A—General Provisions

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AUTHORITY: 21 U.S.C. 321, 341, 342, 343, 348, 351, 360b, 361, 371, 379e.

SOURCE: 42 FR 15636, Mar. 22, 1977, unless otherwise noted.

Subpart A—General Provisions

§ 70.3 Definitions.

(a) *Secretary* means the Secretary of Health and Human Services.

(b) *Department* means the Department of Health and Human Services.

(c) *Commissioner* means the Commissioner of Food and Drugs.

(d) *Act* means the Federal Food, Drug, and Cosmetic Act as amended.

(e) *Color Certification Branch* means the unit established within the Food and Drug Administration located in the Center for Food Safety and Applied Nutrition, charged with the responsibility for the mechanics of the certification procedure hereinafter described, and including the examination of samples of color additives subject to certification.

(f) A *color additive* is any material, not exempted under section 201(t) of the act, that is a dye, pigment, or other substance made by a process of synthesis or similar artifice, or extracted, isolated, or otherwise derived, with or without intermediate or final change of identity, from a vegetable, animal, mineral, or other source and that, when added or applied to a food, drug, or cosmetic or to the human body or any part thereof, is capable (alone or through reaction with another substance) of imparting a color thereto. Substances capable of imparting a color to a container for foods, drugs, or cosmetics are not color additives unless the customary or reasonably foreseeable handling or use of the container may reasonably be expected to result in the transmittal of the color to the contents of the package or any part thereof. Food ingredients such as cherries, green or red peppers, chocolate, and orange juice which contribute their own natural color when mixed with other foods are not regarded as *color additives*; but where a food substance such as beet juice is deliberately used as a color, as in pink lemonade, it is a *color additive*. Food ingredients as authorized by a definitions and standard of identity prescribed by regulations pursuant to section 401 of the act are *color additives*, where the ingredients are specifically designated in the definitions and standards of identity as permitted for use for coloring purposes. An ingredient of an animal feed whose intended function is to impart, through the biological processes of the animal, a color to the meat, milk, or eggs of the animal is a color additive and is not exempt from the requirements of the statute. This definition shall apply whether or not such ingredient has nutritive or other functions in addition to the property of imparting color. An ingested drug the intended function of which is to impart color to the human body is a *color additive*. For the purposes of this part, the term *color* includes black, white, and intermediate grays, but substances including migrants from packaging materials which do not contribute any color apparent to the naked eye are not *color additives*.

(g) For a material otherwise meeting the definition of *color additive* to be exempt from section 721 of the act, on the basis that it is used (or intended to be used) solely for a purpose or purposes other than coloring, the material must be used in a way that any color imparted is clearly unimportant insofar as the appearance, value, marketability, or consumer acceptability is concerned. (It is not enough to warrant exemption if conditions are such that the primary purpose of the material is other than to impart color.)

(h) The exemption that applies to a pesticide chemical, soil or plant nutrient, or other agricultural chemical, where its coloring effect results solely

from its aiding, retarding, or otherwise affecting directly or indirectly, the growth or other natural physiological processes of produce of the soil, applies only to color developed in such product through natural physiological processes such as enzymatic action. If the pesticide chemical, soil or plant nutrient, or other agricultural chemical itself acts as a color or carries as an ingredient a color, and because of this property colors the produce of the soil, it is a *color additive* and is not exempt.

(i) *Safe* means that there is convincing evidence that establishes with reasonable certainty that no harm will result from the intended use of the color additive.

(j) The term *straight color* means a color additive listed in parts 73, 74, and 81 of this chapter, and includes lakes and such substances as are permitted by the specifications for such color.

(k) The term *mixture* means a color additive made by mixing two or more straight colors, or one or more straight colors and one or more diluents.

(l) The term *lake* means a straight color extended on a substratum by adsorption, coprecipitation, or chemical combination that does not include any combination of ingredients made by simple mixing process.

(m) The term *diluent* means any component of a color additive mixture that is not of itself a color additive and has been intentionally mixed therein to facilitate the use of the mixture in coloring foods, drugs, or cosmetics or in coloring the human body. The diluent may serve another functional purpose in the foods, drugs, or cosmetics, as for example sweetening, flavoring, emulsifying, or stabilizing, or may be a functional component of an article intended for coloring the human body.

(n) The term *substratum* means the substance on which the pure color in a lake is extended.

(o) The term *pure color* means the color contained in a color additive, exclusive of any intermediate or other component, or of any diluent or substratum contained therein.

(p) The term *batch* means a homogeneous lot of color additive or color additive mixture produced by an identified production operation, which is set apart and held as a unit for the purpose of obtaining certification of such quantity.

(q) The term *batch number* means the number assigned to a batch by the person who requests certification thereof.

(r) The term *lot number* means an identifying number or symbol assigned to a batch by the Food and Drug Administration.

(s) The term *area of the eye* means the area enclosed with in the circumference of the supra-orbital ridge and the infra-orbital ridge, including the eyebrow, the skin below the eyebrow, the eyelids and the eyelashes, and conjunctival sac of the eye, the eyeball, and the soft areolar tissue that lies within the perimeter of the infra-orbital ridge.

(t) The term *package* means the immediate container in which a color additive or color additive mixture has been packed for shipment or delivery. If the package is then packed in a shipping carton or other protective container, such container shall not be considered to be the immediate container. In the case of color additive mixtures for household use containing less than 15 percent pure color, when two or more containers of 3 ounces each or less, each containing a different color, are distributed as a unit, the immediate container for such unit shall be considered to be the package as defined in this section.

(u) The *hair dye* exemption in section 601(a) of the act applies to coal tar hair dyes intended for use in altering the color of the hair and which are, or which bear or contain, color additives derived from coal tar with the sensitization potential of causing skin irritation in certain individuals and possible blindness when used for dyeing the eyelashes or eyebrows. The exemption is permitted with the condition that the label of any such article bear conspicuously the statutory caution and adequate directions for preliminary patch-testing. The exemption does not apply to coloring ingredients in hair dyes not derived from coal tar, and it does not extend to poisonous or deleterious diluents that may be introduced as wetting agents, hair conditions, emulsifiers, or other components

in a color shampoo, rinse, tint, or similar dual-purpose cosmetic that alter the color of the hair.

(v) The terms *externally applied drugs* and *externally applied cosmetics* mean drugs or cosmetics applied only to external parts of the body and not to the lips or any body surface covered by mucous membrane.

[42 FR 15636, Mar. 22, 1977, as amended at 61 FR 14478, Apr. 2, 1996]

§ 70.5 General restrictions on use of color additives.

(a) *Color additives for use in the area of the eye.* No listing or certification of a color additive shall be considered to authorize the use of any such color additive in any article intended for use in the area of the eye unless such listing or certification of such color additive specifically provides for such use. Any color additive used in or on any article intended for use in the area of the eye, the listing or certification of which color additive does not provide for such use, shall be considered to be a color additive not listed under parts 73, 74, and 81 of this chapter, even though such color additive is certified and/or listed for other uses.

(b) *Color additives for use in injections.* No listing or certification of a color additive shall be considered to authorize the use of any such color additive in any article intended for use in injections unless such listing or certification of such color additive specifically provides for such use. Any color additive used in or on any article intended for use in injections, the listing or certification of which color additive does not provide for such use, shall be considered to be a color additive not listed under parts 73, 74, and 81 of this chapter, even though such color additive is certified and/or listed for other uses.

(c) *Color additives for use in surgical sutures.* No listing or certification of a color additive shall be considered to authorize the use of any such color additive in any article intended for use as a surgical suture unless such listing or certification of such color additive specifically provides for such use. Any color additive used in or on any article intended for use as a surgical suture, the listing or certification of which color additive does not provide for such use, shall be considered to be a color additive not listed under parts 73, 74, and 81 of this chapter, even though such color additive is certified and/or listed for other uses.

§ 70.10 Color additives in standardized foods and new drugs.

(a) *Standardized foods.* (1) Where a petition is received for issuance or amendment of a regulation establishing a definition and standard of identity for a food under section 401 of the act, which proposes the inclusion of a color additive in the standardized food, the provisions of the regulations in part 71 of this chapter shall apply with respect to the information that must be submitted with respect to the safety of the color additive (if such information has not previously been submitted and safety of the color additive for the intended use has not been already established), and the petition must show also that the use of the color additive in the standardized food would be in conformance with section 401 of the act or with the terms of a temporary permit issued under § 130.17 of this chapter.

(2) If a petition for a definition and standard of identity contains a proposal for a color additive regulation, and the petitioner fails to designate it as such, the Commissioner, upon determining that the petition includes a proposal for a color additive regulation, shall so notify the petitioner and shall thereafter proceed in accordance with the regulations in part 71 of this chapter.

(3) A regulation will not be issued allowing the use of a color additive in a food for which a definition and standard of identity is established, unless its issuance is in conformance with section 401 of the act or with the terms of a temporary permit issued under § 130.17 of this chapter. When the contemplated use of such additive complies with the terms of a temporary permit, the color additive regulation will be conditioned on such compliance and will expire with the expiration of the temporary permit.

(b) *New drugs.* (1) Where an application for a new drug is received and this

application proposes, for coloring purposes only, the inclusion of a color additive, the provisions of the regulations in part 71 of this chapter shall apply with respect to the information that must be submitted about the safety of the color additive, if such information has not previously been submitted and safety of the color additive for the intended use has not already been established.

(2) If an application for a new drug inferentially contains a proposal for a color additive regulation, and the applicant fails to designate it as such, the Commissioner, upon determining that the application includes a proposal for a color additive regulation, shall so notify the applicant and shall thereafter proceed in accordance with the regulations in part 71 of this chapter.

(3) Where a petition for a color additive must be filed in accordance with paragraph (b)(2) of this section, the date of filing of the color additive petition shall be considered as the date of filing of the new-drug application.

[42 FR 15636, Mar. 22, 1977, as amended at 64 FR 400, Jan. 5, 1999]

§ 70.11 Related substances.

(a) Different color additives may cause similar or related pharmacological or biological effects, and, in the absence of evidence to the contrary, those that do so will be considered to have additive toxic effects.

(b) Food additives may also cause pharmacological or biological effects similar or related to such effects caused by color additives, and, in the absence of evidence to the contrary, those that do so will be considered as having additive toxic effects.

(c) Pesticide chemicals may also cause pharmacological or biological effects similar or related to such effects caused by color additives, and, in the absence of evidence to the contrary, those that do so will be considered to have additive toxic effects.

(d) In establishing tolerances for color additives, the Commissioner will take into consideration, among other things, the amount of any common component permitted in other color additives, in food additives, and in pesticide chemical residues as well as the similar biological activity (such as cholinesterase inhibition) produced by such substance.

§ 70.19 Fees for listing.

(a) Each petition for the listing of a color additive shall be accompanied by a deposit of $3,000.00 if the proposal is for listing the color additive for use generally in or on foods, in or on drugs, and in or on cosmetics.

(b) If the petition for the listing is for use in or on foods only, the deposit shall be $3,000.00.

(c) If the petition for the listing is for use in or on drugs and/or cosmetics only, the deposit shall be $2,600.00.

(d) The provisions of paragraphs (a), (b), and (c) of this section shall be applicable, whether or not the proposal contemplates any tolerances, limitations, or other restrictions placed upon the use of the color additive.

(e) If a petition proposing the issuance of a regulation is withdrawn before it is finally accepted for filing, the deposit, less a $600.00 fee for clerical handling and administrative and technical review, shall be returned to the petitioner.

(f) If a petition proposing the issuance of a regulation is withdrawn within 30 days after filing, the deposit, less $1,800.00 if the petition is covered by paragraph (a) or (b) of this section, and less $1,600.00, if the petition is covered by paragraph (c) of this section, shall be returned to the petitioner.

(g) When a petition is withdrawn after filing and resubmitted within 6 months, it shall be accompanied by a deposit of $1,800.00 for a petition filed under paragraph (a) or (b) of this section, and $1,600.00 for a petition filed under paragraph (c) of this section. If a petition is resubmitted after 6 months, it shall be accompanied by the deposit that would be required if it were being submitted for the first time.

(h) When the resubmission pertains to a petition that had been withdrawn before acceptance for filing, a new advance deposit shall be made in full as prescribed in paragraph (a), (b), or (c) of this section.

(i) After a color additive has been listed, any request for an amendment or additional tolerance shall be accompanied by a deposit of $1,800.00 for use in the items specified in paragraphs (a)

and (b) of this section, or $1,600.00 for use in items specified in paragraph (c) of this section.

(j) The fee for services in listing a diluent under § 80.35 for use in color additive mixtures shall be $250.00.

(k) Objections and request for public hearing under section 721(d) of the act or section 203(d)(2)(C) of Pub. L. 86–618 (74 Stat. 404; 21 U.S.C. 379e, note) shall be accompanied by a filing fee of $250.00.

(l) In the event of a referral of a petition under this section to an advisory committee, all costs related thereto (including personal compensation of committee members, travel materials, and other costs) shall be borne by the person or organization requesting the referral, such costs to be assessed on the basis of actual cost to the Government: *Provided*, That the compensation of such costs shall include personal compensation of advisory committee members at a rate not to exceed $75.00 per member per day.

(m) In the case of requests of referrals to advisory committees, a special advance deposit shall be made in the amount of $2,500.00. Where required, further advance in increments of $2,500.00 each shall be made upon request of the Commissioner of Food and Drugs. All deposits for referrals to advisory committees in excess of actual expenses shall be refunded to the depositor.

(n) All requests for pharmacological or other scientific studies shall be accompanied by an advance deposit of $5,000.00. Further advance deposits shall be made upon request of the Commissioner of Food and Drugs when necessary to prevent arrears in such cost. Any deposits in excess of actual expenses will be refunded to the depositor. If a request is denied the advance deposit will be refunded less such costs as are incurred for review of the request.

(o) The person who files a petition for judicial review of an order under section 721(d) of the act shall pay the costs of preparing a transcript of the record on which the order is based.

(p) All deposits and fees required by the regulations in this section shall be paid by money order, bank draft or certified check drawn to the order of the Food and Drug Administration, collectible at par at Washington, DC All deposits and fees shall be forwarded to the Center for Food Safety and Applied Nutrition (HFS–200), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, whereupon after making appropriate record thereof they will be transmitted to the Treasurer of the United States for deposit in the special account ''Salaries and Expenses, Certification, Inspection, and Other Services, Food and Drug Administration.''

(q) The Commissioner of Food and Drugs may waive or refund such fees in whole or in part when in his judgment such action will promote the public interest.

(r) Any person who believes that payment of these fees will work a hardship on him may petition the Commissioner of Food and Drugs to waive or refund the fees.

[42 FR 15636, Mar. 22, 1977, as amended at 54 FR 24890, June 12, 1989; 61 FR 14478, Apr. 2, 1996; 66 FR 56035, Nov. 6, 2001; 81 FR 49895, July 29, 2016]

Subpart B—Packaging and Labeling

§ 70.20 Packaging requirements for straight colors (other than hair dyes).

Straight colors shall be packaged in containers which prevent changes in composition. Packages shall be sealed so that they cannot be opened without breaking the seal. An unavoidable change in moisture content caused by the ordinary and customary exposure that occurs in good storage, packing, and distribution practice is not considered a change in composition. If the packaging material is a food additive it shall be authorized by an appropriate regulation in parts 170 through 189 of this chapter.

§ 70.25 Labeling requirements for color additives (other than hair dyes).

(a) *General labeling requirements.* All color additives shall be labeled with sufficient information to assure their safe use and to allow a determination of compliance with any limitations imposed by this part and parts 71, 73, 74,

80, and 81 of this chapter. In addition to all other information required by the act, labels for color additives, except those in a form suitable for coloring the human body, shall state:

(1) The name of the straight color or the name of each ingredient comprising the color additive, if it is a mixture.

(2) A statement indicating general limitations for the use of the color additive, such as ''for food use only''; ''for food, drug, and cosmetic use''; ''for use in drugs for external application only.''

(3) Where regulations issued impose quantitative limitations for a general or specific use of a straight color, the amount of each such straight color in terms of weight per unit/volume or percent by weight.

(4) An expiration date if stability data require it.

(b) *Special labeling for color additives with tolerances.* Where tolerances are imposed for a general or specific use of a color additive, the label shall in addition provide directions for use of the color additive which if followed will preclude the food, drug, or cosmetic to which it is added from containing an amount of the color additive in excess of the tolerance.

(c) *Special labeling for color additives with other limitations.* If use of the color additive is subject to other limitations prescribed in this part, such limitations shall be stated on the label of the color additive by a plain and conspicuous statement. Examples of such limitation statements are: ''Do not use in products used in the area of the eye''; ''Do not use for coloring drugs for injection.''

(d) *Special labeling for color additives not exempt from certification.* Color additives not exempt from the certification procedures shall in addition include in the labeling the lot number assigned by the Color Certification Branch, except that in the case of any mixture for household use which contains not more than 15 percent of pure color and which is in packages containing not more than 3 ounces there appears on the label, a code number which the manufacturer has identified with the lot number by giving to the Food and Drug Administration written notice that such code number will be used in lieu of the lot number.

Subpart C—Safety Evaluation

§ 70.40 Safety factors to be considered.

In accordance with section 721(b)(5)(A)(iii) of the act, the following safety factor will be applied in determining whether the proposed use of a color additive will be safe: Except where evidence is submitted which justifies use of a different safety factor, a safety factor of 100 to 1 will be used in applying animal experimentation data to man; that is, a color additive for use by man will not be granted a tolerance that will exceed 1/100th of the maximum no-effect level for the most susceptible experimental animals tested. The various species of experimental animals used in the tests shall conform to good pharmacological practice.

§ 70.42 Criteria for evaluating the safety of color additives.

(a) In deciding whether a petition is complete and suitable for filing and in reaching a decision on any petition filed, the Commissioner will apply the ''safe-for-use'' principle. This will require the presentation of all needed scientific data in support of a proposed listing to assure that each listed color additive will be safe for its intended use or uses in or on food, drugs, or cosmetics. The Commissioner may list a color additive for use generally in or on food, in or on drugs, or in or on cosmetics when he finds from the data presented that such additive is suitable and may safely be employed for such general use; he may list an additive only for more limited use or uses for which it is proven suitable and may safely be employed; and he is authorized to prescribe broadly the conditions under which the additive may be safely employed for such use or uses. This may allow the use of a particular dye, pigment, or other substance with certain diluents, but not with others, or at a higher concentration with some than with others.

(b) The safety for external color additives will normally be determined by tests for acute oral toxicity, primary irritation, sensitization, subacute dermal toxicity on intact and abraded

skin, and carcinogenicity by skin application. The Commissioner may waive any of such tests if data before him otherwise establish that such test is not required to determine safety for the use proposed.

(c) Upon written request describing the proposed use of a color additive and the proposed experiments to determine its safety, the Commissioner will advise a person who wishes to establish the safety of a color additive whether he believes the experiments planned will yield data adequate for an evaluation of the safety of the additive.

§ 70.45 Allocation of color additives.

Whenever, in the consideration of a petition or a proposal to list a color additive or to alter an existing listing, the data before the Commissioner fail to show that it would be safe to list the color additive for all the uses proposed or at the levels proposed, the Commissioner will notify the petitioner and other interested persons by publication in the FEDERAL REGISTER that it is necessary to allocate the safe tolerance for the straight color in the color additive among the competing needs. This notice shall call for the presentation of data by all interested persons on which the allocation can be made in accordance with section 721(b)(8) of the act. The time for acting upon the petition shall be stayed until such data are presented, whereupon the time limits shall begin to run anew. As promptly as possible after presentation of the data, the Commissioner will, by order, announce the allocation and the tolerance limitations.

§ 70.50 Application of the cancer clause of section 721 of the act.

(a) *Color additives that may be ingested.* Whenever (1) the scientific data before the Commissioner (either the reports from the scientific literature or the results of biological testing) suggest the possibility that the color additive including its components or impurities has induced cancer when ingested by man or animal; or (2) tests which are appropriate for the evaluation of the safety of additives in food suggest that the color additive, including its components or impurities, induces cancer in man or animal, the Commissioner shall determine whether, based on the judgment of appropriately qualified scientists, cancer has been induced and whether the color additive, including its components or impurities, was the causative substance. If it is his judgment that the data do not establish these facts, the cancer clause is not applicable; and if the data considered as a whole establish that the color additive will be safe under the conditions that can be specified in the applicable regulation, it may be listed for such use. But if in the judgment of the Commissioner, based on information from qualified scientists, cancer has been induced, no regulation may issue which permits its use.

(b) *Color additives that will not be ingested.* Whenever the scientific data before the Commissioner suggest the possibility that the color additive, including its components or impurities, has induced cancer in man or animals by routes other than ingestion, the Commissioner shall determine whether, based on the judgment of appropriately qualified scientists, the test suggesting the possibility of carcinogenesis is appropriate for the evaluation of the color additive for a use which does not involve ingestion, cancer has been induced, and the color additive, including its components or impurities, was the causative substance. If it is his judgment that the data do not establish these facts, the cancer clause is not applicable to preclude external drug and cosmetic uses, and if the data as a whole establish that the color additive will be safe under conditions that can be specified in the regulations, it may be listed for such use. But if, in the judgment of the Commissioner, based on information from qualified scientists, the test is an appropriate one for the consideration of safety for the proposed external use, and cancer has been induced by the color additive, including its components or impurities, no regulation may issue which permits its use in external drugs and cosmetics.

(c) *Color additives for use as an ingredient of feed for animals that are raised for food production.* Color additives that are an ingredient of the feed for animals raised for food production and that have the potential to contaminate

human food with residues whose consumption could present a risk of cancer to people must satisfy the requirements of subpart E of part 500 of this chapter.

[42 FR 15636, Mar. 22, 1977, as amended at 43 FR 22675, May 26, 1978; 52 FR 49586, Dec. 31, 1987]

§ 70.51 Advisory committee on the applicability of the anticancer clause.

All requests for and procedures governing any advisory committee on the anticancer clause shall be subject to the provisions of part 14 of this chapter, and particularly subpart H of that part.

§ 70.55 Request for scientific studies.

The Commissioner will consider requests by any interested person who desires the Food and Drug Administration to conduct scientific studies to support a petition for a regulation for a color additive. If favorably acted upon, such studies will be limited to pharmacological investigations, studies of the chemical and physical structure of the color additive, and methods of analysis of the pure color additive (including impurities) and its identification and determination in foods, drugs, or cosmetics, as the case may be. All requests for such studies shall be accompanied by the fee prescribed in § 70.19.

PART 71—COLOR ADDITIVE PETITIONS

Subpart A—General Provisions

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71.37 Exemption of color additives for investigational use.

AUTHORITY: 21 U.S.C. 321, 342, 348, 351, 355, 360, 360b–360f, 360h–360j, 361, 371, 379e, 381; 42 U.S.C. 216, 262.

SOURCE: 42 FR 15639, Mar. 22, 1977, unless otherwise noted.

Subpart A—General Provisions

§ 71.1 Petitions.

(a) Any interested person may propose the listing of a color additive for use in or on any food, drug, or cosmetic or for coloring the human body. Such proposal shall be made in a petition in the form prescribed in paragraph (c) of this section. The petition shall be submitted in triplicate (quadruplicate, if intended uses include uses in meat, meat food product, or poultry product). If any part of the material submitted is in a foreign language, it shall be accompanied by an accurate and complete English translation. The petitioner shall state the post-office address in the United States to which published notices or orders issued or objections filed pursuant to section 721 of the act may be sent.

(b) Pertinent information may be incorporated in, and will be considered as part of, a petition on the basis of specific reference to such information submitted to and retained in the files of the Food and Drug Administration. However, any reference to unpublished information furnished by a person other than the applicant will not be considered unless use of such information is authorized in a written statement signed by the person who submitted the information. Any reference to published information offered in support of a color additive petition should be accompanied by reprints or photostatic copies of such references.

(c) Petitions shall include the following data and be submitted in the following form:

_____ (Date)

Name of petitioner _____
Post-office address _____
Name of color additive and proposed use ____

Office of Food Additive Safety (HFS–200),
Center for Food Safety and Applied Nutrition,
Food and Drug Administration,
5001 Campus Dr.,
College Park, MD 20740
Dear Sir:

Petitioner submits this pursuant to section 721(b)(1) of the Federal Food, Drug, and Cosmetic Act requesting listing by the Commissioner of the color additive _____ as suitable and safe for use in or on _____ subject to the conditions that _____. [Petitioner may propose a listing for general use in food, drugs, or cosmetics or, if such general listing is not believed suitable and safe, the petitioner shall describe the conditions under which he believes the additive can be safely used and for which it will be suitable. These conditions may include tolerance limitations, specifications as to the manner in which the additive may be added or used, and directions and other labeling or packaging safeguards that should be applied. The level of use proposed should not be higher than reasonably required to accomplish the intended color effect.]

Attached hereto, in triplicate (quadruplicate, if intended uses include uses in meat, meat food product, or poultry product), and constituting a part of this petition are the following:

A. The name and all pertinent information concerning the color additive, including chemical identity and composition of the color additive, its physical, chemical, and biological properties, and specifications prescribing its component(s) and identifying and limiting the reaction byproducts and other impurities.

The petition shall contain a description of the chemical and physical tests relied upon to identify the color additive and shall contain a full description of the methods used in, and the facilities and controls used for, the production of the color additive. These shall establish that it is a substance of reproducible composition. Alternative methods and controls and variations in methods and controls, within reasonable limits, that do not affect the characteristics of the substance or the reliability of the controls may be specified.

The petition shall supply a list of all substances used in the synthesis, extraction, or other method of preparation of any straight color, regardless of whether they undergo chemical change in the process. Each substance should be identified by its common or usual name and its complete chemical name, using structural formulas when necessary for specific identification. If any proprietary preparation is used as a component, the proprietary name should be followed by a complete quantitive statement of composition. Reasonable alternatives for any listed substance may be specified.

If the petitioner does not himself perform all the manufacturing, processing, and packing operations for a color additive, the petitioner shall identify each person who will perform a part of such operations and designate the part.

The petition shall include stability data, and, if the data indicate that it is needed to insure the identity, strength, quality, or purity of the color additive, the expiration period that will be employed as well as any packaging and labeling precautions needed to preserve stability.

B. The amount of the color additive proposed for use and the color effect intended to be achieved, together with all directions, recommendations, and suggestions regarding the proposed use, as well as specimens of the labeling proposed for the color additive. If the color effect results or may reasonably be expected to result from use of the color additive in packaging material, the petitioner shall show how this may occur and what residues may reasonably be anticipated.

Typewritten or other draft-labeling copy will be accepted for consideration of the petition provided final printed labeling identical in content to the draft copy is submitted as soon as available, and prior to the marketing of the color additive. The printed labeling shall conform in prominence and conspicuousness with the requirements of the act.

If the color additive is one for which a tolerance limitation is required to assure its safety, the level of use proposed should be no higher than the amount reasonably required to accomplish the intended physical or other technical effect, even though the safety data may support a higher tolerance. If the safety data will not support the use of the amount of the color additive reasonably needed to accomplish the desired color effect, the requested tolerance will not be established. Petitioners are expected to propose the use of color additives in accordance with sound color chemistry.

C.1. A description of practicable methods to determine the pure color and all intermediates, subsidiary colors, and other components of the color additive.

2. A description of practicable methods to determine the amount of the color additive in any raw, processed, and/or finished food, drug, or cosmetic in which use of the color additive is proposed. (The tests proposed shall be those that can be used for food, drug,

or cosmetic control purposes and can be applied with consistent results by any properly equipped laboratory and trained personnel.)

3. A description of methods for identification and determination of any substance formed in or on such food, drug, or cosmetic because of the use of the color additive. (If it is the petitioner's view that any such method would not be needed, under the terms of section 721(b)(5)(A)(iv), a statement shall be submitted in lieu of methods as to the basis for such view.)

D. Full reports of investigation made with respect to the safety of the color additive.

(A petition will be regarded as incomplete unless it includes full reports of adequate tests reasonably applicable to show whether or not the color additive will be safe for its intended use. The reports ordinarily should include detailed data derived from appropriate animal and other biological experiments in which the methods used and the results obtained are clearly set forth. The petition shall not omit without explanation any data that would influence the evaluation of the safety of the color additive).

E. Complete data which will allow the Commissioner to consider, among other things, the probable consumption of, and/or other relevant exposure from the additive and of any substance formed in or on food, drugs, or cosmetics because of such additive; and the cumulative effect, if any, of such additive in the diet of man or animals, taking into account the same or any chemically or pharmacologically related substance or substances in the diet including, but not limited to food additives and pesticide chemicals for which tolerances or exemptions from tolerances have been established.

F. Proposed tolerances and other limitations on the use of the color additive, if tolerances and limitations are required in order to insure its safety. A petitioner may include a proposed regulation.

G. If exemption from batch certification is requested, the reasons why it is believed such certification is not necessary (including supporting data to establish the safety of the intended use).

H. If submitting a petition to alter an existing regulation issued pursuant to section 721(b) of the act, full information on each proposed change that is to be made in the original regulation must be submitted. The petition may omit statements made in the original petition concerning which no change is proposed. A supplemental petition must be submitted for any change beyond the variations provided for in the original petition and the regulation issued on the basis of the original petition.

I. The prescribed fee of $_____ for admitting the color additive to listing is enclosed (unless there is an advance deposit adequate to cover the fee).

Yours very truly,

(Petitioner) _____

By _____ (Indicate authority)

J. The petitioner is required to submit either a claim for categorical exclusion under §25.30 or 25.32 of this chapter or an environmental assessment under §25.40 of this chapter.

(d) The petitioner will be notified of the date on which his petition is filed; and an incomplete petition, or one that has not been submitted in triplicate, will be retained but not filed. A petition shall be retained but shall not be filed if any of the data listed in the above form are lacking or are not set forth so as to be readily understood or if the prescribed fee has not been submitted. The petitioner will be notified in what respects his petition is incomplete.

(e) The petition must be signed by the petitioner or by his attorney or authorized agent, who is a resident of the United States.

(f) The data specified under the several lettered headings should be submitted on separate sheets or sets of sheets, suitably identified. If such data have already been submitted with an earlier application, the present petition may incorporate it by specific reference to the earlier petition.

(g) If nonclinical laboratory studies are involved, petitions filed with the Commissioner under section 721(b) of the act shall include with respect to each nonclinical study contained in the petition, either a statement that the study was conducted in compliance with the good laboratory practice regulations set forth in part 58 of this chapter, or, if the study was not conducted in compliance with such regulations, a brief statement of the reason for the noncompliance.

(h) [Reserved]

(i) If clinical investigations involving human subjects are involved, petitions filed with the Commissioner under section 721(b) of the act shall include statements regarding each such clinical investigation contained in the petition that it either was conducted in compliance with the requirements for institutional review set forth in part 56 of this chapter, or was not subject to such requirements in accordance with

§§ 56.104 or 56.105, and that it was conducted in compliance with the requirements for informed consent set forth in part 50 of this chapter.

(j)(1) If intended uses of the color additive include uses in meat, meat food product, or poultry product subject to regulation by the U.S. Department of Agriculture (USDA) under the Poultry Products Inspection Act (PPIA) (21 U.S.C. 451 *et seq.*) or the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601 *et seq.*), FDA shall, upon filing of the petition, forward a copy of the petition or relevant portions thereof to the Food Safety and Inspection Service, USDA, for simultaneous review under the PPIA and FMIA.

(2) FDA will ask USDA to advise whether the proposed meat and poultry uses comply with the FMIA and PPIA or, if not, whether use of the substance would be permitted in products under USDA jurisdiction under specified conditions or restrictions.

[42 FR 15639, Mar. 22, 1977, as amended at 43 FR 60021, Dec. 22, 1978; 46 FR 8952, Jan. 27, 1981; 50 FR 7491, Feb. 22, 1985; 50 FR 16668, Apr. 26, 1985; 54 FR 24890, June 12, 1989; 61 FR 14478, Apr. 2, 1996; 62 FR 40598, July 29, 1997; 65 FR 51762, Aug. 25, 2000; 66 FR 56035, Nov. 6, 2001; 81 FR 49895, July 29, 2016]

§ 71.2 Notice of filing of petition.

(a) Except where the petition involves a new drug, the Commissioner, within 15 days after receipt, will notify the petitioner of acceptance or nonacceptance of a petition, and if not accepted the reasons therefor. If accepted, the date of the notification letter sent to petitioner becomes the date of filing for the purposes of section 721(d)(1) of the act. If the petitioner desires, he may supplement a deficient petition after being notified regarding deficiencies. If the supplementary material or explanation of the petition is deemed acceptable, petitioner shall be notified. The date of such notification becomes the date of filing. If the petitioner does not wish to supplement or explain the petition and requests in writing that it be filed as submitted, the petition shall be filed and the petitioner so notified. The date of such notification becomes the date of filing. Where the petition involves a new drug, notification to the petitioner will be made in accordance with § 70.10(b)(3) of this chapter.

(b) The Commissioner will cause to be published in the FEDERAL REGISTER within 30 days from the date of filing of such petition a notice of the filing, the name of the petitioner, and a brief description of the proposal in general terms. A copy of the notice will be mailed to the petitioner when the original document is signed.

[42 FR 15639, Mar. 22, 1977, as amended at 64 FR 400, Jan. 5, 1999]

§ 71.4 Samples; additional information.

The Commissioner may request samples of the color additive, articles used as components thereof, or of the food, drug, or cosmetic in which the color additive is proposed to be used, or which comprises the color additive, and any additional information needed to clarify a submitted method or other aspect of a petition at any time while a petition is under consideration. The Commissioner shall specify in the request for a sample of the color additive, or articles used as components thereof, or of the food, drug, or cosmetic in which the color additive is proposed to be used, or which comprises the color additive, a quantity deemed adequate to permit tests of analytical methods to determine quantities of the color additive present in products for which it is intended to be used or adequate for any study or investigation reasonably required with respect to the safety of the color additive or the physical or technical effect it produces. The date used for computing the 90-day limit for the purposes of section 721(d)(1) of the act shall be moved forward 1 day for each day, after mailing date of the request, taken by the petitioner to submit the information and/or sample. If the information or sample is requested a reasonable time in advance of the 180 days, but is not submitted within such 180 days after filing of the petition, the petition will be considered withdrawn without prejudice.

§ 71.6 Extension of time for studying petitions; substantive amendments; withdrawal of petitions without prejudice.

(a) *Extension of time for studying petitions.* If the Commissioner determines that additional time is needed to study and investigate the petition, he shall by written notice to the petitioner extend the 90-day period for not more than 180 days after the filing of the petition.

(b) *Substantive amendments.* After a petition has been filed, the petitioner may submit additional information or data in support thereof. In such cases, if the Commissioner determines that the additional information or data amounts to a substantive amendment, the petition as amended will be given a new filing date, and the time limitation will begin to run anew. If nonclinical laboratory studies are involved, additional information and data submitted in support of filed petitions shall include, with respect to each nonclinical laboratory study contained in the petition, either a statement that the study was conducted in compliance with the requirements set forth in part 58 of this chapter, or, if the study was not conducted in compliance with such regulations, a brief statement of the reason for the noncompliance. If clinical investigations involving human subjects are involved, additional information or data submitted in support of filed petitions shall include statements regarding each such clinical investigation from which the information or data are derived, that it either was conducted in compliance with the requirements for institutional review set forth in part 56 of this chapter, or was not subject to such requirements in accordance with § 56.104 or § 56.105, and that it was conducted in compliance with the requirements for informed consent set forth in part 50 of this chapter.

(c) *Withdrawal of petitions without prejudice.* (1) In some cases the Commissioner may notify the petitioner that the petition, while technically complete, is inadequate to justify the establishment of a regulation or the regulation requested by petitioner. This may be due to the fact that the data are not sufficiently clear or complete. In such cases, the petitioner may withdraw the petition pending its clarification or the obtaining of additional data. This withdrawal will be without prejudice to a future filing. Upon refiling, the time limitation will begin to run anew from the date of refiling.

(2) At any time before the order provided for in § 71.20 has been forwarded to the FEDERAL REGISTER for publication the petitioner may withdraw the petition without prejudice to a future filing. Upon refiling, the time limitation will begin to run anew.

[42 FR 15636, Mar. 22, 1977, as amended at 43 FR 60021, Dec. 22, 1978; 46 FR 8952, Jan. 27, 1981; 50 FR 7491, Feb. 22, 1985]

§ 71.15 Confidentiality of data and information in color additive petitions.

(a) The following data and information in a color additive petition are available for public disclosure, unless extraordinary circumstances are shown, after the notice of filing of the petition is published in the FEDERAL REGISTER or, if the petition is not promptly filed because of deficiencies in it, after the petitioner is informed that it will not be filed because of the deficiencies involved:

(1) All safety and functionality data and information submitted with or incorporated by reference in the petition.

(2) A protocol for a test or study, unless it is shown to fall within the exemption established for trade secrets and confidential commercial information in § 20.61 of this chapter.

(3) Adverse reaction reports, product experience reports, consumer complaints, and other similar data and information, after deletion of:

(i) Names and any information that would identify the person using the product.

(ii) Names and any information that would identify any third party involved with the report, such as a physician or hospital or other institution.

(4) A list of all ingredients contained in a color additive, whether or not it is in descending order of predominance. A particular ingredient or group of ingredients shall be deleted from any such list prior to public disclosure if it is shown to fall within the exemption established in § 20.61 of this chapter, and

a notation shall be made that any such ingredient list is incomplete.

(5) An assay method or other analytical method, unless it serves no regulatory or compliance purpose and is shown to fall within the exemption established in § 20.61 of this chapter.

(6) All records showing the Food and Drug Administration's testing of or action on a particular lot of a certifiable color additive.

(b) The following data and information in a color additive petition are not available for public disclosure unless they have been previously disclosed to the public as defined in § 20.81 of this chapter or they relate to a product or ingredient that has been abandoned and they no longer represent a trade secret or confidential commercial or financial information as defined in § 20.61 of this chapter:

(1) Manufacturing methods or processes, including quality control procedures.

(2) Production, sales, distribution, and similar data and information, except that any compilation of such data and information aggregated and prepared in a way that does not reveal data or information which is not available for public disclosure under this provision is available for public disclosure.

(3) Quantitative or semiquantitative formulas.

(c) All correspondence and written summaries of oral discussions relating to a color additive petition are available for public disclosure in accordance with the provisions of part 20 of this chapter when the color additive regulation is published in the FEDERAL REGISTER.

(d) For purposes of this regulation, safety and functionality data include all studies and tests of a color additive on animals and humans and all studies and tests on a color additive for identity, stability, purity, potency, performance, and usefulness.

§ 71.18 Petition for exemption from certification.

A manufacturer, packer, or distributor of a color additive or color additive mixture may petition for an exemption from certification pursuant to part 10 of this chapter. Any such petition shall show why such certification is not necessary for the protection of public health.

Subpart B—Administrative Action on Petitions

§ 71.20 Publication of regulation.

The Commissioner will forward for publication in the FEDERAL REGISTER, within 90 days after filing of the petition (or within 180 days if the time is extended as provided for in section 721(d)(1) of the act):

(a) A regulation listing in part 73 or 74 of this chapter the color additive on the appropriate list or lists as provided under section 721(b)(1).

(1) Such a regulation may list the color additive for use generally in or on foods, drugs, or cosmetics or for use in coloring the human body, as the case may be, or may prescribe the conditions under which the color additive may be safely used (including, but not limited to, specifications as to the particular food, drug, or cosmetic or classes of food, drugs, or cosmetics in or on which such color additive may be used, or for the material intended for coloring the human body; the maximum quantity of any straight color or diluent that may be used or permitted to remain in or on such food, drug, or cosmetic or article intended for coloring the human body; the manner in which such color additive may be added to or used in or on such food, drug, or cosmetic or for coloring the human body; and any directions or other labeling or packing requirements for such color additives deemed necessary to assure the safety of such use).

(2) Such regulations shall list the color additive only for the use or uses for which it has been found suitable and for which it may safely be employed. Alternatively, the Commissioner shall by order deny the petition, and notify the petitioner of such order and the reasons therefor.

(3) The regulation shall list any use or uses in meat, meat food product, or poultry product subject to the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601 *et seq.*) or the Poultry Products Inspection (PPIA) (21 U.S.C. 451 *et seq.*) for which the color additive has been

found suitable and for which it may safely be employed.

(b) Whenever the Commissioner finds that batch certification is not necessary for the protection of the public health he will, by order, exempt the color additive from the certification procedure. In determining whether certification of a color additive is necessary, the Commissioner will consider the composition of the additive, its manufacturing process, possible impurities, its toxic potential, control and analytical procedures necessary to assure compliance with the listing specifications, and the variability of its composition.

[42 FR 15639, Mar. 22, 1977, as amended at 65 FR 51762, Aug. 25, 2000]

§ 71.22 Deception as a basis for refusing to issue regulations; deceptive use of a color additive for which a regulation has issued.

The Commissioner shall refuse to issue a regulation listing a color additive, if in his judgment the data before him show that such proposed use would promote deception of the consumer or would result in misbranding or adulteration within the meaning of the act. Such a finding shall be by order published in the FEDERAL REGISTER subject to the filing of objections and a request for a hearing by adversely affected parties. The issuance of a regulation for a color additive authorizing its use generally in or on a food, drug, or cosmetic shall not be construed as authorization to use the color additive in a manner that may promote deception or conceal damage or inferiority. The use of a color additive to promote deception or conceal damage or inferiority shall be considered as the use of a color additive for which no regulation has issued pursuant to section 721(b) of the act, even though the regulation is effective for other uses.

§ 71.25 Condition for certification.

(a) When the Commissioner cannot conclude from the information before him that there is a basis for exempting a color additive from the requirement of batch certification, he will so order by appropriate listing in part 74 of this chapter. The Commissioner's order shall state in detail the specifications that shall be met by the color additive.

(b) Each order shall state a period of time after which use of a color additive subject to batch certification but not from a batch certified by procedure prescribed in this section would result in adulteration of the product in which it is used.

§ 71.26 Revocation of exemption from certification.

If information becomes available to the Commissioner that a color additive that has been granted exemption from certification should not, for the protection of the public health, be so exempted, such exemption will be canceled by a notice published in the FEDERAL REGISTER.

§ 71.27 Listing and exemption from certification on the Commissioner's initiative.

Where a petition for a regulation to list a color additive has not been received and the Commissioner has available facts which demonstrate that a color additive should be listed and/or that certification procedure is not necessary in order to protect the public health, he may list such color additive by appropriate regulation and listing in part 73 or 74 of this chapter.

§ 71.30 Procedure for filing objections to regulations.

(a) Objections and hearings relating to color additive regulations under section 721 (b) and (c) of the act shall be governed by parts 10, 12, 13, 14, 15, 16, and 19 of this chapter.

(b) The fees specified in § 70.19 of this chapter shall be applicable.

§ 71.37 Exemption of color additives for investigational use.

(a) A shipment or other delivery of a color additive or of a food, drug, or cosmetic containing such a color additive for investigational use by experts qualified to determine safety shall be exempt from the requirements of section 402(c), 501(a), or 601(e) of the act, provided that the color additive or the food, drug, or cosmetic containing the color additive bears a label which

states prominently, ''Caution—Contains new color additive—For investigational use only.'' No animals used in such investigations, or their products, such as milk or eggs, shall be used for food purposes, unless the sponsor or the investigator has submitted to the Commissioner data demonstrating that such use will be consistent with the public health, and the Commissioner, proceeding as he would in a matter involving section 409(i) of the act, has notified the sponsor or investigator that the proposed disposition for food is authorized. Any person who contests a refusal to grant such authorization shall have an opportunity for a regulatory hearing before the Food and Drug Administration pursuant to part 16 of this chapter.

(b) The person who introduced such shipment or who delivers the color additive or a food, drug, or cosmetic containing such an additive into interstate commerce shall maintain adequate records showing the name and post-office address of the expert to whom the color additive is shipped, date, quantity, and batch or code mark of each shipment and delivery for a period of 2 years after such shipment and delivery. Upon the request of a properly authorized employee of the Department, at reasonable times, he shall make such records available for inspection and copying.

PART 73—LISTING OF COLOR ADDITIVES EXEMPT FROM CERTIFICATION

Subpart A—Foods

Sec.
73.1 Diluents in color additive mixtures for food use exempt from certification.
73.30 Annatto extract.
73.35 Astaxanthin.
73.37 Astaxanthin dimethyldisuccinate.
73.40 Dehydrated beets (beet powder).
73.50 Ultramarine blue.
73.70 Calcium carbonate.
73.75 Canthaxanthin.
73.85 Caramel.
73.90 β-Apo-8′-carotenal.
73.95 β-Carotene.
73.100 Cochineal extract; carmine.
73.125 Sodium copper chlorophyllin.
73.140 Toasted partially defatted cooked cottonseed flour.
73.160 Ferrous gluconate.
73.165 Ferrous lactate.
73.169 Grape color extract.
73.170 Grape skin extract (enocianina).
73.185 Haematococcus algae meal.
73.200 Synthetic iron oxide.
73.250 Fruit juice.
73.260 Vegetable juice.
73.275 Dried algae meal.
73.295 Tagetes (Aztec marigold) meal and extract.
73.300 Carrot oil.
73.315 Corn endosperm oil.
73.340 Paprika.
73.345 Paprika oleoresin.
73.350 Mica-based pearlescent pigments.
73.352 Paracoccus pigment.
73.355 Phaffia yeast.
73.450 Riboflavin.
73.500 Saffron.
73.520 Soy leghemoglobin.
73.530 Spirulina extract.
73.575 Titanium dioxide.
73.585 Tomato lycopene extract; tomato lycopene concentrate.
73.600 Turmeric.
73.615 Turmeric oleoresin.

Subpart B—Drugs

73.1001 Diluents in color additive mixtures for drug use exempt from certification.
73.1010 Alumina (dried aluminum hydroxide).
73.1015 Chromium-cobalt-aluminum oxide.
73.1025 Ferric ammonium citrate.
73.1030 Annatto extract.
73.1070 Calcium carbonate.
73.1075 Canthaxanthin.
73.1085 Caramel.
73.1095 β-Carotene.
73.1100 Cochineal extract; carmine.
73.1125 Potassium sodium copper chlorophyllin (chlorophyllin-copper complex).
73.1150 Dihydroxyacetone.
73.1162 Bismuth oxychloride.
73.1200 Synthetic iron oxide.
73.1298 Ferric ammonium ferrocyanide.
73.1299 Ferric ferrocyanide.
73.1326 Chromium hydroxide green.
73.1327 Chromium oxide greens.
73.1329 Guanine.
73.1350 Mica-based pearlescent pigments.
73.1375 Pyrogallol.
73.1400 Pyrophyllite.
73.1410 Logwood extract.
73.1496 Mica.
73.1530 Spirulina extract.
73.1550 Talc.
73.1575 Titanium dioxide.
73.1645 Aluminum powder.
73.1646 Bronze powder.
73.1647 Copper powder.
73.1991 Zinc oxide.

Subpart C—Cosmetics

73.2030 Annatto.

73.2085 Caramel.
73.2087 Carmine.
73.2095 β-Carotene.
73.2110 Bismuth citrate.
73.2120 Disodium EDTA-copper.
73.2125 Potassium sodium copper chlorophyllin (chlorophyllin-copper complex).
73.2150 Dihydroxyacetone.
73.2162 Bismuth oxychloride.
73.2180 Guaiazulene.
73.2190 Henna.
73.2250 Iron oxides.
73.2298 Ferric ammonium ferrocyanide.
73.2299 Ferric ferrocyanide.
73.2326 Chromium hydroxide green.
73.2327 Chromium oxide greens.
73.2329 Guanine.
73.2396 Lead acetate.
73.2400 Pyrophyllite.
73.2496 Mica.
73.2500 Silver.
73.2575 Titanium dioxide.
73.2645 Aluminum powder.
73.2646 Bronze powder.
73.2647 Copper powder.
73.2725 Ultramarines.
73.2775 Manganese violet.
73.2991 Zinc oxide.
73.2995 Luminescent zinc sulfide.

Subpart D—Medical Devices

73.3100 1,4-Bis[(2-hydroxyethyl)amino]-9,10-anthracenedione bis(2-methyl-2-propenoic)ester copolymers.
73.3105 1,4-Bis[(2-methylphenyl)amino]-9,10-anthracenedione.
73.3106 1,4-Bis[4-(2-methacryloxyethyl) phenylamino]anthraquinone copolymers.
73.3107 Carbazole violet.
73.3110 Chlorophyllin-copper complex, oil soluble.
73.3110a Chromium-cobalt-aluminum oxide.
73.3111 Chromium oxide greens.
73.3112 C.I. Vat Orange 1.
73.3115 2-[[2,5-Diethoxy-4-[(4-methylphenyl)thiol]phenyl]azo]-1,3,5-benzenetriol.
73.3117 16,23-Dihydrodinaphtho[2,3-a:2′,3′-i] naphth [2′,3′:6,7] indolo [2,3-c] carbazole-5,10,15,17,22,24-hexone.
73.3118 N,N′-(9,10-Dihydro-9,10-dioxo-1,5-anthracenediyl) bisbenzamide.
73.3119 7,16-Dichloro-6,15-dihydro-5,9,14,18-anthrazinetetrone.
73.3120 16,17-Dimethoxydinaphtho [1,2,3-cd:3′,2′,1′-lm] perylene-5,10-dione.
73.3121 Poly(hydroxyethyl methacrylate)-dye copolymers.
73.3122 4-[(2,4-dimethylphenyl)azo]-2,4-dihydro-5-methyl-2-phenyl-3H-pyrazol-3-one.
73.3123 6-Ethoxy-2-(6-ethoxy-3-oxobenzo[b]thien-2(3H)-ylidene) benzo[b]thiophen-3 (2H)-one.
73.3124 Phthalocyanine green.
73.3125 Iron oxides.
73.3126 Titanium dioxide.
73.3127 Vinyl alcohol/methyl methacrylate-dye reaction products.
73.3128 Mica-based pearlescent pigments.
73.3129 Disodium 1-amino-4-[[4-[(2-bromo-1-oxoallyl)amino]-2-sulfonatophenyl]amino]-9,10-dihydro-9,10-dioxoanthracene-2-sulfonate.

AUTHORITY: 21 U.S.C. 321, 341, 342, 343, 348, 351, 352, 355, 361, 362, 371, 379e.

SOURCE: 42 FR 15643, Mar. 22, 1977, unless otherwise noted.

EDITORIAL NOTE: Nomenclature changes to part 73 appear at 66 FR 66742, Dec. 27, 2001.

Subpart A—Foods

§ 73.1 Diluents in color additive mixtures for food use exempt from certification.

The following substances may be safely used as diluents in color additive mixtures for food use exempt from certification, subject to the condition that each straight color in the mixture has been exempted from certification or, if not so exempted, is from a batch that has previously been certified and has not changed in composition since certification. If a specification for a particular diluent is not set forth in this part 73, the material shall be of a purity consistent with its intended use.

(a) *General use.* (1) Substances that are generally recognized as safe under the conditions set forth in section 201(s) of the act.

(2) Substances meeting the definitions and specifications set forth under subchapter B of this chapter, and which are used only as prescribed by such regulations.

(3) The following:

Substances	Definitions and specifications	Restrictions
Calcium disodium EDTA (calcium disodium ethyl- enediamine- tetraacetate).	Contains calcium disodium ethyl- enediamine- tetraacetate dihydrate (CAS Reg. No. 6766–87–6) as set forth in the Food Chemicals Codex, 3d ed., p. 50, 1981.	May be used in aqueous solutions and aqueous dispersions as a preservative and sequestrant in color additive mixtures intended only for ingested use; the color additive mixture (solution or dispersion) may contain not more than 1 percent by weight of the diluent (calculated as anhydrous calcium disodium ethyl- enediamine-tetraacetate).
Castor oil	As set forth in U.S.P. XVI	Not more than 500 p.p.m. in the finished food. Labeling of color additive mixtures containing castor oil shall bear adequate directions for use that will result in a food meeting this restriction.
Dioctylsodium sulfosuccinate	As set forth in sec. 172.810 of this chapter.	Not more than 9 p.p.m. in the finished food. Labeling of color additive mixtures containing dioctylsodium sulfosuccinate shall bear adequate directions for use that will result in a food meeting this restriction.
Disodium EDTA (disodium ethyl- enediamine- tetraacetate).	Contains disodium ethyl- enediamine- tetraacetate dihydrate (CAS Reg. No. 6381–92–6) as set forth in the Food Chemicals Codex, 3d ed., p. 104, 1981.	May be used in aqueous solutions and aqueous dispersions as a preservative and sequestrant in color additive mixtures intended only for ingested use; the color additive mixture (solution or dispersion) may contain not more than 1 percent by weight of the diluent (calculated as anhydrous disodium ethyl- enediamine- tetraacetate).

(b) *Special use*—(1) *Diluents in color additive mixtures for marking food*—(i) *Inks for marking food supplements in tablet form, gum, and confectionery*. Items listed in paragraph (a) of this section and the following:

Substances	Definitions and specifications	Restrictions
Alcohol, SDA–3A	As set forth in 26 CFR pt. 212	No residue.
n-Butyl alcohol		Do.
Cetyl alcohol	As set forth in N.F. XI	Do.
Cyclohexane		Do.
Ethyl cellulose	As set forth in sec. 172.868 of this chapter.	
Ethylene glycol monoethyl ether		Do.
Isobutyl alcohol		Do.
Isopropyl alcohol		Do.
Polyoxyethylene sorbitan monooleate (polysorbate 80).	As set forth in sec. 172.840 of this chapter.	
Polyvinyl acetate	Molecular weight, minimum 2,000.	
Polyvinylpyrrolidone	As set forth in sec. 173.55 of this chapter.	
Rosin and rosin derivatives	As set forth in sec. 172.615 of this chapter.	
Shellac, purified	Food grade.	

(ii) *Inks for marking fruit and vegetables*. Items listed in paragraph (a) of this section and the following:

Substances	Definitions and specifications	Restrictions
Acetone	As set forth in N.F. XI	No residue.
Alcohol, SDA–3A	As set forth in 26 CFR pt. 212	Do.
Benzoin	As set forth in U.S.P. XVI.	
Copal, Manila	.	
Ethyl acetate	As set forth in N.F. XI	Do.
Ethyl cellulose	As set forth in sec. 172.868 of this chapter.	
Methylene chloride		Do.
Polyvinylpyrrolidone	As set forth in sec. 173.55 of this chapter.	
Rosin and rosin derivatives	As set forth in sec. 172.615 of this chapter.	

Substances	Definitions and specifications	Restrictions
Silicon dioxide	As set forth in sec. 172.480 of this chapter.	Not more than 2 pct of the ink solids.
Terpene resins, natural	As set forth in sec. 172.615 of this chapter.	
Terpene resins, synthetic	Polymers of α- and β-pinene.	

(2) *Diluents in color additive mixtures for coloring shell eggs.* Items listed in paragraph (a) of this section and the following, subject to the condition that there is no penetration of the color additive mixture or any of its components through the eggshell into the egg:

Alcohol, denatured, formula 23A (26 CFR part 212), Internal Revenue Service.
Damar gum (resin).
Diethylene glycol distearate.
Dioctyl sodium sulfosuccinate.
Ethyl cellulose (as identified in § 172.868 of this chapter).
Ethylene glycol distearate.
Japan wax.
Limed rosin.
Naphtha.
Pentaerythritol ester of fumaric acid-rosin adduct.
Polyethylene glycol 6000 (as identified in § 172.820 of this chapter).
Polyvinyl alcohol.
Rosin and rosin derivatives (as identified in § 172.615 of this chapter).

(3) *Miscellaneous special uses.* Items listed in paragraph (a) of this section and the following:

Substances	Definitions and specifications	Restrictions
Polyvinylpyrrolidone	As set forth in sec. 173.55 of this chapter.	In or as food-tablet coatings; limit, not more than 0.1 pct in the finished food; labeling of color additive mixtures containing polyvinylpyrrolidone shall bear adequate directions for use that will result in a food meeting this restriction.

[42 FR 15643, Mar. 22, 1977, as amended at 57 FR 32175, July 21, 1992; 69 FR 24511, May 4, 2004]

§ 73.30 Annatto extract.

(a) *Identity.* (1) The color additive annatto extract is an extract prepared from annatto seed, *Bixa orellana* L., using any one or an appropriate combination of the food-grade extractants listed in paragraph (a)(1) (i) and (ii) of this section:

(i) Alkaline aqueous solution, alkaline propylene glycol, ethyl alcohol or alkaline solutions thereof, edible vegetable oils or fats, mono- and diglycerides from the glycerolysis of edible vegetable oils or fats. The alkaline alcohol or aqueous extracts may be treated with food-grade acids to precipitate annatto pigments, which are separated from the liquid and dried, with or without intermediate recrystallization, using the solvents listed under paragraph (a)(1)(ii) of this section. Food-grade alkalis or carbonates may be added to adjust alkalinity.

(ii) Acetone, ethylene dichloride, hexane, isopropyl alcohol, methyl alcohol, methylene chloride, trichloroethylene.

(2) Color additive mixtures for food use made with annatto extract may contain only diluents that are suitable and that are listed in this subpart as safe in color additive mixtures for coloring foods.

(b) *Specifications.* Annatto extract, including pigments precipitated therefrom, shall conform to the following specifications:

(1) Arsenic (as As), not more than 3 parts per million; lead as Pb, not more than 10 parts per million.

(2) When solvents listed under paragraph (a)(1)(ii) of this section are used, annatto extract shall contain no more solvent residue than is permitted of the corresponding solvents in spice oleoresins under applicable food additive regulations in parts 170 through 189 of this chapter.

(c) *Uses and restrictions.* Annatto extract may be safely used for coloring

foods generally, in amounts consistent with good manufacturing practice, except that it may not be used to color foods for which standards of identity have been promulgated under section 401 of the act unless added color is authorized by such standards.

(d) *Labeling*. The label of the color additive and any mixtures prepared therefrom and intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter. Labels shall bear information showing that the color is derived from annatto seed. The requirements of § 70.25(a) of this chapter that all ingredients shall be listed by name shall not be construed as requiring the declaration of residues of solvents listed in paragraph (a)(1)(ii) of this section.

(e) *Exemption from certification*. Certification of this color additive is not necessary for the protection of the public health and therefore batches thereof are exempt from the certification requirements of section 721(c) of the act.

§ 73.35 Astaxanthin.

(a) *Identity*. (1) The color additive astaxanthin is 3, 3′-dihydroxy-β, β-carotene-4, 4′-dione.

(2) Astaxanthin may be added to the fish feed only as a component of a stabilized color additive mixture. Color additive mixtures for fish feed use made with astaxanthin may contain only those diluents that are suitable and are listed in this subpart as safe for use in color additive mixtures for coloring foods.

(b) *Specifications*. Astaxanthin shall conform to the following specifications and shall be free from impurities other than those named to the extent that such impurities may be avoided by good manufacturing practice:

Physical state, solid.
0.05 percent solution in chloroform, complete and clear.
Absorption maximum wavelength 484–493 nanometers (in chloroform).
Residue on ignition, not more than 0.1 percent.
Total carotenoids other than astaxanthin, not more than 4 percent.
Lead, not more than 5 parts per million.
Arsenic, not more than 2 parts per million.
Mercury, not more than 1 part per million.
Heavy metals, not more than 10 parts per million.
Assay, minimum 96 percent.

(c) *Uses and restrictions*. Astaxanthin may be safely used in the feed of salmonid fish in accordance with the following prescribed conditions:

(1) The color additive is used to enhance the pink to orange-red color of the flesh of salmonid fish.

(2) The quantity of color additive in feed is such that the color additive shall not exceed 80 milligrams per kilogram (72 grams per ton) of finished feed.

(d) *Labeling requirements*. (1) The labeling of the color additive and any premixes prepared therefrom shall bear expiration dates for the sealed and open container (established through generally accepted stability testing methods), other information required by § 70.25 of this chapter, and adequate directions to prepare a final product complying with the limitations prescribed in paragraph (c) of this section.

(2) The presence of the color additive in finished fish feed prepared according to paragraph (c) of this section shall be declared in accordance with § 501.4 of this chapter.

(3) The presence of the color additive in salmonid fish that have been fed feeds containing astaxanthin shall be declared in accordance with §§ 101.22(k)(2) and 101.100(a)(2) of this chapter.

(e) *Exemption from certification*. Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 721(c) of the act.

[60 FR 18738, Apr. 13, 1995]

§ 73.37 Astaxanthin dimethyldisuccinate.

(a) *Identity*. (1) The color additive astaxanthin dimethyldisuccinate is 3,3′-bis(4-methoxy-1,4-dioxobutoxy)-β,β-carotene–4,4′-dione.

(2) Astaxanthin dimethyldisuccinate may be added to the fish feed only as a component of a stabilized mixture. Color additive mixtures for fish feed use made with astaxanthin dimethyldisuccinate may contain only those diluents that are suitable and are listed in this subpart as safe for use in

color additive mixtures for coloring foods.

(b) *Specifications.* Astaxanthin dimethyldisuccinate shall conform to the following specifications and shall be free from impurities other than those named to the extent that such impurities may be avoided by good manufacturing practice:

(1) Physical state, solid.

(2) 0.05 percent solution in chloroform, complete and clear.

(3) Absorption maximum wavelength 484–493 nanometers (in chloroform).

(4) Residue on ignition, not more than 0.1 percent.

(5) Total carotenoids other than astaxanthin dimethyldisuccinate, not more than 4 percent.

(6) Lead, not more than 5 milligrams per kilogram (mg/kg) (5 parts per million).

(7) Arsenic, not more than 2 mg/kg (2 parts per million).

(8) Mercury, not more than 1 mg/kg (1 part per million).

(9) Heavy metals, not more than 10 mg/kg (10 parts per million).

(10) Assay including astaxanthin dimethyldisuccinate, astaxanthin monomethylsuccinate, and astaxanthin, minimum 96 percent.

(c) *Uses and restrictions.* Astaxanthin dimethyldisuccinate may be safely used in the feed of salmonid fish in accordance with the following prescribed conditions:

(1) The color additive is used to enhance the pink to orange-red color of the flesh of salmonid fish.

(2) The quantity of astaxanthin dimethyldisuccinate in the finished feed, when used alone or in combination with other astaxanthin color additive sources listed in this part 73, shall not exceed 110 milligrams per kilogram (mg/kg), which is equivalent to 80 mg/kg astaxanthin (72 grams per ton).

(d) *Labeling requirements.* (1) The labeling of the color additive and any premixes prepared therefrom shall bear expiration dates for the sealed and open container (established through generally accepted stability testing methods), other information required by § 70.25 of this chapter, and adequate directions to prepare a final product complying with the limitations prescribed in paragraph (c) of this section.

(2) The presence of the color additive in finished fish feed prepared according to paragraph (c) of this section shall be declared in accordance with § 501.4 of this chapter.

(3) The presence of the color additive in salmonid fish that have been fed feeds containing astaxanthin dimethyldisuccinate shall be declared in accordance with §§ 101.22(b), (c), and (k)(2), and 101.100(a)(2) of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 721(c) of the act.

[74 FR 57251, Nov. 5, 2009]

§ 73.40 Dehydrated beets (beet powder).

(a) *Identity.* (1) The color additive dehydrated beets is a dark red powder prepared by dehydrating sound, mature, good quality, edible beets.

(2) Color additive mixtures made with dehydrated beets may contain as diluents only those substances listed in this subpart as safe and suitable for use in color additive mixtures for coloring foods.

(b) *Specifications.* The color additive shall conform to the following specifications:

Volatile matter, not more than 4 percent.
Acid insoluble ash, not more than 0.5 percent.
Lead (as Pb), not more than 10 parts per million.
Arsenic (as As), not more than 1 part per million.
Mercury (as Hg), not more than 1 part per million.

(c) *Uses and restrictions.* Dehydrated beets may be safely used for the coloring of foods generally in amounts consistent with good manufacturing practice, except that it may not be used to color foods for which standards of identity have been promulgated under section 401 of the act, unless the use of added color is authorized by such standards.

(d) *Labeling.* The label of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 721(c) of the act.

§ 73.50 Ultramarine blue.

(a) *Identity.* The color additive ultramarine blue is a blue pigment obtained by calcining a mixture of kaolin, sulfur, sodium carbonate, and carbon at temperatures above 700 °C. Sodium sulfate and silica may also be incorporated in the mixture in order to vary the shade. The pigment is a complex sodium aluminum sulfo-silicate having the approximate formula $Na_7Ai_6Si_6O_{24}S_3$.

(b) *Specifications.* Ultramarine blue shall conform to the following specifications:

Lead (as Pb), not more than 10 parts per million.
Arsenic (as As), not more than 1 part per million.
Mercury (as Hg), not more than 1 part per million.

(c) *Uses and restrictions.* The color additive ultramarine blue may be safely used for coloring salt intended for animal feed subject to the restriction that the quantity of ultramarine blue does not exceed 0.5 percent by weight of the salt.

(d) *Labeling requirements.* The color additive shall be labeled in accordance with the requirements of § 70.25 of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 721(c) of the act.

§ 73.70 Calcium carbonate.

(a) *Identity.* (1) The color additive calcium carbonate is a fine, white powder consisting essentially of calcium carbonate ($CaCO_3$) prepared either by grinding naturally occurring limestone or synthetically, by precipitation.

(2) Color additive mixtures for food use made with calcium carbonate may contain only those diluents that are suitable and that are listed in this subpart as safe for use in color additive mixtures for coloring foods.

(b) *Specifications.* The color additive meets the specifications of the Food Chemicals Codex, 10th ed. (2016), pp. 213–214 (calcium carbonate) and p. 754 (limestone, ground), which is incorporated by reference. The Director of the Office of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain copies from the United States Pharmacopeial Convention, 12601 Twinbrook Pkwy., Rockville, MD 20852 (internet address *http://www.usp.org*). Copies may be examined at the Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301–796–2039, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

(c) *Uses and restrictions.* Calcium carbonate may be safely used in amounts consistent with good manufacturing practice to color soft and hard candies and mints, and in inks used on the surface of chewing gum, except that it may not be used to color chocolate for which standards of identity have been promulgated under section 401 of the Federal Food, Drug, and Cosmetic Act unless added color is authorized by such standards.

(d) *Labeling requirements.* The label of the color additive and of any mixtures prepared therefrom intended solely or in part for coloring purposes must conform to the requirements of § 70.25 of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and, therefore, batches thereof are exempt from the certification requirements of section 721(c) of the Federal Food, Drug, and Cosmetic Act.

[82 FR 51557, Nov. 7, 2017]

§ 73.75 Canthaxanthin.

(a) *Identity.* (1) The color additive canthaxanthin is β-carotene-4,4′-dione.

(2) Color additive mixtures for food use made with canthaxanthin may contain only those diluents that are suitable and that are listed in this subpart as safe for use in color additive mixtures for coloring foods.

(b) *Specifications.* Canthaxanthin shall conform to the following specifications and shall be free from impurities other than those named to the extent that such other impurities may be avoided by good manufacturing practice:

Physical state, solid.
1 percent solution in chloroform, complete and clear.
Melting range (decomposition), 207 °C. to 212 °C. (corrected).
Loss on drying, not more than 0.2 percent.
Residue on ignition, not more than 0.2 percent.
Total carotenoids other than trans-canthaxanthin, not more than 5 percent.
Lead, not more than 10 parts per million.
Arsenic, not more than 3 parts per million.
Mercury, not more than 1 part per million.
Assay, 96 to 101 percent.

(c) *Use and restrictions.* (1) The color additive canthaxanthin may be safely used for coloring foods generally subject to the following restrictions:

(i) The quantity of canthaxanthin does not exceed 30 milligrams per pound of solid or semisolid food or per pint of liquid food; and

(ii) It may not be used to color foods for which standards of identity have been promulgated under section 401 of the act unless added color is authorized by such standards.

(2) Canthaxanthin may be safely used in broiler chicken feed to enhance the yellow color of broiler chicken skin in accordance with the following conditions: The quantity of canthaxanthin incorporated in the feed shall not exceed 4.41 milligrams per kilogam (4 grams per ton) of complete feed to supplement other known sources of xanthophyll and associated carotenoids to accomplish the intended effect.

(3) Canthaxanthin may be safely used in the feed of salmonid fish in accordance with the following prescribed conditions:

(i) Canthaxanthin may be added to the fish feed only in the form of a stabilized color additive mixture;

(ii) The color additive is used to enhance the pink to orange-red color of the flesh of salmonid fish; and

(iii) The quantity of color additive in feed shall not exceed 80 milligrams per kilogram (72 grams per ton) of finished feed.

(d) *Labeling requirements.* (1) The labeling of the color additive and any mixture prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(2) For purposes of coloring fish, the labeling of the color additive and any premixes prepared therefrom shall bear expiration dates (established through generally accepted stability testing methods) for the sealed and open container, other information required by § 70.25 of this chapter, and adequate directions to prepare a final product complying with the limitations prescribed in paragraph (c)(3) of this section.

(3) The presence of the color additive in finished fish feed prepared according to paragraph (c)(3) of this section shall be declared in accordance with § 501.4 of this chapter.

(4) The presence of the color additive in salmonid fish that have been fed feeds containing canthaxanthin shall be declared in accordance with §§ 101.22(b), (c), and (k)(2), and 101.100(a)(2) of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 721(c) of the act.

[42 FR 15643, Mar. 22, 1977, as amended at 50 FR 47534, Nov. 19, 1985; 63 FR 14817, Mar. 27, 1998]

§ 73.85 Caramel.

(a) *Identity.* (1) The color additive caramel is the dark-brown liquid or solid material resulting from the carefully controlled heat treatment of the following food-grade carbohydrates:

Dextrose.
Invert sugar.
Lactose.
Malt sirup.
Molasses.
Starch hydrolysates and fractions thereof.
Sucrose.

(2) The food-grade acids, alkalis, and salts listed in this subparagraph may be employed to assist caramelization, in amounts consistent with good manufacturing practice.

(i) Acids:

Acetic acid.
Citric acid.
Phosphoric acid.
Sulfuric acid.
Sulfurous acid.

(ii) Alkalis:

Ammonium hydroxide.
Calcium hydroxide U.S.P.
Potassium hydroxide.
Sodium hydroxide.

(iii) Salts: Ammonium, sodium, or potassium carbonate, bicarbonate, phosphate (including dibasic phosphate and monobasic phosphate), sulfate, and sulfite.

(3) Polyglycerol esters of fatty acids, identified in § 172.854 of this chapter, may be used as antifoaming agents in amounts not greater than that required to produce the intended effect.

(4) Color additive mixtures for food use made with caramel may contain only diluents that are suitable and that are listed in this subpart as safe in color additive mixtures for coloring foods.

(b) *Specifications*. Caramel shall conform to the following specifications:

Lead (as Pb), not more than 10 parts per million.
Arsenic (as As), not more than 3 parts per million.
Mercury (as Hg), not more than 0.1 part per million.

(c) *Uses and restrictions*. Caramel may be safely used for coloring foods generally, in amounts consistent with good manufacturing practice, except that it may not be used to color foods for which standards of identity have been promulgated under section 401 of the act unless added color is authorized by such standards.

(d) *Labeling*. The label of the color additive and any mixtures prepared therefrom and intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Exemption from certification*. Certification of this color additive is not necessary for the protection of the public health and therefore batches thereof are exempt from the certification requirements of section 721(c) of the act.

§ 73.90 β-Apo-8′-carotenal.

(a) *Identity*. (1) The color additive is β-apo-8′-carotenal.

(2) Color additive mixtures for food use made with β-apo-8′-carotenal may contain only diluents that are suitable and that are listed in this subpart as safe in color additive mixtures for coloring foods.

(b) *Specifications*. β-Apo-8′-carotenal shall conform to the following specifications:

Physical state, solid.
1 percent solution in chloroform, clear.
Melting point (decomposition), 136 °C.–140 °C. (corrected).
Loss of weight on drying, not more than 0.2 percent.
Residue on ignition, not more than 0.2 percent.
Lead (as Pb), not more than 10 parts per million.
Arsenic (as As), not more than 1 part per million.
Assay (spectrophotometric), 96–101 percent.

(c) *Uses and restrictions*. The color additive β-apo-8′-carotenal may be safely used for coloring foods generally, subject to the following restrictions:

(1) The quantity of β-apo-8′-carotenal does not exceed 15 milligrams per pound of solid or semisolid food or 15 milligrams per pint of liquid food.

(2) It may not be used to color foods for which standards of identity have been promulgated under section 401 of the act unless added color is authorized by such standards.

(d) *Labeling*. The label of the color additive and any mixtures prepared therefrom and intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Exemption from certification*. Certification of this color additive is not necessary for the protection of the public health and therefore batches thereof are exempt from the certification requirements of section 721(c) of the act.

§ 73.95 β-Carotene.

(a) *Identity*. (1) The color additive is β-carotene prepared synthetically or obtained from natural sources.

(2) Color additive mixtures for food use made with β-carotene may contain only diluents that are suitable and that are listed in this subpart as safe in color additive mixtures for coloring foods.

(b) *Specifications*. β-carotene shall conform to the following specifications:

Physical state, solid.
1 percent solution in chloroform, clear.
Loss of weight on drying, not more than 0.2 percent.
Residue on ignition, not more than 0.2 percent.
Lead (as Pb), not more than 10 parts per million.
Arsenic (as As), not more than 3 parts per million.
Assay (spectrophotometric), 96–101 percent.

(c) *Uses and restrictions*. The color additive β-carotene may be safely used for coloring foods generally, in amounts consistent with good manufacturing practice, except that it may not be used to color those foods for which standards of identity have been promulgated under section 401 of the act unless added color is authorized by such standards.

(d) *Labeling*. The label of the color additive and any mixtures prepared therefrom and intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Exemption from certification*. Certification of this color additive is not necessary for the protection of the public health and therefore batches thereof are exempt from the certification requirements of section 721(c) of the act.

§ 73.100 Cochineal extract; carmine.

(a) *Identity*. (1) The color additive cochineal extract is the concentrated solution obtained after removing the alcohol from an aqueous-alcoholic extract of cochineal (*Dactylopius coccus costa* (*Coccus cacti* L.)). The coloring principle is chiefly carminic acid.

(2) The color additive carmine is the aluminum or calcium-aluminum lake on an aluminum hydroxide substrate of the coloring principles, chiefly carminic acid, obtained by an aqueous extraction of cochineal (*Dactylopius coccus costa* (*Coccus cacti* L.)).

(3) Color additive mixtures for food use made with cochineal extract or carmine may contain only diluents that are suitable and that are listed in this subpart as safe in color additive mixtures for coloring foods.

(b) *Specifications*. (1) Cochineal extract shall conform to the following specifications:

pH, not less than 5.0 and not more than 5.5 at 25 °C.
Protein (N × 6.25), not more than 2.2 percent.
Total solids, not less than 5.7 and not more than 6.3 percent.
Methyl alcohol, not more than 150 parts per million.
Lead (as Pb), not more than 10 parts per million.
Arsenic (as As), not more than 1 part per million.
Carminic acid, not less than 1.8 percent.

(2) Carmine shall conform to the following specifications:

Volatile matter (at 135 °C. for 3 hours), not more than 20.0 percent.
Ash, not more than 12.0 percent.
Lead (as Pb), not more than 10 parts per million.
Arsenic (as As), not more than 1 part per million.
Carminic acid, not less than 50.0 percent.

Carmine and cochineal extract shall be pasteurized or otherwise treated to destroy all viable Salmonella microorganisms. Pasteurization or such other treatment is deemed to permit the adding of safe and suitable substances (other than chemical preservatives) that are essential to the method of pasteurization or other treatment used. For the purposes of this paragraph, safe and suitable substances are those substances that perform a useful function in the pasteurization or other treatment to render the carmine and cochineal extract free of viable Salmonella microorganisms, which substances are not food additives as defined in section 201(s) of the act or, if they are food additives as so defined, are used in conformity with regulations established pursuant to section 409 of the act.

(c) *Uses and restrictions*. Carmine and cochineal extract may be safely used for coloring foods generally in amounts consistent with good manufacturing practice, except that they may not be used to color foods for which standards

of identity have been promulgated under section 401 of the act unless added color is authorized by such standards.

(d) *Labeling requirements.* (1) The label of the color additives and any mixtures intended solely or in part for coloring purposes prepared therefrom shall conform to the requirements of § 70.25 of this chapter.

(2) The label of food products intended for human use, including butter, cheese, and ice cream, that contain cochineal extract or carmine shall specifically declare the presence of the color additive by listing its respective common or usual name, ''cochineal extract'' or ''carmine,'' in the statement of ingredients in accordance with § 101.4 of this chapter.

(e) *Exemption from certification.* Certification of these color additives is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 721(c) of the act.

[42 FR 15643, Mar. 22, 1977, as amended at 74 FR 216, Jan. 5, 2009]

§ 73.125 Sodium copper chlorophyllin.

(a) *Identity.* (1) The color additive sodium copper chlorophyllin is a green to black powder prepared from chlorophyll by saponification and replacement of magnesium by copper. Chlorophyll is extracted from alfalfa (*Medicago sativa*) using any one or a combination of the solvents acetone, ethanol, and hexane.

(2) Color additive mixtures made with sodium copper chlorophyllin may contain only those diluents that are suitable and are listed in this subpart as safe for use in color additive mixtures for coloring foods.

(b) *Specifications.* Sodium copper chlorophyllin shall conform to the following specifications and shall be free from impurities other than those named to the extent that such impurities may be avoided by good manufacturing practice:

(1) Moisture, not more than 5.0 percent.

(2) Solvent residues (acetone, ethanol, and hexane), not more than 50 parts per million, singly or, in combination.

(3) Total copper, not less than 4 percent and not more than 6 percent.

(4) Free copper, not more than 200 parts per million.

(5) Lead (as Pb), not more than 10 parts per million.

(6) Arsenic (as As), not more than 3 parts per million.

(7) Mercury (as Hg), not more than 0.5 part per million.

(8) Ratio of absorbance at 405 nanometers (nm) to absorbance at 630 nm, not less than 3.4 and not more than 3.9.

(9) Total copper chlorophyllins, not less than 95 percent of the sample dried at 100 °C for 1 hour.

(c) *Uses and restrictions.* Sodium copper chlorophyllin may be safely used to color citrus-based dry beverage mixes in an amount not exceeding 0.2 percent in the dry mix.

(d) *Labeling requirements.* The label of the color additive and any mixtures prepared therefrom shall conform to the requirements of § 70.25 of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 721(c) of the act.

[67 FR 35431, May 20, 2002]

§ 73.140 Toasted partially defatted cooked cottonseed flour.

(a) *Identity.* (1) The color additive toasted partially defatted cooked cottonseed flour is a product prepared as follows: Food quality cottonseed is delinted and decorticated; the meats are screened, aspirated, and rolled; moisture is adjusted, the meats heated, and the oil expressed; the cooked meats are cooled, ground, and reheated to obtain a product varying in shade from light to dark brown.

(2) Color additive mixtures for food use made with toasted partially defatted cooked cottonseed flour may contain only diluents that are suitable and that are listed in this subpart as safe in color additive mixtures for coloring foods.

(b) *Specifications.* Toasted partially defatted cooked cottonseed flour shall conform to the following specifications:

Arsenic: It contains no added arsenic compound and therefore may not exceed a maximum natural background level of 0.2 part per million total arsenic, calculated as As.

Lead (as Pb), not more than 10 parts per million.

Free gossypol content, not more than 450 parts per million.

(c) *Uses and restrictions.* The color additive toasted partially defatted cooked cottonseed flour may be safely used for coloring foods generally, in amounts consistent with good manufacturing practice, except that it may not be used to color foods for which standards of identity have been promulgated under section 401 of the act, unless added color is authorized by such standards.

(d) *Labeling.* The label of the color additive and any mixtures prepared therefrom and intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health and therefore batches thereof are exempt from the certification requirements of section 721(c) of the act.

§ 73.160 Ferrous gluconate.

(a) *Identity.* The color additive ferrous gluconate is the ferrous gluconate defined in the Food Chemicals Codex, 3d Ed. (1981), pp. 122–123, which is incorporated by reference. Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

(b) *Specifications.* Ferrous gluconate shall meet the specifications given in the Food Chemicals Codex, 3d Ed. (1981), which is incorporated by reference. The availability of this incorporation by reference is given in paragraph (a) of this section.

(c) *Uses and restrictions.* Ferrous gluconate may be safely used in amounts consistent with good manufacturing practice for the coloring of ripe olives.

(d) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 721(c) of the act.

[42 FR 15643, Mar. 22, 1977, as amended at 47 FR 946, Jan. 8, 1982; 49 FR 10089, Mar. 19, 1984]

§ 73.165 Ferrous lactate.

(a) *Identity.* The color additive ferrous lactate is the ferrous lactate defined in § 184.1311 of this chapter.

(b) *Specifications.* Ferrous lactate shall meet the specifications given in the Food Chemicals Codex, 4th ed. (1996), pp. 154 to 155, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301–796–2039, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

(c) *Uses and restrictions.* Ferrous lactate may be safely used in amounts consistent with good manufacturing practice for the coloring of ripe olives.

(d) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 721(c) of the Federal Food, Drug, and Cosmetic Act (the act).

[61 FR 40319, Aug. 2, 1996, as amended at 66 FR 66742, Dec. 27, 2001; 81 FR 5590, Feb. 3, 2016]

§ 73.169 Grape color extract.

(a) *Identity*. (1) The color additive grape color extract is an aqueous solution of anthocyanin grape pigments made from Concord grapes or a dehydrated water soluble powder prepared from the aqueous solution. The aqueous solution is prepared by extracting the pigments from precipitated lees produced during the storage of Concord grape juice. It contains the common components of grape juice, namely anthocyanins, tartrates, malates, sugars, and minerals, etc., but not in the same proportion as found in grape juice. The dehydrated water soluble powder is prepared by spray drying the aqueous solution containing added malto-dextrin.

(2) Color additive mixtures for food use made with grape color extract may contain only those diluents listed in this subpart as safe and suitable in color additive mixtures for coloring foods.

(b) *Specifications*. Grape color extract shall conform to the following specifications: Pesticide residues, not more than permitted in or on grapes by regulations promulgated under section 408 of the Federal Food, Drug, and Cosmetic Act. Lead (as Pb), not more than 10 parts per million. Arsenic (as As), not more than 1 part per million.

(c) *Uses and restrictions*. Grape color extract may be safely used for the coloring of nonbeverage food, except that it may not be used to color foods for which standards of identity have been promulgated under section 401 of the act, unless the use of added color is authorized by such standards.

(d) *Labeling*. The color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall bear, in addition to the other information required by the act, labeling in accordance with the provisions of § 70.25 of this chapter.

(e) *Exemption from certification*. Certification of this color additive is not necessary for the protection of the public health, and therefore batches are exempt from the certification requirements of section 721(c) of the Act.

[46 FR 47532, Sept. 29, 1981]

§ 73.170 Grape skin extract (enocianina).

(a) *Identity*. (1) The color additive grape skin extract (enocianina) is a purplish-red liquid prepared by the aqueous extraction (steeping) of the fresh deseeded marc remaining after grapes have been pressed to produce grape juice or wine. It contains the common components of grape juice; namely, anthocyanins, tartaric acid, tannins, sugars, minerals, etc., but not in the same proportions as found in grape juice. During the steeping process, sulphur dioxide is added and most of the extracted sugars are fermented to alcohol. The extract is concentrated by vacuum evaporation, during which practically all of the alcohol is removed. A small amount of sulphur dioxide may be present.

(2) Color additive mixtures for food use made with grape skin extract (enocianina) may contain only those diluents listed in this subpart as safe and suitable in color additive mixtures for coloring foods.

(b) *Specifications*. Grape skin extract (enocianina) shall conform to the following specifications:

Pesticide residues, not more than permitted in or on grapes by regulations promulgated under section 408 of the Federal Food, Drug, and Cosmetic Act.

Lead (as Pb), not more than 10 parts per million.

Arsenic (as As), not more than 1 part per million.

(c) *Uses and restrictions*. Grape skin extract (enocianina) may be safely used for the coloring of still and carbonated drinks and ades, beverage bases, and alcoholic beverages subject to the following restrictions:

(1) It may not be used to color foods for which standards of identity have been promulgated under section 401 of the act unless artificial color is authorized by such standards.

(2) Its use in alcoholic beverages shall be in accordance with the provisions of parts 4 and 5, title 27 CFR.

(d) *Labeling requirements*. The label of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter. The common or usual name of the color additive is ''grape

skin extract'' followed, if desired, by ''(enocianina)''.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 721(c) of the act.

§ 73.185 Haematococcus algae meal.

(a) *Identity.* (1) The color additive haematococcus algae meal consists of the comminuted and dried cells of the alga *Haematococcus pluvialis*.

(2) Haematococcus algae meal may be added to the fish feed only as a component of a stabilized color additive mixture. Color additive mixtures for fish feed use made with haematococcus algae meal may contain only those diluents that are suitable and are listed in this subpart as safe for use in color additive mixtures for coloring foods.

(b) *Specifications.* Haematococcus algae meal shall conform to the following specifications and shall be free from impurities other than those named to the extent that such impurities may be avoided by good manufacturing practice:

Physical state, solid.
Lead, not more than 5 parts per million.
Arsenic, not more than 2 parts per million.
Mercury, not more than 1 part per million.
Heavy metals (as Pb), not more than 10 parts per million.
Astaxanthin, not less than 1.5 percent.

(c) *Uses and restrictions.* Haematococcus algae meal may be safely used in the feed of salmonid fish in accordance with the following prescribed conditions:

(1) The color additive is used to enhance the pink to orange-red color of the flesh of salmonid fish.

(2) The quantity of astaxanthin in finished feed, from haematococcus algae meal when used alone or in combination with other astaxanthin color additive sources listed in this part 73, shall not exceed 80 milligrams per kilogram (72 grams per ton) of finished feed.

(d) *Labeling requirements.* (1) The labeling of the color additive and any premixes prepared therefrom shall bear expiration dates for the sealed and open container (established through generally accepted stability testing methods), other information required by § 70.25 of this chapter, and adequate directions to prepare a final product complying with the limitations prescribed in paragraph (c) of this section.

(2) The presence of the color additive in finished fish feed prepared according to paragraph (c) of this section shall be declared in accordance with § 501.4 of this chapter.

(3) The presence of the color additive in salmonid fish that have been fed feeds containing haematococcus algae meal shall be declared in accordance with §§ 101.22(b), (c), and (k)(2), and 101.100(a)(2) of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 721(c) of the act.

[65 FR 41584, July 6, 2000]

§ 73.200 Synthetic iron oxide.

(a) *Identity.* (1) The color additive synthetic iron oxide consists of any one or any combination of synthetically prepared iron oxides, including the hydrated forms. It is free from admixture with other substances.

(2) Color additive mixtures for food use made with synthetic iron oxide may contain only those diluents that are suitable and that are listed in this subpart as safe for use in color additive mixtures for coloring foods.

(b) *Specifications.* (1) Synthetic iron oxide for human food use shall conform to the following specifications:

Arsenic (as As), not more than 3 milligrams per kilogram (mg/kg) (3 parts per million (ppm)).
Lead (as Pb), not more than 5 mg/kg (5 ppm).
Mercury (as Hg), not more than 1 mg/kg (1 ppm).

(2) Synthetic iron oxide for dog and cat food use shall conform to the following specifications:

Arsenic (as As), not more than 5 parts per million.
Lead (as Pb), not more than 20 parts per million.
Mercury (as Hg), not more than 3 parts per million.

(c) *Uses and restrictions.* (1) Synthetic iron oxide may be safely used for

human food use subject to the following restrictions:

(i) In sausage casings intended for human consumption in an amount not exceeding 0.10 percent by weight of the finished food.

(ii) In soft and hard candy, mints, and chewing gum at levels consistent with good manufacturing practice, except that it may not be used to color foods for which standards of identity have been issued under section 401 of the Federal Food, Drug, and Cosmetic Act, unless the use of the added color is authorized by such standards.

(iii) In dietary supplement tablets and capsules, including coatings and printing inks, such that the total amount of elemental iron per day for labeled dosages does not exceed 5 milligrams.

(2) Synthetic iron oxide may be safely used for the coloring of dog and cat foods in an amount not exceeding 0.25 percent by weight of the finished food.

(d) *Labeling requirements*. The label of the color additive and any mixture prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Exemption from certification*. Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 721(c) of the act.

[42 FR 15643, Mar. 22, 1977, as amended at 59 FR 10578, Mar. 7, 1994; 80 FR 14842, Mar. 20, 2015; 83 FR 54872, Nov. 1, 2018]

§ 73.250 Fruit juice.

(a) *Identity*. (1) The color additive fruit juice is prepared either by expressing the juice from mature varieties of fresh, edible fruits, or by the water infusion of the dried fruit. The color additive may be concentrated or dried. The definition of fruit juice in this paragraph is for the purpose of identity as a color additive only and shall not be construed as a standard of identity under section 401 of the act. However, where a standard of identity for a particular fruit juice has been promulgated under section 401 of the act, it shall conform to such standard.

(2) Color additive mixtures made with fruit juice may contain as diluents only those substances listed in this subpart as safe and suitable in color additive mixtures for coloring foods.

(b) *Uses and restrictions*. Fruit juice may be safely used for the coloring of foods generally, in amounts consistent with good manufacturing practice, except that it may not be used to color foods for which standards of identity have been promulgated under section 401 of the act, unless the use of added color is authorized by such standards.

(c) *Labeling*. The color additive and any mixtures intended solely or in part for coloring purposes prepared therefrom shall bear, in addition to the other information required by the act, labeling in accordance with the provisions of § 70.25 of this chapter.

(d) *Exemption from certification*. Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 721(c) of the act.

[42 FR 15643, Mar. 22, 1977, as amended at 60 FR 52629, Oct. 10, 1995]

§ 73.260 Vegetable juice.

(a) *Identity*. (1) The color additive vegetable juice is prepared either by expressing the juice from mature varieties of fresh, edible vegetables, or by the water infusion of the dried vegetable. The color additive may be concentrated or dried. The definition of vegetable juice in this paragraph is for the purpose of identity as a color additive only, and shall not be construed as a standard of identity under section 401 of the act. However, where a standard of identity for a particular vegetable juice has been promulgated under section 401 of the act, it shall conform to such standard.

(2) Color additive mixtures made with vegetable juice may contain as diluents only those substances listed in this subpart as safe and suitable in color additive mixtures for coloring foods.

(b) *Uses and restrictions*. Vegetable juice may be safely used for the coloring of foods generally, in amounts consistent with good manufacturing practice, except that it may not be used to

color foods for which standards of identity have been promulgated under section 401 of the act, unless the use of added color is authorized by such standards.

(c) *Labeling*. The color additive and any mixtures intended solely or in part for coloring purposes prepared therefrom shall bear, in addition to the other information required by the act, labeling in accordance with the provisions of § 70.25 of this chapter.

(d) *Exemption from certification*. Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 721(c) of the act.

[42 FR 15643, Mar. 22, 1977, as amended at 60 FR 52629, Oct. 10, 1995]

§ 73.275 Dried algae meal.

(a) *Identity*. The color additive dried algae meal is a dried mixture of algae cells (genus *Spongiococcum*, separated from its culture broth), molasses, cornsteep liquor, and a maximum of 0.3 percent ethoxyquin. The algae cells are produced by suitable fermentation, under controlled conditions, from a pure culture of the genus *Spongiococcum*.

(b) *Uses and restrictions*. The color additive dried algae meal may be safely used in chicken feed in accordance with the following prescribed conditions:

(1) The color additive is used to enhance the yellow color of chicken skin and eggs.

(2) The quantity of the color additive incorporated in the feed is such that the finished feed:

(i) Is supplemented sufficiently with xanthophyll and associated carotenoids so as to accomplish the intended effect described in paragraph (b)(1) of this section; and

(ii) Meets the tolerance limitation for ethoxyquin in animal feed prescribed in § 573.380 of this chapter.

(c) *Labeling*. The label of the color additives and any premixes prepared therefrom shall bear in addition to the information required by § 70.25 of this chapter.

(1) A statement of the concentrations of xanthophyll and ethoxyquin contained therein.

(2) Adequate directions to provide a final product complying with the limitations prescribed in paragraph (b) of this section.

(d) *Exemption from certification*. Certification of this color additive is not necessary for the protection of the public health and therefore batches thereof are exempt from the certification requirements of section 721(c) of the act.

§ 73.295 Tagetes (Aztec marigold) meal and extract.

(a) *Identity*. (1) The color additive tagetes (Aztec marigold) meal is the dried, ground flower petals of the Aztec marigold (*Tagetes erecta* L.) mixed with not more than 0.3 percent ethoxyquin.

(2) The color additive tagetes (Aztec marigold) extract is a hexane extract of the flower petals of the Aztec marigold (*Tagetes erecta* L.). It is mixed with an edible vegetable oil, or with an edible vegetable oil and a hydrogenated edible vegetable oil, and not more than 0.3 percent ethoxyquin. It may also be mixed with soy flour or corn meal as a carrier.

(b) *Specifications*. (1) Tagetes (Aztec marigold) meal is free from admixture with other plant material from *Tageteserecta* L. or from plant material or flowers of any other species of plants.

(2) Tagetes (Aztec marigold) extract shall be prepared from tagetes (Aztec marigold) petals meeting the specifications set forth in paragraph (b)(1) of this section and shall conform to the following additional specifications:

Melting point	53.5–55.0 °C.
Iodine value	132–145.
Saponification value	175–200.
Acid value	0.60–1.20.
Titer	35.5–37.0 °C.
Unsaponifiable matter	23.0 percent–27.0 percent.
Hexane residue	Not more than 25 p.p.m.

All determinations, except the hexane residue, shall be made on the initial extract of the flower petals (after drying in a vacuum oven at 60 °C. for 24 hours) prior to the addition of the oils and ethoxyquin. The hexane determination shall be made on the color additive after the addition of the vegetable oils, hydrogenated vegetable oils, and ethoxyquin.

(c) *Uses and restrictions*. The color additives tagetes (Aztec marigold) meal and extract may be safely used in

chicken feed in accordance with the following prescribed conditions:

(1) The color additives are used to enhance the yellow color of chicken skin and eggs.

(2) The quantity of the color additives incorporated in the feed is such that the finished feed:

(i) Is supplemented sufficiently with xanthophyll and associated carotenoids so as to accomplish the intended effect described in paragraph (c)(1) of this section; and

(ii) Meets the tolerance limitation for ethoxyquin in animal feed prescribed in § 573.380 of this chapter.

(d) *Labeling requirements*. The label of the color additives and any premixes prepared therefrom shall bear, in addition to the information required by § 70.25 of this chapter:

(1) A statement of the concentrations of xanthophyll and ethoxyquin contained therein.

(2) Adequate directions to provide a final product complying with the limitations prescribed in paragraph (c) of this section.

(e) *Exemption from certification*. Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 721(c) of the act.

§ 73.300 Carrot oil.

(a) *Identity*. (1) The color additive carrot oil is the liquid or the solid portion of the mixture or the mixture itself obtained by the hexane extraction of edible carrots (*Daucus carota* L.) with subsequent removal of the hexane by vacuum distillation. The resultant mixture of solid and liquid extractives consists chiefly of oils, fats, waxes, and carrotenoids naturally occurring in carrots. The definition of carrot oil in this paragraph is for the purpose of identity as a color additive only and shall not be construed as setting forth an official standard for carrot oil or carrot oleoresin under section 401 of the act.

(2) Color additive mixtures for food use made with carrot oil may contain only those diluents listed in this subpart as safe and suitable in color additive mixtures for coloring foods.

(b) *Specifications*. Carrot oil shall contain no more than 25 parts per million of hexane.

(c) *Uses and restrictions*. Carrot oil may be safely used for coloring foods generally, in amounts consistent with good manufacturing practice, except that it may not be used to color foods for which standards of identity have been promulgated under section 401 of the act unless the use of added color is authorized by such standards.

(d) *Labeling requirements*. The label of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Exemption from certification*. Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 721(c) of the act.

§ 73.315 Corn endosperm oil.

(a) *Identity*. (1) The color additive corn endosperm oil is a reddish-brown liquid composed chiefly of glycerides, fatty acids, sitosterols, and carotenoid pigments obtained by isopropyl alcohol and hexane extraction from the gluten fraction of yellow corn grain. The definition of corn endosperm oil in this paragraph is for the purpose of definition as a color additive only and shall not be construed as a food standard of identity under section 401 of the act.

(2) Color additive mixtures for food use made with corn endosperm oil may contain only those diluents listed in this subpart as safe and suitable in color additive mixtures for coloring foods.

(b) *Specifications*. Corn endosperm oil conforms to the following specifications:

Total fatty acids, not less than 85 percent.
Iodine value, 118 to 134.
Saponification value, 165 to 185.
Unsaponifiable matter, not more than 14 percent.
Hexane, not more than 25 parts per million.
Isopropyl alcohol, not more than 100 parts per million.

(c) *Uses and restrictions*. The color additive corn endosperm oil may be safely used in chicken feed in accordance

with the following prescribed conditions:

(1) The color additive is used to enhance the yellow color of chicken skin and eggs.

(2) The quantity of the color additive incorporated in the feed is such that the finished feed is supplemented sufficiently with xanthophyll and associated carotenoids so as to accomplish the intended effect described in paragraph (c)(1) of this section.

(d) *Labeling requirements*. The label of the color additive and any premixes prepared therefrom shall bear, in addition to the information required by § 70.25 of this chapter, a statement of the concentration of xanthophyll contained therein.

(e) *Exemption from certification*. Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 721(c) of the act.

§ 73.340 Paprika.

(a) *Identity*. (1) The color additive paprika is the ground dried pod of mild capsicum (*Capsicum annuum* L.). The definition of paprika in this paragraph is for the purpose of identity as a color additive only and shall not be construed as setting forth an official standard for paprika under section 401 of the act.

(2) Color additive mixtures made with paprika may contain as diluents only those substances listed in this subpart as safe and suitable in color additive mixtures for coloring foods.

(b) *Uses and restrictions*. Paprika may be safely used for the coloring of foods generally, in amounts consistent with good manufacturing practice, except that it may not be used to color foods for which standards of identity have been promulgated under section 401 of the act, unless the use of added color is authorized by such standards.

(c) *Labeling*. The color additive and any mixtures intended solely or in part for coloring purposes prepared therefrom shall bear, in addition to the other information required by the act, labeling in accordance with the provisions of § 70.25 of this chapter.

(d) *Exemption from certification*. Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 721(c) of the act.

§ 73.345 Paprika oleoresin.

(a) *Identity*. (1) The color additive paprika oleoresin is the combination of flavor and color principles obtained from paprika (*Capsicum annuum* L.) by extraction, using any one or a combination of the following solvents:

Acetone	Isopropyl alcohol
Ethyl alcohol	Methyl alcohol
Ethylene dichloride	Methylene chloride
Hexane	Trichloroethylene

The definition of paprika oleoresin in this paragraph is for the purpose of identity as a color additive only, and shall not be construed as setting forth an official standard for paprika oleoresin under section 401 of the act.

(2) Color additive mixtures made with paprika oleoresin may contain as diluents only those substances listed in this subpart as safe and suitable in color additive mixtures for coloring foods.

(b) *Specifications*. Paprika oleoresin shall contain no more residue of the solvents listed in paragraph (a)(1) of this section than is permitted of the corresponding solvents in spice oleoresins under applicable food additive regulations in parts 170 through 189 of this chapter.

(c) *Uses and restrictions*. Paprika oleoresin may be safely used for the coloring of foods generally in amounts consistent with good manufacturing practice, except that it may not be used to color foods for which standards of identity have been promulgated under section 401 of the act, unless the use of added color is authorized by such standards.

(d) *Labeling*. The color additive and any mixtures intended solely or in part for coloring purposes prepared therefrom shall bear, in addition to the other information required by the act, labeling in accordance with the provisions of § 70.25 of this chapter.

(e) *Exemption from certification*. Certification of this color additive is not

necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 721(c) of the act.

§ 73.350 Mica-based pearlescent pigments.

(a) *Identity*. (1) The color additive is formed by depositing titanium salts onto mica, followed by heating to produce titanium dioxide on mica. Mica used to manufacture the color additive shall conform in identity to the requirements of § 73.1496(a)(1).

(2) Color additive mixtures for food use made with mica-based pearlescent pigments may contain only those diluents listed in this subpart as safe and suitable for use in color additive mixtures for coloring food.

(b) *Specifications*. Mica-based pearlescent pigments shall conform to the following specifications and shall be free from impurities other than those named to the extent that such other impurities may be avoided by good manufacturing practice:

(1) Lead (as Pb), not more than 4 parts per million (ppm).

(2) Arsenic (as As), not more than 3 ppm.

(3) Mercury (as Hg), not more than 1 ppm.

(c) *Uses and restrictions*. (1) The substance listed in paragraph (a) of this section may be safely used as a color additive in food as follows:

(i) In amounts up to 1.25 percent, by weight, in the following foods: Cereals, confections and frostings, gelatin desserts, hard and soft candies (including lozenges), nutritional supplement tablets and gelatin capsules, and chewing gum.

(ii) In amounts up to 0.07 percent, by weight, in the following:

(A) Distilled spirits containing not less than 18 percent and not more than 25 percent alcohol by volume.

(B) Cordials, liqueurs, flavored alcoholic malt beverages, wine coolers, and cocktails.

(C) Non-alcoholic cocktail mixes and mixers, such as margarita mix, Bloody Mary mix, and daiquiri mix, but excluding eggnog, tonic water, and beverages that are typically consumed without added alcohol (*e.g.*, fruit juices, fruit juice drinks, and soft drinks).

(iii) In egg decorating kits used for coloring the shells of eggs in amounts consistent with good manufacturing practice.

(2) The color additive may not be used to color foods for which standards of identity have been issued under section 401 of the act, unless the use of the added color is authorized by such standards.

(d) *Labeling*. The label of the color additive and of any mixture prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Exemption from certification*. Certification of this color additive is not necessary for the protection of the public health and therefore batches thereof are exempt from the certification requirements of section 721(c) of the act.

[71 FR 31929, June 2, 2006, as amended at 78 FR 35117, June 12, 2013; 80 FR 32307, June 8, 2015; 80 FR 58602, Sept. 30, 2015]

§ 73.352 Paracoccus pigment.

(a) *Identity*. (1) The color additive paracoccus pigment consists of the heat-killed, dried cells of a nonpathogenic and nontoxicogenic strain of the bacterium *Paracoccus carotinifaciens* and may contain added calcium carbonate to adjust the astaxanthin level.

(2) Color additive mixtures for fish feed use made with paracoccus pigment may contain only those diluents that are suitable and are listed in this subpart as safe for use in color additive mixtures for coloring foods.

(b) *Specifications*. Paracoccus pigment shall conform to the following specifications and shall be free from impurities, other than those named, to the extent that such impurities may be avoided by good manufacturing practice:

(1) Physical state, solid.

(2) Lead, not more than 5 milligrams per kilogram (mg/kg) (5 parts per million (ppm)).

(3) Arsenic, not more than 2 mg/kg (2 ppm).

(4) Mercury, not more than 1 mg/kg (1 ppm).

(5) Heavy metals (as Pb), not more than 10 mg/kg (10 ppm).

(6) Astaxanthin, not less than 1.75 percent.

(c) *Uses and restrictions*. Paracoccus pigment may be safely used in the feed of salmonid fish in accordance with the following prescribed conditions:

(1) The color additive is used to enhance the pink to orange-red color of the flesh of salmonid fish.

(2) The quantity of astaxanthin in finished feed, from paracoccus pigment when used alone or in combination with other astaxanthin color additive sources listed in this part 73, shall not exceed 80 mg/kg (72 grams per ton) of finished feed.

(d) *Labeling requirements*. (1) The labeling of the color additive and any premixes prepared therefrom shall bear expiration dates for the sealed and open container (established through generally accepted stability testing methods), other information required by § 70.25 of this chapter, and adequate directions to prepare a final product complying with the limitations prescribed in paragraph (c) of this section.

(2) The presence of the color additive in finished fish feed prepared according to paragraph (c) of this section shall be declared in accordance with § 501.4 of this chapter.

(3) The presence of the color additive in salmonid fish that have been fed feeds containing paracoccus pigment shall be declared in accordance with §§ 101.22(b), (c), and (k)(2), and 101.100(a)(2) of this chapter.

(e) *Exemption from certification*. Certification of this color additive is not necessary for the protection of the public health, and therefore, batches thereof are exempt from the certification requirements of section 721(c) of the act.

[74 FR 58845, Nov. 16, 2009]

§ 73.355 Phaffia yeast.

(a) *Identity*. (1) The color additive phaffia yeast consists of the killed, dried cells of a nonpathogenic and nontoxicogenic strain of the yeast *Phaffia rhodozyma*.

(2) Phaffia yeast may be added to the fish feed only as a component of a stabilized color additive mixture. Color additive mixtures for fish feed use made with phaffia yeast may contain only those diluents that are suitable and are listed in this subpart as safe for use in color additive mixtures for coloring foods.

(b) *Specifications*. Phaffia yeast shall conform to the following specifications and shall be free from impurities other than those named to the extent that such impurities may be avoided by good manufacturing practice:

Physical state, solid.
Lead, not more than 5 parts per million.
Arsenic, not more than 2 parts per million.
Mercury, not more than 1 part per million.
Heavy metals (as Pb), not more than 10 parts per million.
Astaxanthin, not less than 0.4 percent.

(c) *Uses and restrictions*. Phaffia yeast may be safely used in the feed of salmonid fish in accordance with the following prescribed conditions:

(1) The color additive is used to enhance the pink to orange-red color of the flesh of salmonid fish.

(2) The quantity of astaxanthin in finished feed, from phaffia yeast when used alone or in combination with other astaxanthin color additive sources listed in this part 73, shall not exceed 80 milligrams per kilogram (72 grams per ton) of finished feed.

(d) *Labeling requirements*. (1) The labeling of the color additive and any premixes prepared therefrom shall bear expiration dates for the sealed and open container (established through generally accepted stability testing methods), other information required by § 70.25 of this chapter, and adequate directions to prepare a final product complying with the limitations prescribed in paragraph (c) of this section.

(2) The presence of the color additive in finished fish feed prepared according to paragraph (c) of this section shall be declared in accordance with § 501.4 of this chapter.

(3) The presence of the color additive in salmonid fish that have been fed feeds containing phaffia yeast shall be declared in accordance with §§ 101.22(b), (c), and (k)(2) and 101.100(a)(2) of this chapter.

(e) *Exemption from certification*. Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 721(c) of the act.

[65 FR 41587, July 6, 2000]

§ 73.450 Riboflavin.

(a) *Identity*. (1) The color additive riboflavin is the riboflavin defined in the Food Chemicals Codex, 3d Ed. (1981), pp. 262–263, which is incorporated by reference. Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*.

(2) Color additive mixtures made with riboflavin may contain as diluents only those substances listed in this subpart as safe and suitable for use in color additive mixtures for coloring foods.

(b) *Specifications*. Riboflavin shall meet the specifications given in the Food Chemicals Codex, 3d Ed. (1981), which is incorporated by reference. The availability of this incorporation by reference is given in paragraph (a)(1) of this section.

(c) *Uses and restrictions*. Riboflavin may be safely used for the coloring of foods generally, in amounts consistent with good manufacturing practice; except that it may not be used to color foods for which standards of identity have been promulgated under section 401 of the act, unless the use of added color is authorized by such standards.

(d) *Labeling*. The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(e) *Exemption from certification*. Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 721(c) of the Act.

[42 FR 15643, Mar. 22, 1977, as amended at 47 FR 947, Jan. 8, 1982; 49 FR 10089, Mar. 19, 1984]

§ 73.500 Saffron.

(a) *Identity*. (1) The color additive saffron is the dried stigma of Crocus sativus L. The definition of saffron in this paragraph is for the purpose of identity as a color additive only, and shall not be construed as setting forth an official standard for saffron under section 401 of the act.

(2) Color additive mixtures made with saffron may contain as diluents only those substances listed in this subpart as safe and suitable in color additive mixtures for coloring foods.

(b) *Uses and restrictions*. Saffron may be safely used for the coloring of foods generally, in amounts consistent with good manufacturing practice, except that it may not be used to color foods for which standards of identity have been promulgated under section 401 of the act, unless the use of added color is authorized by such standards.

(c) *Labeling*. The color additive and any mixtures intended solely or in part for coloring purposes prepared therefrom shall bear, in addition to the other information required by the act, labeling in accordance with the provisions of § 70.25 of this chapter.

(d) *Exemption from certification*. Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 721(c) of the act.

§ 73.520 Soy leghemoglobin.

(a) *Identity*. (1) The color additive soy leghemoglobin is a stabilized product of controlled fermentation of a nonpathogenic and non-toxicogenic strain of the yeast, *Pichia pastoris*, genetically engineered to express soy leghemoglobin protein. Soy leghemoglobin protein is the principal coloring component of the color additive and imparts a reddish-brown color.

(2) Color additive mixtures made with soy leghemoglobin may contain only those diluents that are suitable and are listed in this subpart as safe for use in color additive mixtures for coloring foods.

(b) *Specifications*. Soy leghemoglobin shall conform to the following specifications and shall be free from impurities, other than those named, to the extent that such impurities may be avoided by good manufacturing practice:

(1) Soy leghemoglobin protein purity on protein basis (weight/weight), not less than 65 percent, as determined by sodium dodecyl sulfate-polyacrylamide gel electrophoresis.

(2) Lead, not more than 0.4 milligrams per kilogram (mg/kg) (0.4 parts per million (ppm)).

(3) Arsenic, not more than 0.05 mg/kg (0.05 ppm).

(4) Mercury, not more than 0.05 mg/kg (0.05 ppm).

(5) Cadmium, not more than 0.2 mg/kg (0.2 ppm).

(c) *Uses and restrictions.* Soy leghemoglobin may be safely used in ground beef analogue products such that the amount of soy leghemoglobin protein does not exceed 0.8 percent by weight of the uncooked ground beef analogue product.

(d) *Labeling.* The label of the color additive and of any mixture prepared therefrom intended solely or in part for coloring purposes must conform to § 70.25 of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 721(c) of the Federal Food, Drug, and Cosmetic Act.

[84 FR 37576, Aug. 1, 2019]

§ 73.530 Spirulina extract.

(a) *Identity.* (1) The color additive spirulina extract is prepared by the filtered aqueous extraction of the dried biomass of *Arthrospira platensis.* The color additive contains phycocyanins as the principal coloring components.

(2) Color additive mixtures for food use made with spirulina extract may contain only those diluents that are suitable and are listed in this subpart as safe for use in color additive mixtures for coloring foods.

(b) *Specifications.* Spirulina extract must conform to the following specifications and must be free from impurities, other than those named, to the extent that such other impurities may be avoided by good manufacturing practice:

(1) Lead, not more than 2 milligrams per kilogram (mg/kg) (2 part per million (ppm));

(2) Arsenic, not more than 2 mg/kg (2 ppm);

(3) Mercury, not more than 1 mg/kg (1 ppm); and

(4) Negative for microcystin toxin.

(c) *Uses and restrictions.* Spirulina extract may be safely used for coloring confections (including candy and chewing gum), frostings, ice cream and frozen desserts, dessert coatings and toppings, beverage mixes and powders, yogurts, custards, puddings, cottage cheese, gelatin, breadcrumbs, ready-to-eat cereals (excluding extruded cereals), coating formulations applied to dietary supplement tablets and capsules, at levels consistent with good manufacturing practice, and to seasonally color the shells of hard-boiled eggs, except that it may not be used to color foods for which standards of identity have been issued under section 401 of the Federal Food, Drug, and Cosmetic Act, unless the use of the added color is authorized by such standards.

(d) *Labeling requirements.* The label of the color additive and of any mixture prepared therefrom intended solely or in part for coloring purposes must conform to § 70.25 of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 721(c) of the Federal Food, Drug, and Cosmetic Act.

[78 FR 49120, Aug. 13, 2013, as amended at 79 FR 20098, May 13, 2014; 80 FR 50765, Aug. 21, 2015; 82 FR 30734, July 3, 2017]

§ 73.575 Titanium dioxide.

(a) *Identity.* (1) The color additive titanium dioxide is synthetically prepared TiO_2, free from admixture with other substances.

(2) Color additive mixtures for food use made with titanium dioxide may contain only those diluents that are suitable and that are listed in this subpart as safe in color additive mixtures for coloring foods, and the following: Silicon dioxide, SiO_2 and/or aluminum oxide, Al_2 O_3, as dispersing aids—not more than 2 percent total.

(b) *Specifications.* Titanium dioxide shall conform to the following specifications:

Lead (as Pb), not more than 10 parts per million.

Arsenic (as As), not more than 1 part per million.

Antimony (as Sb), not more than 2 parts per million.

Mercury (as Hg), not more than 1 part per million.
Loss on ignition at 800 °C. (after drying for 3 hours at 105 °C.), not more than 0.5 percent.
Water soluble substances, not more than 0.3 percent.
Acid soluble substances, not more than 0.5 percent.
TiO_2, not less than 99.0 percent after drying for 3 hours at 105 °C.

Lead, arsenic, and antimony shall be determined in the solution obtained by boiling 10 grams of the titanium dioxide for 15 minutes in 50 milliliters of 0.5*N* hydrochloric acid.

(c) *Uses and restrictions.* The color additive titanium dioxide may be safely used for coloring foods generally, subject to the following restrictions:

(1) The quantity of titanium dioxide does not exceed 1 percent by weight of the food.

(2) It may not be used to color foods for which standards of identity have been promulgated under section 401 of the act unless added color is authorized by such standards.

(d) *Labeling.* The label of the color additive and any mixtures intended solely or in part for coloring purposes prepared therefrom shall conform to the requirements of § 70.25 of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health and therefore batches thereof are exempt from the certification requirements of section 721(c) of the act.

§ 73.585 Tomato lycopene extract; tomato lycopene concentrate.

(a) *Identity.* (1) The color additive tomato lycopene extract is a red to dark brown viscous oleoresin extracted with ethyl acetate from tomato pulp followed by removal of the solvent by evaporation. The pulp is produced from fresh, edible varieties of the tomato by removing the liquid. The main coloring component is lycopene.

(2) The color additive tomato lycopene concentrate is a powder prepared from tomato lycopene extract by removing most of the tomato lipids with ethyl acetate and then evaporating off the solvent.

(3) Color additive mixtures made with tomato lycopene extract or tomato lycopene concentrate may contain only those diluents listed in this subpart as safe and suitable for use in color additive mixtures for coloring food.

(b) *Specifications.* (1) Tomato lycopene extract shall conform to the following specification: Lycopene, not less than 5.5 percent of oleoresin as determined by the method entitled ''Qualitative Analysis of Lycopene, Its Isomers and Other Carotenoids in Different Concentrations of Lyc-O-Mato® (Tomato Oleoresin) and in Tomato Pulp by High Performance Liquid Chromatography (HPLC),'' S.O.P. number : Lab/119/01, Revision 01, dated May 30, 2001, published by LycoRed Natural Products Industries, which is incorporated by reference, or an equivalent method. The Director of the Office of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain a copy of the method from the Center for Food Safety and Applied Nutrition (HFS–200), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740. You may inspect a copy at theFood and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301–796–2039, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*

(2) Tomato lycopene concentrate shall conform to the following specification: Lycopene, not less than 60 percent of oleoresin as determined by the method identified in paragraph (b)(1) of this section.

(c) *Uses and restrictions.* Tomato lycopene extract and tomato lycopene concentrate may be safely used for coloring foods generally in amounts consistent with good manufacturing practice, except that they may not be used to color foods for which standards of identity have been issued under section 401 of the act, unless the use of added color is authorized by such standards.

(d) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not

necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 721(c) of the act.

[70 FR 43045, July 26, 2005, as amended at 81 FR 5590, Feb. 3, 2016; 81 FR 49895, July 29, 2016]

§ 73.600 Turmeric.

(a) *Identity*. (1) The color additive turmeric is the ground rhizome of Curcuma longa L. The definition of turmeric in this paragraph is for the purpose of identity as a color additive only, and shall not be construed as setting forth an official standard for turmeric under section 401 of the act.

(2) Color additive mixtures made with turmeric may contain as diluents only those substances listed in this subpart as safe and suitable in color additive mixtures for coloring foods.

(b) *Uses and restrictions*. Turmeric may be safely used for the coloring of foods generally, in amounts consistent with good manufacturing practice, except that it may not be used to color foods for which standards of identity have been promulgated under section 401 of the act, unless the use of added color is authorized by such standards.

(c) *Labeling*. The color additive and any mixtures intended solely or in part for coloring purposes prepared therefrom shall bear, in addition to the other information required by the act, labeling in accordance with the provisions of § 70.25 of this chapter.

(d) *Exemption from certification*. Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 721(c) of the act.

§ 73.615 Turmeric oleoresin.

(a) *Identity*. (1) The color additive turmeric oleoresin is the combination of flavor and color principles obtained from turmeric (Curcuma longa L.) by extraction using any one or a combination of the following solvents:

Acetone	Isopropyl alcohol
Ethyl alcohol	Methyl alcohol
Ethylene dichloride	Methylene chloride
Hexane	Trichloroethylene

The definition of turmeric oleoresin in this paragraph is for the purpose of identity as a color additive only, and shall not be construed as setting forth an official standard for turmeric oleoresin under section 401 of the act.

(2) Color additive mixtures made with turmeric oleoresin may contain as diluents only those substances listed in this subpart as safe and suitable in color additive mixtures for coloring foods.

(b) *Specifications*. Turmeric oleoresin shall contain no more residue of the solvents listed under paragraph (a)(1) of this section than is permitted for the corresponding solvents in spice oleoresins under applicable food additive regulation in parts 170 through 189 of this chapter.

(c) *Uses and restrictions*. Turmeric oleoresin may be safely used for the coloring of foods generally, in amounts consistent with good manufacturing practice, except that it may not be used to color foods for which standards of identity have been promulgated under section 401 of the act, unless the use of added color is authorized by such standards.

(d) *Labeling*. The color additive and any mixtures intended solely or in part for coloring purposes prepared therefrom shall bear, in addition to the other information required by the act, labeling in accordance with the provisions of § 70.25 of this chapter.

(e) *Exemption from certification*. Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 721(c) of the act.

Subpart B—Drugs

§ 73.1001 Diluents in color additive mixtures for drug use exempt from certification.

The following diluents may be safely used in color additive mixtures that are exempt from certification and which are to be used for coloring drugs, subject to the condition that each straight color in the mixture has been exempted from certification or, if not so exempted, is from a batch that has previously been certified and has not changed in composition since certification. Such listing of diluents is not to be construed as superseding any of

the other requirements of the Federal Food, Drug, and Cosmetic Act with respect to drugs, including new drugs. If a definition and specification for a particular diluent is not set forth in this subpart, the material shall be of a purity consistent with its intended use.

(a) *Ingested drugs*—(1) *General use*. Diluents listed in § 73.1(a) and the following:

Substances	Definitions and specifications	Restrictions
Alcohol, specially denatured	As set forth in 26 CFR, pt. 212	As set forth in 26 CFR, pt. 211.
Cetyl alcohol	As set forth in N.F. XI.	
Isopropyl alcohol		In color coatings for pharmaceutical forms, no residue.
Polyoxyethylene (20) sorbitan monostearate (Polysorbate 60).	As set forth in sec. 172.836 of this chapter.	
Polyoxyethylene (20) sorbitan tristearate (Polysorbate 65).	As set forth in sec. 172.838 of this chapter.	
Polysorbate 80	As set forth in sec. 172.840 of this chapter.	
Polyvinyl-pyrrolidone	As set forth in sec. 173.55 of this chapter.	
Sorbitan monooleate.		
Sorbitan monostearate	As set forth in sec. 172.842 of this chapter.	
Sorbitan trioleate.		

(2) *Special use; inks for branding pharmaceutical forms*. Items listed in paragraph (a)(1) of this section, § 73.1(b)(1)(i), and the following:

Ethyl lactate
Polyoxyethylene sorbitan monolaurate (20)

(b) *Externally applied drugs*. Diluents listed in paragraph (a)(1) of this section and the following:

Substances	Definitions and specifications
Benzyl alcohol	As set forth in N.F. XI.
Ethyl cellulose	As set forth in § 172.868 of this chapter.
Hydroxyethyl cellulose.	
Hydroxypropyl cellulose	As set forth in § 172.870 of this chapter.

§ 73.1010 Alumina (dried aluminum hydroxide).

(a) *Identity*. (1) The color additive alumina (dried aluminum hydroxide) is a white, odorless, tasteless, amorphous powder consisting essentially of aluminum hydroxide ($Al_2O_3 \cdot XH_2O$).

(2) Color additive mixtures for drug use made with alumina (dried aluminum hydroxide) may contain only those diluents listed in this subpart as safe and suitable for use in color additive mixtures for coloring drugs.

(b) *Specifications*. Alumina (dried aluminum hydroxide) shall conform to the following specifications:

Acidity or alkalinity: Agitate 1 gram of the color additive with 25 milliliters of water and filter. The filtrate shall be neutral to litmus paper.

Matter insoluble in dilute hydrochloric acid, not more than 0.5 percent.

Lead (as Pb), not more than 10 parts per million.

Arsenic (as As), not more than 1 part per million.

Mercury (as Hg), not more than 1 part per million.

Aluminum oxide (Al_2O_3), not less than 50 percent.

(c) *Uses and restrictions*. Alumina (dried aluminum hydroxide) may be safely used in amounts consistent with good manufacturing practice to color drugs generally.

(d) *Labeling requirements*. The label of the color additive and of any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Exemption from certification*. Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 721(c) of the act.

§ 73.1015 Chromium-cobalt-aluminum oxide.

(a) *Identity*. The color additive chromium-cobalt-aluminum oxide is a blue-green pigment obtained by calcining a mixture of chromium oxide, cobalt carbonate, and aluminum oxide. It may

contain small amounts (less than 1 percent each) of oxides of barium, boron, silicon, and nickel.

(b) *Specifications*. Chromium-cobalt-aluminum oxide shall conform to the following specifications:

Chromium, calculated as Cr_2O_3, 34–37 percent.
Cobalt, calculated as CoO, 29–34 percent.
Aluminum, calculated as AL_2O_3, 29–35 percent.
Lead (as Pb), not more than 30 parts per million.
Arsenic (as As), not more than 3 parts per million.
Total oxides of aluminum, chromium, and cobalt not less than 97 percent.

Lead and arsenic shall be determined in the solution obtained by boiling 10 grams of the chromium-cobalt-aluminum oxide for 15 minutes in 50 milliliters of 0.5 *N* hydrochloric acid.

(c) *Uses and restrictions*. The color additive chromium-cobalt-aluminum oxide may be safely used for coloring linear polyethylene surgical sutures, United States Pharmacopeia (U.S.P.), for use in general surgery, subject to the following restrictions:

(1) For coloring procedure, the color additive is blended with the polyethylene resin. The mixture is heated to a temperature of 500–550 °F. and extruded through a fixed orifice. The filaments are cooled, oriented by drawing, and set by annealing.

(2) The quantity of the color additive does not exceed 2 percent by weight of the suture material.

(3) The dyed suture shall conform in all respects to the requirements of the U.S.P. XX (1980).

(4) When the sutures are used for the purpose specified in their labeling, there is no migration of the color additive to the surrounding tissue.

(5) If the suture is a new drug, an approved new drug application, pursuant to section 505 of the Federal Food, Drug, and Cosmetic Act, is in effect for it.

(d) *Labeling*. The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(e) *Exemption from certification*. Certification of this color additive is not necessary for the protection of the public health, and batches thereof are exempt from the certification requirements of section 721(c) of the act.

[42 FR 15643, Mar. 22, 1977, as amended at 49 FR 10089, Mar. 19, 1984]

§ 73.1025 Ferric ammonium citrate.

(a) *Identity*. The color additive ferric ammonium citrate consists of complex chelates prepared by the interaction of ferric hydroxide with citric acid in the presence of ammonia. The complex chelates occur in brown and green forms, are deliquescent in air, and are reducible by light.

(b) *Specifications*. Ferric ammonium citrate shall conform to the following specifications and shall be free from impurities other than those named to the extent that such impurities may be avoided by good manufacturing practice:

Iron (as Fe), not less than 14.5 percent and not more than 18.5 percent.
Lead (as Pb), not more than 20 p/m.
Arsenic (as As), not more than 3 p/m.

(c) *Uses and restrictions*. Ferric ammonium citrate may be safely used in combination with pyrogallol (as listed in § 73.1375), for coloring plain and chromic catgut sutures for use in general and ophthalmic surgery subject to the following conditions:

(1) The dyed suture shall conform in all respects to the requirements of the United States Pharmacopeia XX (1980).

(2) The level of the ferric ammonium citrate-pyrogallol complex shall not exceed 3 percent of the total weight of the suture material.

(3) When the sutures are used for the purposes specified in their labeling, there is no migration of the color additive to the surrounding tissue.

(4) If the suture is a new drug, an approved new drug application, pursuant to section 505 of the act, is in effect for it.

(d) *Labeling*. The labeling of the color-additive shall conform to the requirements of § 70.25 of this chapter.

(e) *Exemption from certification*. Certification of this color additive is not necessary for the protection of the public health and therefore batches thereof are exempt from the requirements of section 721(c) of the act.

[42 FR 15643, Mar. 22, 1977, as amended at 49 FR 10089, Mar. 19, 1984]

§ 73.1030 Annatto extract.

(a) *Identity and specifications.* (1) The color additive annatto extract shall conform in identity and specifications to the requirements of § 73.30(a)(1) and (b).

(2) Color additive mixtures for drug use made with annatto extract may contain only those diluents that are suitable and that are listed in this subpart as safe in color additive mixtures for coloring ingested drugs.

(b) *Uses and restrictions.* Annatto extract may be safely used for coloring drugs generally, including those intended for use in the area of the eye, in amounts consistent with good manufacturing practice.

(c) *Labeling.* The label of the color additive and any mixtures prepared therefrom and intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter. Labels shall bear information showing that the color is derived from annatto seed. The requirements of § 70.25(a) of this chapter that all ingredients shall be listed by name shall not be construed as requiring the declaration of residues of solvents listed in § 73.30(a)(1)(ii) of this chapter.

(d) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health and therefore batches thereof are evempt from the certification requirements of section 721(c) of the act.

[42 FR 15643, Mar. 22, 1977, as amended at 42 FR 36994, July 19, 1977]

§ 73.1070 Calcium carbonate.

(a) *Identity.* (1) The color additive calcium carbonate is a fine, white, synthetically prepared powder consisting essentially of precipitated calcium carbonate ($CaCO_3$).

(2) Color additive mixtures for drug use made with calcium carbonate may contain only those diluents listed in this subpart as safe and suitable for use in color additive mixtures for coloring drugs.

(b) *Specifications.* Calcium carbonate shall meet the specifications for precipitated calcium carbonate in the United States Pharmacopeia XX (1980).

(c) *Uses and restrictions.* Calcium carbonate may be safely used in amounts consistent with good manudacturing practice to color drugs generally.

(d) *Labeling requirements.* The label of the color additive and of any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 721(c) of the act.

[42 FR 15643, Mar. 22, 1977, as amended at 49 FR 10089, Mar. 19, 1984]

§ 73.1075 Canthaxanthin.

(a) *Identity and specifications.* (1) The color additive canthaxanthin shall conform in identity and specifications to the requirements of § 73.75(a)(1) and (b).

(2) Color additive mixtures for ingested drug use made with canthaxanthin may contain only those diluents that are suitable and that are listed in this subpart as safe in color additive mixtures for coloring ingested drugs.

(b) *Uses and restrictions.* Canthaxanthin may be safely used for coloring ingested drugs generally in amounts consistent with good manufacturing practice.

(c) *Labeling requirements.* The label of the color additive and of any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(d) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 721(c) of the act.

§ 73.1085 Caramel.

(a) *Identity and specifications.* (1) The color additive caramel shall conform in identity and specifications to the requirements of § 73.85(a) (1), (2), and (3) and (b).

(2) The diluents in color additive mixtures for drug use containing caramel shall be limited to those listed in this subpart as safe and suitable in color additive mixtures for coloring drugs.

(b) *Uses and restrictions*. Caramel may be used for coloring ingested and topically applied drugs generally in amounts consistent with good manufacturing practice.

(c) *Exemption from certification*. Certification of this color additive is not necessary for the protection of the public health and therefore batches thereof are exempt from the certification requirement of section 721(c) of the act.

§ 73.1095 β-Carotene.

(a) *Identity and specifications*. (1) The color additive β-carotene shall conform in identity and specifications to the requirements of § 73.95(a)(1) and (b).

(2) The diluents in color additive mixtures for drug use containing β-carotene are limited to those listed in this subpart as safe and suitable in color additive mixtures for coloring ingested drugs.

(b) *Uses and restrictions*. The color additive β-carotene may be safely used in coloring drugs generally, including those intended for use in the area of the eye, in amounts consistent with good manufacturing practice.

(c) *Labeling requirements*. The labeling of the color additive and any mixtures intended solely or in part for coloring purposes prepared therefrom shall conform to the requirements of § 70.25 of this chapter.

(d) *Exemption from certification*. Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 721(c) of the act.

[42 FR 15643, Mar. 22, 1977, as amended at 42 FR 33722, July 1, 1977]

§ 73.1100 Cochineal extract; carmine.

(a) *Identity and specifications*. (1) The color additives cochineal extract and carmine shall conform in identity and specifications to the requirements of § 73.100(a) (1) and (2) and (b).

(2) Color additive mixtures for drug use made with carmine and cochineal extract may contain only those diluents that are suitable and that are listed in this subpart as safe in color additive mixtures for coloring drugs.

(b) *Uses and restrictions*. Cochineal extract and carmine may be safely used for coloring ingested and externally applied drugs in amounts consistent with good manufacturing practice.

(c) *Labeling requirements*. The label of the color additives and any mixtures intended solely or in part for coloring purposes prepared therefrom shall conform to the requirements of § 70.25 of this chapter.

(d) *Exemption from certification*. Certification of these color additives is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 721(c) of the act.

§ 73.1125 Potassium sodium copper chloropyhllin (chlorophyllin-copper complex).

(a) *Identity*. (1) The color additive potassium sodium copper chlorophyllin is a green to black powder obtained from chlorophyll by replacing the methyl and phytyl ester groups with alkali and replacing the magnesium with copper. The source of the chlorophyll is dehydrated alfalfa.

(2) Color additive mixtures for drug use made with potassium sodium copper chlorophyllin may contain only those diluents that are suitable and that are listed in this subpart as safe for use in color additive mixtures for coloring drugs.

(b) *Specifications*. Potassium sodium copper chlorophyllin shall conform to the following specifications and shall be free from impurities other than those named to the extent that such other impurities may be avoided by good manufacturing practice:

Moisture, not more than 5.0 percent.
Nitrogen, not more than 5.0 percent.
pH of 1 percent solution, 9 to 11.
Total copper, not less than 4 percent and not more than 6 percent.
Free copper, not more than 0.25 percent.
Iron, not more than 0.5 percent.
Lead (as Pb)), not more than 20 parts per million.
Arsenic (as As), not more than 5 parts per million.
Ratio, absorbance at 405 mμ to absorbance at 630 mμ, not less than 3.4 and not more than 3.9.
Total color, not less than 75 percent.

(c) *Uses and restrictions*. Potassium sodium copper chlorophyllin may be safely used for coloring dentifrices that are drugs at a level not to exceed 0.1

percent. Authorization for this use shall not be construed as waiving any of the requirements of section 505 of the act with respect to the drug in which it is used.

(d) *Labeling*. The label of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Exemption from certification*. Certification of this color additive is not necessary for the protection of the public health and therefore batches thereof are exempt from the certification requirements of section 721(c) of the act.

§ 73.1150 Dihydroxyacetone.

(a) *Identity*. (1) The color additive dihydroxyacetone is 1,3-dihydroxy-2-propanone.

(2) Color additive mixtures for drug use made with dihydroxyacetone may contain only those diluents that are listed in this subpart as safe and suitable in color additive mixtures for coloring externally applied drugs.

(b) *Specifications*. Dihydroxyacetone shall conform to the following specifications and shall be free from impurities other than those named to the extent that such impurities may be avoided by good manufacturing practice:

Volatile matter (at 34.6 °C. for 3 hours at a pressure of not more than 30 mm. mercury), not more than 0.5 percent.
Residue on ignition, not more than 0.4 percent.
Lead (as Pb), not more than 20 parts per million.
Arsenic (as As), not more than 3 parts per million.
Iron (as Fe), not more than 25 parts per million.
1,3-dihydroxy-2-propanone, not less than 98 percent.

(c) *Uses and restrictions*. Dihydroxyacetone may be safely used in amounts consistent with good manufacturing practice in externally applied drugs intended solely or in part to impart a color to the human body. Authorization for this use shall not be construed as waiving any of the requirements of section 505 of the act with respect to the drug in which it is used.

(d) *Labeling requirements*. The label of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Exemption from certification*. Certification of this color additive is not necessary for the protection of the public health and therefore batches thereof are exempt from the certification requirements of section 721(c) of the act.

§ 73.1162 Bismuth oxychloride.

(a) *Identity*. (1) The color additive bismuth oxychloride is a synthetically prepared white or nearly white amorphous or finely crystalline, odorless powder consisting principally of BiOCl.

(2) Color additive mixtures for drug use made with bismuth oxychloride may contain only those diluents that are suitable and that are listed in this subpart as safe in color additive mixtures for coloring externally applied drugs.

(b) *Specifications*. The color additive bismuth oxychloride shall conform to the following specifications and shall be free from impurities other than those named to the extent that such other impurities may be avoided by good manufacturing practice:

Volatile matter, not more than 0.5 percent.
Lead (as Pb), not more than 20 parts per million.
Arsenic (as As), not more than 3 parts per million.
Mercury (as Hg), not more than 1 part per million.
Bismuth oxychloride, not less than 98 percent.

(c) *Uses and restrictions*. The color additive bismuth oxychloride may be safely used in coloring externally applied drugs, including those intended for use in the area of the eye, in amounts consistent with good manufacturing practice.

(d) *Labeling*. The color additive and any mixture prepared therefrom intended solely or in part for coloring purposes shall bear, in addition to any information required by law, labeling in accordance with the provisions of § 70.25 of this chapter.

(e) *Exemption from certification*. Certification of this color additive is not

necessary for the protection of the public health, and therefore batches thereof are exempt from certification pursuant to section 721(c) of the act.

[42 FR 52394, Sept. 30, 1977]

§ 73.1200 Synthetic iron oxide.

(a) *Identity*. (1) The color additive synthetic iron oxide consists of any one or any combination of synthetically prepared iron oxides, including the hydrated forms. It is free from admixture with other substances.

(2) Color additive mixtures for drug use made with synthetic iron oxide may contain only those diluents listed in this subpart as safe and suitable in color additive mixtures for coloring drugs.

(b) *Specifications*. Synthetic iron oxide shall conform to the following specifications, all on an ''as is'' basis:

Arsenic (as As), not more than 3 parts per million.
Lead (as Pb), not more than 10 parts per million.
Mercury (as Hg), not more than 3 parts per million.

(c) *Uses and restrictions*. The color additive synthetic iron oxide may be safely used to color ingested or topically applied drugs generally subject to the restriction that if the color additive is used in drugs ingested by man the amount consumed in accordance with labeled or prescribed dosages shall not exceed 5 milligrams, calculated as elemental iron, per day.

(d) *Labeling requirements*. The label of the color additive and any mixtures intended solely or in part for coloring purposes prepared therefrom shall conform to the requirements of § 70.25 of this chapter.

(e) *Exemption from certification*. Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from certification requirements of section 721(c) of the act.

§ 73.1298 Ferric ammonium ferrocyanide.

(a) *Identity*. (1) The color additive ferric ammonium ferrocyanide is the blue pigment obtained by oxidizing under acidic conditions with sodium dichromate the acid digested precipitate resulting from mixing solutions of ferrous sulfate and sodium ferrocyanide in the presence of ammonium sulfate. The oxidized product is filtered, washed, and dried. The pigment consists principally of ferric ammonium ferrocyanide with smaller amounts of ferric ferrocyanide and ferric sodium ferrocyanide.

(2) Color additive mixtures for drug use made with ferric ammonium ferrocyanide may contain only those diluents listed in this subpart as safe and suitable for use in color additive mixtures for coloring drugs.

(b) *Specifications*. Ferric ammonium ferrocyanide shall conform to the following specifications and shall be free of impurities other than those named to the extent that the other impurities may be avoided by good manufacturing practice:

Oxalic acid or its salts, not more than 0.1 percent.
Water soluble matter, not more than 3 percent.
Water soluble cyanide, not more than 10 parts per million.
Volatile matter, not more than 4 percent.
Lead (as Pb), not more than 20 parts per million.
Arsenic (as As), not more than 3 parts per million.
Nickel (as Ni), not more than 200 parts per million.
Cobalt (as Co), not more than 200 parts per million.
Mercury (as Hg), not more than 1 part per million.
Total iron (as Fe corrected for volatile matter), not less than 33 percent and not more than 39 percent.

(c) *Uses and restrictions*. Ferric ammonium ferrocyanide may be safely used in amounts consistent with good manufacturing practice to color externally applied drugs, including those for use in the area of the eye.

(d) *Labeling requirements*. The label of the color additive and of any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Exemption from certification*. Certification of this color additive is not necessary for the protection of the public health, and therfore batches thereof

are exempt from the certification requirements of section 721(c) of the act.

[42 FR 38562, July 29, 1977, as amended at 44 FR 28322, May 15, 1979]

§ 73.1299 Ferric ferrocyanide.

(a) *Identity*. (1) The color additive ferric ferrocyanide is a ferric hexacyanoferrate pigment characterized by the structual formula $Fe_4[Fe(CN)_6]_3 \cdot XH_2O$, which may contain small amounts of ferric sodium ferrocyanide and ferric potassium ferrocyanide.

(2) Color additive mixtures for drug use made with ferric ferrocyanide may contain only those diluents listed in this subpart as safe and suitable for use in color additive mixtures for coloring drugs.

(b) *Specifications*. Ferric ferrocyanide shall conform to the following specifications and shall be free from impurities other than those named to the extent that such impurities may be avoided by good manufacturing practice:

Water soluble cyanide, not more than 10 parts per million.
Lead (as Pb), not more than 20 parts per million.
Arsenic (as As), not more than 3 parts per million.
Nickel (as Ni), not more than 200 parts per million.
Cobalt (as Co), not more than 200 parts per million.
Mercury (as Hg), not more than 1 part per million.
Oxalic acid, not more than 0.1 percent.
Water soluble matter, not more than 3 percent.
Volatile matter, not more than 10 percent.
Total iron (as Fe corrected for volatile matter), not less than 37 percent and not more than 45 percent.

(c) *Uses and restrictions*. Ferric ferrocyanide may be safely used in amounts consistent with good manufacturing practice to color externally applied drugs including those intended for use in the area of the eye.

(d) *Labeling requirements*. The label of the color additive and of any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Exemption from certification*. Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from certification requirements of section 721(c) of the act.

[43 FR 54235, Nov. 21, 1978]

§ 73.1326 Chromium hydroxide green.

(a) *Identity*. (1) The color additive chromium hydroxide green is principally hydrated chromic sesquioxide ($Cr_2O_3 \cdot XH_2O$).

(2) Color additive mixtures for drug use made with chromium hydroxide green may contain only those diluents listed in this subpart as safe and suitable for use in color additive mixtures for coloring drugs.

(b) *Specifications*. Chromium hydroxide green shall conform to the following specifications and shall be free from impurities other than those named to the extent that such impurities may be avoided by good manufacturing practice:

Water soluble matter, not more than 2.5%.
Chromium in 2% NaOH extract, not more than 0.1% as Cr_2O_3 (based on sample weight).
Boron (as B_2O_3), not more than 8 percent.
Total volatile matter at 1000 °C, not more than 20%.
Cr_2O_3 not less than 75%.
Lead (as Pb), not more than 20 parts per million.
Arsenic (as As), not more than 3 parts per million.
Mercury (as Hg), not more than 1 part per million.

(c) *Uses and restrictions*. Chromium hydroxide green may be safely used in amounts consistent with good manufacturing practice to color externally applied drugs, including those for use in the area of the eye.

(d) *Labeling requirements*. The label of the color additive and of any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Exemption from certification*. Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 721(c) of the act.

[42 FR 36451, July 15, 1977, as amended at 42 FR 59852, Nov. 22, 1977]

§ 73.1327 Chromium oxide greens.

(a) *Identity*. (1) The color additive chromium oxide greens is principally chromic sesquioxide (Cr_2O_3).

(2) Color additive mixtures for drug use made with chromium oxide greens may contain only those diluents listed in this subpart as safe and suitable for use in color additive mixtures for coloring drugs.

(b) *Specifications*. the color additive chormium oxide greens shall conform to the following specifications and shall be free from impurities other than those named to the extent that such impurities may be avoided by good manufacturing practice:

Chromium in 2% NaOH extract, not more than 0.075% as Cr_2O_3 (based on sample weight).
Arsenic (as As), not more than 3 parts per million.
Lead (as Pb), not more than 20 parts per million.
Mercury (as Hg), not more than 1 part per million.
Cr_2O_3, not less than 95%.

(c) *Uses and restrictions*. Chromium oxide greens is safe for use in coloring externally applied drugs, including those intended for use in the area of eye, in amounts consistent with good manufacturing practice.

(d) *Labeling*. The color additive and any mixture prepared therefrom intended solely or in part for coloring purposes shall bear, in addition to any information required by law, labeling in accordance with § 70.25 of this chapter.

(e) *Exemption from certification*. Certification of this color additive is not necessary for the protection of the public health, and therefore batches therof are exempt from certification pursuant to section 721(c) of the act.

[42 FR 36451, July 15, 1977]

§ 73.1329 Guanine.

(a) *Identity*. (1) The color additive guanine is the crystalline material obtained from fish scales and consists principally of the two purines, guanine and hypoxanthine. The guanine content will vary from 75 to 97 percent, and the hypoxanthine will vary from 3 to 25 percent, depending on the particular fish and tissue from which the crystals are derived.

(2) Color additive mixtures for drug use made with guanine may contain only those diluents listed in this subpart as safe and suitable for use in color additive mixtures for coloring externally applied drugs.

(b) *Specifications*. The color additive guanine shall conform to the following specifications and shall be free from impurities other than those named to the extent that such other impurities may be avoided by good manufacturing practice:

Guanine, not less than 75 percent.
Hypoxanthine, not more than 25 percent.
Ash (ignition at 800 °C), not more than 2 percent.
Lead (as Pb), not more than 20 parts per million.
Arsenic (as As), not more than 3 parts per million.
Assay, not less than 96 percent total purines.
Mercury (as Hg), not more than 1 part per million.

(c) *Uses and restrictions*. Guanine is safe for use in coloring externally applied drugs, including those intended for use in the area of the eye, in amounts consistent with good manufacturing practice.

(d) *Labeling*. The color additive and any mixture prepared therefrom intended solely or in part for coloring purposes shall bear, in addition to any information required by law, labeling in accordance with § 70.25 of this chapter.

(e) *Exemption from certification*. Certification of this color additive is not necessary for the protection of the public health, and therefore batches therof are exempt from certification pursuant to section 721(c) of the act.

[42 FR 37537, July 22, 1977]

§ 73.1350 Mica-based pearlescent pigments.

(a) *Identity*. (1) The color additive is formed by depositing titanium and/or iron salts onto mica, followed by heating to produce one of the following combinations: Titanium dioxide on mica; iron oxide on mica; titanium dioxide and iron oxide on mica. Mica used to manufacture the color additive shall conform in identity to the requirements of § 73.1496(a)(1).

(2) Color additive mixtures for drug use made with mica-based pearlescent pigments may contain only those diluents listed in this subpart as safe and suitable for use in color additive mixtures for coloring ingested drugs.

(b) *Specifications.* Mica-based pearlescent pigments shall conform to the following specifications and shall be free from impurities other than those named to the extent that such other impurities may be avoided by good manufacturing practice:

(1) Lead (as Pb), not more than 4 parts per million (ppm).

(2) Arsenic (as As), not more than 3 ppm.

(3) Mercury (as Hg), not more than 1 ppm.

(c) *Uses and restrictions.* Mica-based pearlescent pigments may be safely used to color ingested drugs in amounts up to 3 percent, by weight, of the final drug product. The maximum amount of iron oxide to be used in producing said pigments is not to exceed 55 percent, by weight, in the finished pigment.

(d) *Labeling.* The label of the color additive and of any mixture prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 721(c) of the Federal Food, Drug, and Cosmetic Act.

[70 FR 42273, July 22, 2005. Redesignated at 72 FR 10357, Mar. 8, 2007]

§ 73.1375 Pyrogallol.

(a) *Identity.* The color additive pyrogallol is 1,2,3-trihydroxybenzene.

(b) *Specifications.* Pyrogallol shall conform to the following specifications and shall be free from impurities other than those named to the extent that such impurities may be avoided by good manufacturing practice:

Melting point, between 130° and 133 °C.

Residue on ignition, not more than 0.1 percent.

Lead (as Pb), not more than 20 p/m (parts per million).

Arsenic (as As), not more than 3 p/m.

(c) *Uses and restrictions.* Pyrogallol may be safely used in combination with ferric ammonium citrate (as listed in § 73.1025), for coloring plain and chromic catgut sutures for use in general and ophthalmic surgery, subject to the following restrictions:

(1) The dyed suture shall conform in all respects to the requirements of the United States Pharmacopeia XX (1980).

(2) The level of the ferric ammonium citrate-pyrogallol complex shall not exceed 3 percent of the total weight of the suture material.

(3) When the sutures are used for the purposes specified in their labeling, there is no migration of the color additive to the surrounding tissues.

(4) If the suture is a new drug, an approved new drug application, pursuant to section 505 of the act, is in effect for it.

(d) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health and therefore batches thereof are exempt from the certification requirements of section 721(c) of the act.

[42 FR 15643, Mar. 22, 1977, as amended at 49 FR 10089, Mar. 19, 1984]

§ 73.1400 Pyrophyllite.

(a) *Identity.* (1) The color additive pyrophyllite is a naturally occurring mineral substance consisting predominantly of a hydrous aluminum silicate, $Al_2O_3 \cdot 4SiO_2 \cdot H_2O$, intimately mixed with lesser amounts of finely divided silica, SiO_2. Small amounts, usually less than 3 percent, of other silicates, such as potassium aluminum silicate, may be present. Pyrophyllite may be identified and semiquantitatively determined by its characteristic X-ray powder diffraction pattern and by its optical properties.

(2) Color additive mixtures made with pyrophyllite are limited to those listed in this subpart as safe and suitable in color additive mixtures for coloring externally applied drugs.

(b) *Specifications.* Pyrophyllite shall conform to the following specifications:

Lead (as Pb), not more than 20 parts per million.
Arsenic (as As), not more than 3 parts per million.

Lead and arsenic shall be determined in the solution obtained by boiling 10 grams of the pyrophyllite for 15 minutes in 50 milliliters of 0.5*N* hydrochloric acid.

(c) *Uses and restrictions.* Pyrophyllite may be safely used in amounts consistent with good manufacturing practice to color drugs that are to be externally applied.

(d) *Labeling requirements.* The labeling of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 721(c) of the act.

§ 73.1410 Logwood extract.

(a) *Identity.* The color additive logwood extract is a reddish brown-to-black solid material extracted from the heartwood of the leguminous tree *Haematoxylon campechianum.* The active colorant substance is principally hematein. The latent coloring material is the unoxidized or leuco form of hematein called hematoxylin. The leuco form is oxidized by air.

(b) *Specifications.* Logwood extract shall conform to the following specifications and shall be free from impurities other than those named to the extent that such imnurities may be avoided by good manufacturing practice:

Volatile matter (at 110 °C), not more than 15 percent.
Sulfated ash, not more than 20 percent.
Hematein, not less than 5 percent and not more than 20 percent.
Lead (as Pb), not more than 70 parts per million.
Arsenic (as As), not more than 4 parts per million.
Mercury (as Hg), not more than 3 parts per million.

(c) *Use and restrictions.* Logwood extract may be safely used to color nylon 66 (the copolymer of hexamethylenediamine and adipic acid), nylon 6 (the polymer of *e*-caprolactam), or silk non-absorable sutures for use in general and ophthalmic surgery subject to the following restrictions:

(1) The quantity of color additive does not exceed 1.0 percent by weight of the suture.

(2) When the sutures are used for the purposes specified in their labeling, there is no migration of the color additive to the surrounding tissue.

(3) If the suture is a new drug, an approved new drug application, pursuant to section 505 of the act, is in effect for it.

(d) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 721(c) of the act.

[42 FR 52393, Sept. 30, 1977; 43 FR 1490, Jan. 10, 1978]

§ 73.1496 Mica.

(a) *Identity.* (1) The color additive mica is a white powder obtained from the naturally occurring mineral, muscovite mica, consisting predominantly of a potassium aluminum silicate, $K_2Al_4(Al_2Si_6O_{20})(OH)_4$ or, alternatively, $H_2KAl_3(SiO_4)_3$. Mica may be identified and semiquantitatively determined by its characteristic X-ray diffraction pattern and by its optical properties.

(2) Color additive mixtures for drug use made with mica may contain only those diluents listed in this subpart as safe and suitable for use in color additive mixtures for coloring drugs.

(b) *Specifications.* Mica shall conform to the following specifications and shall be free from impurities other than those named to the extent that such other impurities may be avoided by good manufacturing practice:

Fineness, 100 percent shall pass through a 100-mesh sieve.
Loss on ignition at 600–650 °C, not more than 2 percent.
Lead (as Pb), not more than 20 parts per million.
Arsenic (as As), not more than 3 parts per million.

Mercury (as Hg), not more than 1 part per million.

(c) *Uses and restrictions.* Mica may be safely used in amounts consistent with good manufacturing practice to color dentifrices and externally applied drugs, including those for use in the area of the eye.

(d) *Labeling requirements.* The label of the color additive and of any mixture prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches therof are exempt from the certification requirements of section 721(c) of the act.

[42 FR 38561, July 29, 1977, as amended at 52 FR 29665, Aug. 11, 1987]

§ 73.1530 Spirulina extract.

(a) *Identity.* (1) The color additive spirulina extract is prepared by the filtered aqueous extraction of the dried biomass of *Arthrospira platensis.* The color additive contains phycocyanins as the principal coloring components.

(2) Color additive mixtures for drug use made with spirulina extract may contain only those diluents that are suitable and are listed in this subpart as safe for use in color additive mixtures for coloring ingested drugs.

(b) *Specifications.* Spirulina extract must conform to the following specifications and must be free from impurities, other than those named, to the extent that such other impurities may be avoided by good manufacturing practice:

(1) Lead, not more than 2 milligrams per kilogram (mg/kg) (2 parts per million (ppm));

(2) Arsenic, not more than 2 mg/kg (2 ppm);

(3) Mercury, not more than 1 mg/kg (1 ppm); and

(4) Negative for microcystin toxin.

(c) *Uses and restrictions.* Spirulina extract may be safely used for coloring coating formulations applied to drug tablets and capsules, at levels consistent with good manufacturing practice.

(d) *Labeling requirements.* The label of the color additive and any mixture prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 721(c) of the Federal Food, Drug, and Cosmetic Act.

[80 FR 50765, Aug. 21, 2015]

§ 73.1550 Talc.

(a) *Identity.* (1) The color additive talc is a finely powdered, native, hydrous magnesium silicate sometimes containing a small proportion of aluminum silicate.

(2) Color additive mixtures for drug use made with talc may contain only those diluents listed in this subpart as safe and suitable for use in color additive mixtures for coloring drugs.

(b) *Specifications.* Talc shall meet the specifications for talc in the United States Pharmacopeia XX (1980) and the following:

Lead (as Pb), not more than 20 parts per million.

Arsenic (as As), not more than 3 parts per million.

Lead and arsenic shall be determined in the solution obtained by boiling 10 grams of the talc for 15 minutes in 50 milliliters of 0.5*N* hydrochloric acid.

(c) *Uses and restrictions.* Talc may be safely used in amounts consistent with good manufacturing practice to color drugs generally.

(d) *Labeling requirements.* The label of the color additive and of any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 721(c) of the act.

[42 FR 15643, Mar. 22, 1977, as amended at 49 FR 10089, Mar. 19, 1984]

§ 73.1575 Titanium dioxide.

(a) *Identity and specifications.* (1) The color additive titanium dioxide shall

conform in identity and specifications to the requirements of § 73.575(a)(1) and (b).

(2) Color additive mixtures for drug use made with titanium dioxide may contain only those diluents that are suitable and that are listed in this subpart as safe in color additive mixtures for coloring drugs, and the following: Silicon dioxide, SiO_2, and/or aluminum oxide, Al_2O_3, as dispersing aids—not more than 2 percent total.

(b) *Uses and restrictions*. The color additive titanium dioxide may be used for coloring ingested and externally applied drugs generally, in amounts consistent with good manufacturing practice. External application includes use in the area of the eye.

(c) *Labeling*. The label of the color additive and any mixtures prepared therefrom and intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of the chapter.

(d) *Exemption from certification*. Certification of this color additive is not necessary for the protection of the public health and therefore batches thereof are exempt from the certification requirements of section 721(c) of the act.

§ 73.1645 Aluminum powder.

(a) *Identity*. (1) The color additive aluminum powder shall be composed of finely divided particles of aluminum prepared from virgin aluminum. It is free from admixture with other substances.

(2) Color additive mixtures for external drug use made with aluminum powder may contain only those diluents listed in this subpart as safe and suitable in color additive mixtures for coloring externally applied drugs.

(b) *Specifications*. Aluminum powder shall conform to the following specifications and shall be free from impurities other than those named to the extent that such impurities may be avoided by good manufacturing practice:

Fineness, 100 percent shall pass through a 200-mesh screen and 95 percent shall pass through a 325-mesh screen.
Mercury, not more than 1 part per million.
Arsenic, not more than 3 parts per million.
Lead, not more than 20 parts per million.
Aluminum, not less than 99 percent.

(c) *Uses and restrictions*. Aluminum powder is safe for use in externally applied drugs, including those intended for use in the area of the eye, in amounts consistent with good manufacturing practice.

(d) *Labeling*. The color additive and any mixture prepared therefrom intended solely or in part for coloring purposes shall bear, in addition to any information required by law, labeling in accordance with § 70.25 of this chapter.

(e) *Exemption from certification*. Certification of this color additive is not necessary for the protection of the public health, and therefore batches therof are exempt from certification pursuant to section 721(c) of the act.

[42 FR 38563, July 29, 1977]

§ 73.1646 Bronze powder.

(a) *Identity*. (1) The color additive bronze powder is a very fine metallic powder prepared from alloys consisting principally of virgin electrolytic copper and zinc with small amounts of the virgin metals aluminum and tin. It contains small amounts of stearic or oleic acid as lubricants.

(2) Color additive mixtures for drug use made with bronze powder may contain only those diluents listed in this subpart as safe and suitable for use in color additive mixtures for coloring externally applied drugs.

(b) *Specifications*. Bronze powder shall conform to the following specifications and shall be free from impurities other than those named to the extent that such impurities may be avoided by good manufacturing practice:

Stearic or oleic acid, not more than 5 percent.
Cadmium (as Cd), not more than 15 parts per million.
Lead (as Pb), not more than 20 parts per million.
Arsenic (as As), not more than 3 parts per million.
Mercury (as Hg), not more than 1 part per million
Aluminum (as Al), not more than 0.5 percent.
Tin (as Sn), not more than 0.5 percent.
Copper (as Cu), not more than 95 percent and not less than 70 percent.
Zinc (as Zn), not more than 30 percent.
Maximum particle size 45μ (95 percent minimum).

Aluminum, zinc, tin, and copper content shall be based on the weight of the dried powder after being thoroughly washed with ether.

(c) *Uses and restrictions*. Bronze powder may be safely used in color externally applied drugs, including those intended for use in the area of the eye, in amounts consistent with good manufacturing practice.

(d) *Labeling*. The color additive and any mixture prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Exemption from certification*. Certification of the color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 721(c) of the act.

[42 FR 33723, July 1, 1977]

§ 73.1647 Copper powder.

(a) *Identity*. (1) The color additive copper powder is a very fine free-flowing metallic powder prepared from virgin electrolytic copper. It contains small amounts of stearic or oleic acid as lubricants.

(2) Color additive mixtures for drug use made with copper powder may contain only those diluents listed in this subpart as safe and suitable for use in color additive mixtures for coloring externally applied drugs.

(b) *Specifications*. Copper powder shall conform to the following specifications and shall be free from impurities other than those named to the extent that such impurities may be avoided by good manufacturing practice:

Stearic or oleic acid, not more than 5 percent.
Cadmium (as Cd), not more than 15 parts per million.
Lead (as Pb), not more than 20 parts per million.
Arsenic (as As), not more than 3 parts per million.
Mercury (as Hg), not more than 1 part per million.
Copper (as Cu), not less than 95 percent.
Maximum particle size 45μ (95 percent minimum).

(c) *Uses and restrictions*. Copper powder may be safely used in coloring externally applied drugs, including those intended for use in the area of the eye, in amounts consistent with good manufacturing practice.

(d) *Labeling*. The color additive and any mixture prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Exemption from certification*. Certification of the color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 721(c) of the act.

[42 FR 33723, July 1, 1977]

§ 73.1991 Zinc oxide.

(a) *Identity*. (1) The color additive zinc oxide is a white or yellow-white amorphous powder manufactured by the French process (described as the indirect process whereby zinc metal isolated from the zinc-containing ore is vaporized and then oxidized). It is principally composed of Zn.

(2) Color additive mixtures for drug use made with zinc oxide may contain only those diluents listed in this subpart as safe and suitable in color additive mixtures for coloring externally applied drugs.

(b) *Specifications*. Zinc oxide shall conform to the following specifications and shall be free from impurities other than those named to the extent that such impurities may be avoided by good manufacturing practice:

Zinc oxide (as ZnO), not less than 99 percent.
Loss on ignition at 800 °C, not more than 1 percent.
Cadmium (as Cd), not more than 15 parts per million.
Mercury (as Hg), not more than 1 part per million.
Arsenic (as As), not more than 3 parts per million.
Lead (as Pb), not more than 20 parts per million.

(c) *Uses and restrictions*. The color additive zinc oxide may be safely used for coloring externally applied drugs, including those used in the area of the eye, in amounts consistent with good manufacturing practice.

(d) *Labeling*. The color additive and any mixtues prepared therefrom intended solely or in part for coloring purposes shall bear, in addition to any information required by law, labeling

in accordance with the provisions of § 70.25 of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches therof are exempt from the certifiation pursuant to section 721(c) of the act.

[42 FR 37537, July 22, 1977]

Subpart C—Cosmetics

§ 73.2030 Annatto.

(a) *Identity and specification.* The color additive annatto shall conform in identify and specification to the requirements for annatto extract in § 73.30(a) (1) and (b).

(b) *Use and restriction.* The color additive annatto may be safely used in coloring cosmetics generally, including cosmetics intended for use in the area of the eye, in amounts consistent with good manufacturing practice.

(c) *Labeling.* The color additive and any mixture prepared therefrom intended solely or in part for coloring purposes shall bear, in addition to any information required by law, labeling in accordance with the provisions of § 70.25 of this chapter.

(d) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 721(c) of the act.

[42 FR 36994, July 19, 1977]

§ 73.2085 Caramel.

(a) *Identity and specifications.* The color additive caramel shall conform in identity and specifications to the requirements of § 73.85(a)(1), (2), and (3) and (b).

(b) *Uses and restrictions.* Caramel is safe for use in coloring cosmetics generally, including cosmetics applied to the area of the eye, in amounts consistent with good manufacturing practice.

(c) *Labeling requirements.* The label of the color additive and any mixtures intended solely or in part for coloring purposes prepared therefrom shall conform to the requirements of § 70.25 of this chapter.

(d) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirement of section 721(c) of the act.

[46 FR 38501, July 28, 1981]

§ 73.2087 Carmine.

(a) *Identity and specifications.* The color additive carmine shall conform in identity and specifications to the requirements of § 73.100 (a)(2) and (b)(2).

(b) *Use and restrictions.* Carmine may be safely used in cosmetics generally, including cosmetics intended for use in the area of the eye, in amounts consistent with good manufacturing practices.

(c) *Labeling.* (1) The color additive and any mixture prepared therefrom intended solely or in part for coloring purposes shall bear, in addition to any information required by law, labeling in accordance with the provisions of § 70.25 of this chapter.

(2) Cosmetics containing carmine that are not subject to the requirements of § 701.3 of this chapter shall specifically declare the presence of carmine prominently and conspicuously at least once in the labeling. For example: ''Contains carmine as a color additive.''

(d) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification pursuant to section 721(c) of the act.

[42 FR 32228, June 24, 1977, as amended at 74 FR 216, Jan. 5, 2009]

§ 73.2095 β-Carotene.

(a) *Identity and specifications.* The color additive β-carotene shall conform in identity and specifications to the requirements of § 73.95(a)(1) and (b).

(b) *Uses and restrictions.* The color additive β-carotene may be safely used in coloring cosmetics generally, including cosmetics intended for use in the area of the eye, in amounts consistent with good manufacturing practices.

(c) *Labeling.* The color additive and any mixture prepared therefrom intended solely or in part for coloring purposes shall bear, in addition to any

information required by law, labeling in accordance with the provisions of § 70.25 of this chapter.

(d) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches therof are exempt from the certification pursuant to section 721(c) of the act.

[42 FR 33722, July 1, 1977]

§ 73.2110 Bismuth citrate.

(a) *Identity.* The color additive bismuth citrate is the synthetically prepared crystalline salt of bismuth and citric acid, consisting principally of $BiC_6H_5O_7$.

(b) *Specifications.* The color additive bismuth citrate shall conform to the following specifications and shall be free from impurities other than those named to the extent that those impurities may be avoided by good manufacturing practice:

Bismuth citrate, not less than 97 percent.
Mercury (as Hg), not more than 1 part per million.
Arsenic (as As), not more than 3 parts per million.
Lead (as Pb), not more than 20 parts per million.
Volatile matter, not more than 1 percent.

(c) *Uses and restrictions.* The color additive bismuth citrate may be safely used in cosmetics intended for coloring hair on the scalp, subject to the following restrictions:

(1) The amount of bismuth citrate in the cosmetic shall not be in excess of 2.0 percent (w/v).

(2) The cosmetic may not be used for coloring eyelashes, eyebrows, or hair on parts of the body other than the scalp.

(d) *Labeling.* (1) The label of the color additive bismuth citrate shall bear, in addition to any information required by law, labeling in accordance with the provisions of § 70.25 of this chapter.

(2) The label of a cosmetic containing the color additive bismuth citrate shall bear, in addition to other information required by law, the following statement, conspicuously displayed thereon:

Keep this product out of children's reach. Do not use on cut or abraded scalp. Do not use to color eyelashes, eyebrows, or hair on parts of the body other than the scalp. Wash hands thoroughly after each use.

(e) *Exemption from certification.* Certification of this color additive for the prescribed use is not necessary for the protection of the public health, and, therefore, batches thereof are exempt from certification requirements of section 721(c) of the act.

[43 FR 44831, Sept. 29, 1978, as amended at 75 FR 14493, Mar. 26, 2010]

§ 73.2120 Disodium EDTA-copper.

(a) *Identity.* The color additive disodium EDTA-copper is disodium [[*N*,*N*′-1,2- ethanediylbis[*N* - (carboxymethyl) glycinato]] (4-)-*N*,*N*′,*O*,*O*′,O^N,$O^{N'}$] cuprate (2-).

(b) *Specifications.* Disodium EDTA-copper shall conform to the following specifications and shall be free from impurities other than those named to the extent that such impurities may be avoided by good manufacturing practice:

Total copper, not less than 13.5 percent.
Total (ethylene-dinitrilo) tetracetic acid, not less than 62.5 percent.
Free copper, not more than 100 parts per million.
Free disodium salt of (ethylene-dinitrilo) tetraacetic acid, not more than 1.0 percent.
Moisture, not more than 15 percent.
Water insoluble matter, not more than 0.2 percent.
Lead (as Pb), not more than 20 parts per million.
Arsenic (as As), not more than 3 parts per million.

(c) *Uses and restrictions.* Disodium EDTA-copper may be safely used in amounts consistent with good manufacturing practices in the coloring of shampoos which are cosmetics.

(d) *Labeling requirements.* The labeling of the color additive shall conform to the requirements of § 70.25 of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health and therefore batches thereof are exempt from the requirements of section 721(c) of the act.

§ 73.2125 Potassium sodium copper chlorophyllin (chlorophyllin-copper complex).

(a) *Identity and specifications.* The color additive potassium sodium copper chlorophyllin shall conform in

identity and specifications to the requirements of § 73.1125(a)(1) and (b).

(b) *Uses and restrictions*. Potassium sodium copper chlorophyllin may be safely used for coloring dentifrices that are cosmetics subject to the following conditions:

(1) It shall not be used at a level in excess of 0.1 percent.

(2) It may be used only in combination with the following substances:

Water.
Glycerin.
Sodium carboxymethylcellulose.
Tetrasodium pyrophosphate.
Sorbitol.
Magnesium phosphate, tribasic.
Calcium carbonate.
Calcium phosphate, dibasic.
Sodium *N*-lauroyl sarcosinate.
Artificial sweeteners that are generally recognized as safe or that are authorized under subchapter B of this chapter.
Flavors that are generally recognized as safe or that are authorized under subchapter B of this chapter.
Preservatives that are generally recognized as safe or that are authorized under subchapter B of this chapter.

(c) *Labeling*. The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Exemption from certification*. Certification of this color additive is not necessary for the protection of the public health and therefore batches thereof are exempt from the certification requirements of section 721(c) of the act.

§ 73.2150 Dihydroxyacetone.

(a) *Identity and specifications*. The color additive dihydroxyacetone shall conform in identity and specifications to the requirements of § 73.1150 (a)(1) and (b).

(b) *Uses and restrictions*. Dihydroxyacetone may be safely used in amounts consistent with good manufacturing practice in externally applied cosmetics intended solely or in part to impart a color to the human body.

(c) *Labeling requirements*. The labeling of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(d) *Exemption from certification*. Certification of this color additive is not necessary for the protection of the public health and therefore batches thereof are exempt from the requirements of section 721(c) of the act.

§ 73.2162 Bismuth oxychloride.

(a) *Identity and specifications*. (1) The color additive bismuth oxychloride shall conform in identity and specifications to the requirements of § 73.1162(a)(1) and (b).

(2) Color additive mixtures of bismuth oxychloride may contain the following diluents:

(i) For coloring cosmetics generally, only those diluents listed under § 73.1001(a)(1);

(ii) For coloring externally applied cosmetics, only those diluents listed in § 73.1001(b) and, in addition, nitrocellulose.

(b) *Uses and restrictions*. The color additive bismuth oxychloride may be safely used in coloring cosmetics generally, including cosmetics intended for use in the area of the eye, in amounts consistent with good manufacturing practice.

(c) *Labeling*. The color additive and any mixture prepared therefrom intended solely or in part for coloring purposes shall bear, in addition to any information required by law, labeling in accordance with the provisions of § 70.25 of this chapter.

(d) *Exemption from certification*. Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from certification pursuant to section 721(c) of the act.

[42 FR 52394, Sept. 30, 1977]

§ 73.2180 Guaiazulene.

(a) *Identity*. (1) The color additive, guaiazulene, is principally 1,4-dimethyl-7-isopropyl-azulene.

(2) Color additive mixtures of guaiazulene for cosmetic use may contain the following diluent:

Polyethylene glycol-40 castor oil (PEG–40 castor oil).
Saponification No., 60 to 70.
Hydroxyl No., 63 to 78.
Acid No., 2.
Specific gravity, 1.05 to 1.07.

(b) *Specifications*. Guaiazulene shall conform to the following specifications and shall be free from impurities, other

than those named, to the extent that such other impurities may be avoided by good manufacturing practice.

Melting point, 30.5 °C to 31.5 °C.
Lead (as Pb), not more than 20 parts per million.
Arsenic (as As), not more than 3 parts per million.
Mercury (as Hg), not more than 1 part per million.
Total color, not less than 99 percent.

(c) *Uses and restrictions*. Guaiazulene may be safely used in externally applied cosmetics in amounts consistent with good manufacturing practice.

(d) *Labeling*. The label of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Exemption from certification*. Certification of this color additive for the prescribed use is not necessary for the protection of the public health and therefore batches thereof are exempt from the certification requirements of section 721(c) of the act.

§ 73.2190 Henna.

(a) *Identity*. The color additive henna is the dried leaf and petiole of *Lawsonia alba* Lam. (*Lawsonia inermis* L.). It may be identified by its characteristic odor and by characteristic plant histology.

(b) *Specifications*. Henna shall conform to the following specifications:

It shall not contain more than 10 percent of plant material from *Lawsonia alba* Lam. (*Lawsonia inermis* L.) other than the leaf and petiole, and shall be free from admixture with material from any other species of plant.
Moisture, not more than 10 percent.
Total ash, not more than 15 percent.
Acid-insoluble ash, not more than 5 percent.
Lead (as Pb), not more than 20 parts per million.
Arsenic (as As), not more than 3 parts per million.

(c) *Uses and restrictions*. The color additive henna may be safely used for coloring hair only. It may not be used for coloring the eyelashes or eyebrows, or generally in the area of the eye.

(d) *Labeling*. The label for henna shall bear the information required by § 70.25 of this chapter and the following statements or their equivalent:

''Do not use in the area of the eye.''

''Do not use on cut or abraded scalp.''

(e) *Exemption from certification*. Certification of this color additive for the prescribed use is not necessary for the protection of the public health and therefore batches thereof are exempt from the certification requirements of section 721(c) of the act.

§ 73.2250 Iron oxides.

(a) *Identity*. The color additives iron oxides consist of any one or any combination of synthetically prepared iron oxides, including the hydrated forms. It is free from admixture with other substances.

(b) *Specifications*. Iron oxides shall conform to the following specifications, all on an ''as is'' basis:

Arsenic (as As), not more than 3 parts per million.
Lead (as Pb), not more than 10 parts per million.
Mercury (as Hg), not more than 3 parts per million.

(c) *Uses and restrictions*. Iron oxides are safe for use in coloring cosmetics generally, including cosmetics applied to the area of the eye, in amounts consistent with good manufacturing practice.

(d) *Labeling*. The color additive and any mixture prepared therefrom intended solely or in part for coloring purposes shall bear, in addition to any information required by law, labeling in accordance with § 70.25 of this chapter.

(e) *Exemption from certification*. Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from certification pursuant to section 721(c) of the act.

§ 73.2298 Ferric ammonium ferrocyanide.

(a) *Identity and specifications*. The color additive ferric ammonium ferrocyanide shall conform in identify and specifications to the requirements of § 73.1298 (a)(1) and (b).

(b) *Uses and restrictions*. Ferric ammonium ferrocyanide is safe for use in coloring externally applied cosmetics, including cosmetics applied to the area of the eye, in amounts consistent with good manufacturing practice.

(c) *Labeling*. The color additive and any mixture prepared therefrom intended solely or in part for coloring purposes shall bear, in addition to any information required by law, labeling in accordance with § 70.25 of this chapter.

(d) *Exemption from certification*. Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification pursuant to section 721(c) of the act.

[42 FR 38562, July 29, 1977, as amended at 43 FR 6939, Feb. 17, 1978]

§ 73.2299 Ferric ferrocyanide.

(a) *Identity and specifications*. The color additive ferric ferrocyanide shall conform in identity and specifications to the requirements of § 73.1299(a)(1) and (b).

(b) *Uses and restrictions*. Ferric ferrocyanide is safe for use in coloring externally applied cosmetics, including cosmetics applied to the area of the eye, in amounts consistent with good manufacturing practice.

(c) *Labeling*. The color additive and any mixture prepared therefrom intended solely or in part for coloring purposes shall bear, in addition to any information required by law, labeling in accordance with § 70.25 of this chapter.

(d) *Exemption from certification*. Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from certification under section 721(c) of the act.

[43 FR 54236, Nov. 21, 1978]

§ 73.2326 Chromium hydroxide green.

(a) *Identity and specifications*. The color additive chromium hydroxide green shall conform in identity and specifications to the requirements of § 73.1326 (a)(1) and (b).

(b) *Uses and restrictions*. Chromium hydroxide green is safe for use in coloring externally applied cosmetics, including those intended for use in the area of the eye, in amounts consistent with good manufacturing practice.

(c) *Labeling*. The color additive and any mixture prepared therefrom intended solely or in part for coloring purposes shall bear, in addition to any information required by law, labeling in accordance with § 70.25 of this chapter.

(d) *Exemption from certification*. Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from certification pursuant to section 721(c) of the act.

[42 FR 36452, July 15, 1977]

§ 73.2327 Chromium oxide greens.

(a) *Identity and specifications*. The color additive chromium oxide greens shall conform in identify and specifications to the requirements of § 73.1327 (a)(1) and (b).

(b) *Uses and restrictions*. The color additive chromium oxide greens may be safely used in externally applied cosmetics, including cosmetics intended for use in the area of the eye, in amounts consistent with good manufacturing practice.

(c) *Labeling requirements*. The color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall bear, in addition to any information required by law, labeling in accordance with the provisions of § 70.25 of this chapter.

(d) *Exemption from certification*. Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification pursuant to section 721(c) of the act.

[42 FR 36452, July 15, 1977]

§ 73.2329 Guanine.

(a) *Identity and specifications*. (1) The color additive guanine shall conform in identity and specifications to the requirements of § 73.1329 (a)(1) and (b).

(2) Color additive mixtures of guanine may contain the following diluents:

(i) For coloring cosmetics generally, only those diluents listed under § 73.1001(a)(1);

(ii) For coloring externally applied cosmetics, only those diluents listed in § 73.1001(b) and, in addition, nitrocellulose.

(b) *Use and restrictions*. The color additive guanine may be safely used in

cosmetics generally, including cosmetics intended for use in the area of the eye, in amounts consistent with good manufacturing practice.

(c) *Labeling requirements.* The color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall bear, in addition to any information required by law, labeling in accordance with the provisions of § 70.25 of this chapter.

(d) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification pursuant to section 721(c) of the act.

[42 FR 37537, July 22, 1977]

§ 73.2396 Lead acetate.

(a) *Identity.* The color additive lead acetate is the trihydrate of lead (2+) salt of acetic acid. The color additive has the chemical formula $Pb(OOCCH_3)_2 \cdot 3H_2O$.

(b) *Specifications.* Lead acetate shall conform to the following specifications and shall be free from impurities other than those named to the extent that such impurities may be avoided by good manufacturing practice:

(1) Water-insoluble matter, not more than 0.02 percent.

(2) pH (30 percent solution weight to volume at 25 °C), not less than 4.7 and not more than 5.8.

(3) Arsenic (as As), not more than 3 parts per million.

(4) Lead acetate, not less than 99 percent.

(5) Mercury (as Hg), not more than 1 part per million.

(c) *Uses and restrictions.* The color additive lead acetate may be safely used in cosmetics intended for coloring hair on the scalp only, subject to the following restrictions:

(1) The amount of the lead acetate in the cosmetic shall be such that the lead content, calculated as Pb, shall not be in excess of 0.6 percent (weight to volume).

(2) The cosmetic is not to be used for coloring mustaches, eyelashes, eyebrows, or hair on parts of the body other than the scalp.

(d) *Labeling requirements.* (1) The label of the color additive lead acetate shall conform to the requirements of § 70.25 of this chapter, and bear the following statement or equivalent:

Wash thoroughly if the product comes into contact with the skin.

(2) The label of the cosmetic containing the color additive lead acetate, in addition to other information required by the Federal Food, Drug, and Cosmetic Act, shall bear the following cautionary statement, conspicuously displayed thereon:

CAUTION: Contains lead acetate. For external use only. Keep this product out of children's reach. Do not use on cut or abraded scalp. If skin irritation develops, discontinue use. Do not use to color mustaches, eyelashes, eyebrows, or hair on parts of the body other than the scalp. Do not get in eyes. Follow instructions carefully and wash hands thoroughly after each use.

(e) *Exemption for certification.* Certification of this color additive for the prescribed use is not necessary for the protection of the public health and therefore batches thereof are exempt from the certification requirements of section 721(c) of the Federal Food, Drug, and Cosmetic Act.

[84 FR 12082, Apr. 1, 2019]

§ 73.2400 Pyrophyllite.

(a) *Identity and specifications.* The color additive pyrophyllite shall conform in identity and specifications to the requirements of § 73.1400 (a)(1) and (b).

(b) *Uses and restrictions.* Pyrophyllite may be safely used for coloring externally applied cosmetics, in amounts consistent with good manufacturing practice.

(c) *Labeling requirements.* The labeling of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to all applicable requirements of law, including the requirements of § 70.25 of this chapter.

(d) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health and therefore batches thereof are exempt from the certification requirements of section 721(c) of the act.

§ 73.2496 Mica.

(a) *Identity and specifications.* The color additive mica shall conform in identity and specifications to the requirements of § 73.1496(a)(1) and (b).

(b) *Uses and restrictions.* Mica is safe for use in coloring cosmetics generally, including cosmetics applied to the area of the eye, in amounts consistent with good manufacturing practice.

(c) *Labeling.* The color additive and any mixture prepared therefrom intended solely or in part for coloring purposes shall bear, in addition to any information required by law, labeling in accordance with of § 70.25 of this chapter.

(d) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification pursuant to section 721(c) of the act.

[42 FR 38561, July 29, 1977]

§ 73.2500 Silver.

(a) *Identity.* (1) The color additive, silver, is a crystalline powder of high purity silver prepared by the reaction of silver nitrate with ferrous sulfate in the presence of nitric, phosphoric and sulfuric acids. Polyvinyl alcohol is used to prevent the agglomeration of crystals and the formation of amorphous silver.

(2) Color additive mixtures of silver may contain only those diluents listed in § 73.1001(b) and, in addition, nitrocellulose.

(b) *Specifications.* Silver shall conform to the following specifications and shall be free from impurities other than those named to the extent that such other impurities may be avoided by good manufacturing practice:

Lead (as Pb), not more than 10 parts per million.
Arsenic (as As), not more than 5 parts per million.
Mercury (as Hg), not more than 1 part per million.
Silver (as Ag), not less than 99.9 percent.

(c) *Uses and restrictions.* The color additive silver may be safely used for coloring fingernail polish at a level not to exceed 1 percent of the final product.

(d) *Labeling.* The color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall bear, in addition to any other information required by law, labeling in accordance with the provisions of § 70.25 of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health and therefore batches thereof are exempt from the certification requirements of section 721(c) of the act.

[44 FR 65974, Nov. 16, 1979]

§ 73.2575 Titanium dioxide.

(a) *Identity and specifications.* The color additive titanium dioxide shall conform in identity and specifications to the requirements on § 73.575 (a)(1) and (b).

(b) *Uses and restrictions.* The color additive titanium dioxide may be safely used in cosmetics, including cosmetics intended for use in the area of the eye, in amounts consistent with good manufacturing practice.

(c) *Labeling requirements.* The color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall bear, in addition to any other information required by law, labeling in accordance with the provisions of § 70.25 of this chapter.

(d) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from certification pursuant to section 721(c) of the act.

§ 73.2645 Aluminum powder.

(a) *Identity and specifications.* The color additive aluminum powder shall conform in identity and specifications to the requirements of § 73.1645 (a)(1) and (b).

(b) *Uses and restrictions.* Aluminum powder may be safely used in coloring externally applied cosmetics, including cosmetics intended for use in the area of the eye, in amounts consistent with good manufacturing practice.

(c) *Labeling*. The color additive and any mixture prepared therefrom intended solely or in part for coloring purposes shall bear, in addition to any information required by law, labeling in accordance with the provisions of § 70.25 of this chapter.

(d) *Exemption from certification*. Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification pursuant to section 721(c) of the act.

[42 FR 38563, July 29, 1977]

§ 73.2646 Bronze powder.

(a) *Identity and specifications*. The color additive bronze powder shall conform in identity and specifications to the requirements of § 73.1646 (a)(1) and (b).

(b) *Uses and restrictions*. Bronze powder may be safely used in coloring cosmetics generally, including cosmetics intended for use in the area of the eye, in amounts consistent with good manufacturing practice.

(c) *Labeling*. The color additive and any mixture prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(d) *Exemption from certification*. Certification of the color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 721(c) of the act.

[42 FR 33724, July 1, 1977]

§ 73.2647 Copper powder.

(a) *Identity and specifications*. The color additive copper powder shall conform in identity and specifications to the requirements of § 73.1647 (a)(1) and (b).

(b) *Uses and restrictions*. Copper powder may be safely used in coloring cosmetics generally, including cosmetics intended for use in the area of the eye, in amounts consistent with good manufacturing practice.

(c) *Labeling*. The color additive and any mixture prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(d) *Exemption from certification*. Certification of the color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 721(c) of the act.

[42 FR 33724, July 1, 1977]

§ 73.2725 Ultramarines.

(a) *Identity*. The color additives, ultramarines (blue, green, pink, red, and violet) are pigments obtained by calcining at temperatures above 700 °C. a mixture of kaolin, sulfur, sodium carbonate, silicious matter, sodium sulfate, and carbonaceous matter, but not necessarily all these substances, to produce a single color. The ultramarines are complex sodium aluminum sulfosilicates having a typical formula Na(AlSiO)S with proportions of each element varying with each color.

(b) *Specifications*. The ultramarines shall conform to the following specifications and shall be free from impurities other than those named, to the extent that such other impurities may be avoided by good manufacturing practice.

Lead (as Pb), not more than 20 parts per million.

Arsenic (as As), not more than 3 parts per million.

Mercury (as Hg), not more than 1 part per million.

(c) *Uses and restrictions*. The ultramarine pigments may be safely used for coloring externally applied cosmetics, including cosmetics intended for use in the area of the eye, in amounts consistent with good manufacturing practice.

(d) *Labeling requirements*. The color additives and any mixtures prepared therefrom intended solely or in part for coloring purposes shall bear, in addition to any other information required by law, labeling in accordance with § 70.25 of this chapter.

(e) *Exemption from certification*. Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from certification pursuant to section 721(c) of the act.

§ 73.2775 Manganese violet.

(a) *Identity*. The color additive manganese violet is a violet pigment obtained by reacting phosphoric acid, ammonium dihydrogen orthophosphate, and manganese dioxide at temperatures above 450 °F. The pigment is a manganese ammonium pyrophosphate complex having the approximate formula: $Mn(III)NH_4P_2O_7$.

(b) *Specifications*. Manganese violet shall conform to the following specifications and shall be free from impurities other than those named, to the extent that such other impurities may be avoided by good manufacturing practice:

Ash (at 600 °C), not less than 81 percent.
Volatile matter at 135 °C for 3 hours, not more than 1 percent.
Water soluble substances, not more than 6 percent.
pH of filtrate of 10 grams color additive (shaken occasionally for 2 hours with 100 milliliters of freshly boiled distilled water), not more than 4.7 and not less than 2.5.
Lead (as Pb), not more than 20 parts per million.
Arsenic (as As), not more than 3 parts per million.
Mercury (as Hg), not more than 1 part per million.
Total color, based on Mn content in ''as is'' sample, not less than 93 percent.

(c) *Uses and restrictions*. Manganese violet is safe for use in coloring cosmetics generally, including cosmetics applied to the area of the eye, in amounts consistent with good manufacturing practice.

(d) *Labeling*. The color additive and any mixture prepared therefrom intended solely or in part for coloring purposes shall bear, in addition to any information required by law, labeling in accordance with § 70.25 of this chapter.

(e) *Exemption from certification*. Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from certification pursuant to section 721(c) of the act.

§ 73.2991 Zinc oxide.

(a) *Identity and specifications*. The color additive zinc oxide shall conform in identity and specifications to the requirements of § 73.1991 (a)(1) and (b).

(b) *Uses and restrictions*. Zinc oxide may be safely used in cosmetics, including cosmetics intended for use in the area of the eye, in amounts consistent with good manufacturing practice.

(c) *Labeling*. The color additive and any mixture prepared therefrom intended solely or in part for coloring purposes shall bear, in addition to any information required by law, labeling in accordance with § 70.25 of this chapter.

(d) *Exemption from certification*. Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification pursuant to section 721(c) of the act.

[42 FR 37538, July 22, 1977]

§ 73.2995 Luminescent zinc sulfide.

(a) *Identity*. The color additive luminescent zinc sulfide is zinc sulfide containing a copper activator. Following excitation by daylight or a suitable artificial light, luminescent zinc sulfide produces a yellow-green phosphorescence with a maximum at 530 nanometers.

(b) *Specifications*. Luminescent zinc sulfide shall conform to the following specifications and shall be free from impurities other than those named to the extent that such impurities may be avoided by good manufacturing practice:

Zinc sulfide, not less than 99.8 percent.
Copper, 100 ± 5 parts per million.
Lead, not more than 20 parts per million.
Arsenic, not more than 3 parts per million.
Mercury, not more than 1 part per million.
Cadmium, not more than 15 parts per million.

(c) *Uses and restrictions*. The color additive luminescent zinc sulfide may be safely used for coloring externally applied facial makeup preparations and nail polish included under § 720.4(c)(7)(ix) and (c)(8)(v) of this chapter, respectively, to the following restrictions:

(1) The amount of luminescent zinc sulfide in facial makeup preparations shall not exceed 10 percent by weight of the final product.

(2) Facial makeup preparations containing luminescent zinc sulfide are intended for use only on limited, infrequent occasions, e.g., Halloween, and not for regular or daily use.

(d) *Labeling requirements.* (1) The label of the color additive and any mixtures prepared therefrom shall bear expiration dates for the sealed and open container (established through generally accepted stability testing methods), other information required by § 70.25 of this chapter, and adequate directions to prepare a final product complying with the limitations prescribed in paragraph (c) of this section.

(2) The label of a facial makeup preparation containing the color additive shall bear, in addition to other information required by the law, the following statement conspicuously displayed:

Do not use in the area of the eye.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 721(c) of the act.

[65 FR 48377, Aug. 8, 2000; 65 FR 75158, Dec. 1, 2000]

Subpart D—Medical Devices

§ 73.3100 1,4-Bis[(2-hydroxyethyl)amino]-9,10-anthracenedione bis(2-methyl-2-propenoic)ester copolymers.

(a) *Identity.* The color additives are the copolymers formed as the reaction product of 1,4-bis[(2-hydroxyethyl)amino]-9,10-anthracenedione bis(2-methyl-2-propenoic)ester (C.I. Reactive Blue 247) (CAS Reg. No. 109561–07–1) with one or more vinyl and/or acrylic monomers to form the contact lens material.

(b) *Uses and restrictions.* (1) The substances listed in paragraph (a) of this section may be used in amounts not to exceed the minimum reasonably required to accomplish the intended coloring effect.

(2) Authorization and compliance with these uses shall not be construed as waiving any of the requirements of sections 510(k), 515, and 520(g) of the Federal Food, Drug, and Cosmetic Act (the act) with respect to the contact lens made from the color additives.

(c) *Labeling.* The label of the color additives shall conform to the requirements of § 70.25 of this chapter.

(d) *Exemption from certification.* Certification of these color additives is not necessary for the protection of the public health and therefore the color additives are exempt from the certification requirements of section 721(c) of the act.

[61 FR 51586, Oct. 3, 1996, as amended at 78 FR 19415, Apr. 1, 2013]]

§ 73.3105 1,4-Bis[(2-methylphenyl)amino]-9,10-anthracenedione.

(a) *Identity.* The color additive is 1,4-bis[(2-methylphenyl)amino]-9,10-anthracenedione (CAS Reg. No. 6737–68–4).

(b) *Uses and restrictions.* (1) The substance listed in paragraph (a) of this section may be used as a color additive in contact lenses in amounts not to exceed the minimum reasonably required to accomplish the intended coloring effect.

(2) Authorization and compliance with this use shall not be construed as waiving any of the requirements of sections 510(k), 515, and 520(g) of the Federal Food, Drug, and Cosmetic Act (the act). A person intending to introduce a device containing 1,4-bis[(2-methylphenyl)amino]-9,10-anthracenedione listed under this section into commerce shall submit to the Food and Drug Administration either a premarket notification in accordance with subpart E of part 807 of this chapter, if the device is not subject to premarket approval, or submit and receive approval of an original or supplemental premarket approval application if the device is subject to premarket approval.

(c) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore the color additive is exempt from the certification requirements of section 721(c) of the act.

[49 FR 30066, July 26, 1984]

§ 73.3106 1,4-Bis[4-(2-methacryloxyethyl) phenylamino]anthraquinone copolymers.

(a) *Identity*. The color additives are the copolymers formed as the reaction product of 1,4-bis[4-(2-methacryloxyethyl)phenylamino]-anthraquinone (C.I. Reactive Blue 246) (CAS Reg. No. 121888–69–5) with one or more vinyl and/or acrylic monomers to form the contact lens material.

(b) *Uses and restrictions*. (1) The substances listed in paragraph (a) of this section may be used in amounts not to exceed the minimum reasonably required to accomplish the intended coloring effect.

(2) Authorization and compliance with these uses shall not be construed as waiving any of the requirements of sections 510(k), 515, and 520(g) of the Federal Food, Drug, and Cosmetic Act (the act) with respect to contact lenses made from the color additives.

(c) *Labeling*. The label of the color additives shall conform to the requirements of § 70.25 of this chapter.

(d) *Exemption from certification*. Certification of these color additives is not necessary for the protection of the public health and, therefore, the color additives are exempt from the certification requirements of section 721(c) of the act.

[58 FR 17507, Apr. 5, 1993, as amended at 60 FR 10497, Feb. 27, 1995; 78 FR 19415, Apr. 1, 2013]

§ 73.3107 Carbazole violet.

(a) *Identity*. The color additive is carbazole violet (Pigment Violet 23) (CAS Reg. No. 6358–30–1, Colour Index No. 51319).

(b) *Uses and restrictions*. (1) The substance listed in paragraph (a) of this section may be used as a color additive in contact lenses in amounts not to exceed the minimum reasonably required to accomplish the intended coloring effect.

(2) Authorization for this use shall not be construed as waiving any of the requirements of sections 510(k), 515, and 520(g) of the Federal Food, Drug, and Cosmetic Act (the act) with respect to the contact lens in which the color additive is used.

(c) *Labeling*. The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Exemption from certification*. Certification of this color additive is not necessary for the protection of the public health, and therefore the color additive is exempt from the certification requirements of section 721(c) of the act.

[53 FR 41324, Oct. 21, 1988]

§ 73.3110 Chlorophyllin-copper complex, oil soluble.

(a) *Identity*. The color additve is chlorophyllin-copper complex, oil soluble. The chlorophyllin is obtained by extraction from a mixture of fescue and rye grasses. The chlorophyll is acid-treated to remove chelated magnesium which is replaced with hydrogen, which is turn is replaced with copper. This mixture is diluted to a 5 percent concentration with a mixture of palm oil, peanut oil, and hydrogenated peanut oil.

(b) *Specifications*. The color additive chlorophyllin-copper complex, oil soluble (5 percent in palm oil, peanut oil, and hydrogenated peanut oil), shall conform to the following specifications and shall be free from impurities other than those named to the extent that such other impurities may be avoided by current good manufacturing practice:

Moisture, not more than 0.5 percent.
Nitrogen, not less than 0.2 percent and not more than 0.3 percent.
Total copper, not less than 0.2 percent and not more than 0.4 percent.
Free copper, not more than 200 parts per million.
Lead, not more than 20 parts per million.
Arsenic, not more than 5 parts per million.
Sulfated ash, not more than 2.5 percent.
Total color, not less than 4.5 percent and not more than 5.5 percent.

(c) *Uses and restrictions*. (1) The color additive chlorophyllin-copper complex, oil soluble (5 percent in palm oil, peanut oil, and hydrogenated peanut oil), may be safely used to color polymethylmethacrylate bone cement. Chlorophyllin-copper complex may be used at levels that do not exceed 0.003 percent by weight of the bone cement.

(2) Authorization for this use shall not be construed as waiving any of the

requirements of sections 510(k), 515, and 520(g) of the Federal Food, Drug, and Cosmetic Act with respect to the polymethylmethacrylate bone cement in which chlorophyllin-copper complex, oil soluble, is used.

(d) *Labeling*. The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(e) *Exemption from certification*. Certification of this color additive is not necessary for the protection of the public health, and therefore the color additive is exempt from the certification requirements of section 721(c) of the act.

[48 FR 56370, Dec. 21, 1983]

§ 73.3110a Chromium-cobalt-aluminum oxide.

(a) *Identity*. The color additive chromium-cobalt-aluminum oxide (Pigment Blue 36) (CAS Reg. No. 68187–11–1, Colour Index No. 77343) shall conform in identity and specifications to the requirements of § 73.1015 (a) and (b).

(b) *Uses and restrictions*. (1) The substance listed in paragraph (a) of this section may be used as a color additive in contact lenses in amounts not to exceed the minimum reasonably required to accomplish the intended coloring effect.

(2) Authorization for this use shall not be construed as waiving any of the requirements of sections 510(k), 515, and 520(g) of the Federal Food, Drug, and Cosmetic Act (the act) with respect to the contact lens in which the color additive is used.

(c) *Labeling*. The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Exemption from certification*. Certification of this color additive is not necessary for the protection of the public health, and therefore the color additive is exempt from the certification requirements of section 721(c) of the act.

[53 FR 41325, Oct. 21, 1988]

§ 73.3111 Chromium oxide greens.

(a) *Identity and specifications*. The color additive chromium oxide greens (chromic oxide) (CAS Reg. No. 1308–38–9), Color Index No. 77288, shall conform in identity and specifications to the requirements of § 73.1327 (a)(1) and (b).

(b) *Uses and restrictions*. (1) The substance listed in paragraph (a) of this section may be used as a color additive in contact lenses in amounts not to exceed the minimum reasonably required to accomplish the intended coloring effect.

(2) Authorization and compliance with this use shall not be construed as waiving any of the requirements of sections 510(k), 515, and 520(g) of the Federal Food, Drug, and Cosmetic Act with respect to the contact lenses in which the additive is used.

(c) *Labeling*. The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Exemption from certification*. Certification of this color additive is not necessary for the protection of the public health, and therefore the color additive is exempt from the certification requirements of section 721(c) of the act.

[51 FR 24816, July 9, 1986]

§ 73.3112 C.I. Vat Orange 1.

(a) *Identity*. The color additive is C.I. Vat Orange 1, Colour Index No. 59105.

(b) *Uses and restrictions*. (1) The substance listed in paragraph (a) of this section may be used as a color additive in contact lenses in amounts not to exceed the minimum reasonably required to accomplish the intended coloring effect.

(2) Authorization for this use shall not be construed as waiving any of the requirements of sections 510(k), 515, and 520(g) of the Federal Food, Drug, and Cosmetic Act (the act) with respect to the contact lens in which the color additive is used. A person intending to introduce a device containing C.I. Vat Orange 1 into commerce shall submit to the Food and Drug Administration either a premarket notification in accordance with subpart E of part 807 of this chapter, if the device is not subject to premarket approval, or submit and receive approval of an original or supplemental premarket approval application if the device is subject to premarket approval.

(c) *Labeling*. The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore the color additive is exempt from the certification requirements of section 721(c) of the act.

[50 FR 20407, May 16, 1985]

§ 73.3115 2-[[2,5-Diethoxy-4-[(4-methylphenyl)thiol]phenyl]azo]-1,3,5-benzenetriol.

(a) *Identity.* The color additive2-[[2,5-diethoxy-4-[(4-methylphenyl)thio]phenyl]azo]-1,3,5-benzenetriol is formed in situ in soft (hydrophilic) contact lenses.

(b) *Uses and restrictions.* The color additive 2-[[2,5-diethoxy-4-[(4-methylphenyl)thio]phenyl]azo]-1,3,5-benzenetriol may be safely used to mark soft (hydrophilic) contact lenses with the letter R or the letter L for identification purposes subject to the following restrictions:

(1) The quantity of the color additive does not exceed 1.1×10^{-7} grams in a soft (hydrophilic) contact lens.

(2) When used as specified in the labeling, there is no measurable migration of the color additive from the contact lens to the surrounding ocular tissue.

(3) Authorization for this use shall not be construed as waiving any of the requirements of section 510(k) and 515 of the Federal Food, Drug, and Cosmetic Act with respect to the contact lens in which the color additive is used.

(c) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore the color additive is exempt from the certification requirements of section 721(c) of the act.

[48 FR 22706, May 20, 1983]

§ 73.3117 16,23-Dihydrodinaphtho[2,3-a:2′,3′-i] naphth [2′,3′:6,7] indolo [2,3-c] carbazole-5,10,15,17,22,24-hexone.

(a) *Identity.* The color additive is 16,23-dihydrodinaphtho [2,3- *a*:2′,3′-*i*] napth [2′,3′:6,7] indolo [2, 3-*c*] carbazole-5,10, 15,17,22,24-hexone (CAS Reg. No. 2475–33–4), Colour Index No. 70800.

(b) *Uses and restrictions.* (1) The substance listed in paragraph (a) of this section may be used as a color additive in contact lenses in amounts not to exceed the minimum reasonably required to accomplish the intended coloring effect.

(2) Authorization for this use shall not be construed as waiving any of the requirements of sections 510(k), 515, and 520(g) of the Federal Food, Drug, and Cosmetic Act with respect to the contact lens in which the color additive is used.

(c) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore the color additive is exempt from the certification requirements of section 721(c) of the act.

[48 FR 31375, July 8, 1983]

§ 73.3118 N,N′-(9,10-Dihydro-9,10-dioxo-1,5-anthracenediyl) bisbenzamide.

(a) *Identity.* The color additive is *N*,*N*′-(9,10-dihydro-9,10-dioxo-1,5-anthracenediyl) bisbenzamide (CAS Reg. No. 82–18–8), Colour Index No. 61725.

(b) *Uses and restrictions.* (1) The substance listed in paragraph (a) of this section may be used as a color additive in contact lenses in amounts not to exceed the minimum reasonably required to accomplish the intended coloring effect.

(2) Authorization for this use shall not be construed as waiving any of the requirements of sections 510(k), 515, and 520(g) of the Federal Food, Drug, and Cosmetic Act with respect to the contact lens in which the color additive is used.

(c) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore the color additive is exempt from the certification requirements of section 721(c) of the act.

[48 FR 31375, July 8, 1983]

§ 73.3119 7,16-Dichloro-6,15-dihydro-5,9,14,18-anthrazinetetrone.

(a) *Identity*. The color additive is 7,16-dichloro-6,15-dihydro-5,9,14,18-anthrazinetetrone (CAS Reg. No. 130–20–1), Colour Index No. 69825.

(b) *Uses and restrictions*. (1) The substance listed in paragraph (a) of this section may be used as a color additive in contact lenses in amounts not to exceed the minimum reasonably required to accomplish the intended coloring effect.

(2) Authorization for this use shall not be construed as waiving any of the requirements of sections 510(k), 515, and 520(g) of the Federal Food, Drug, and Cosmetic Act with respect to the contact lens in which the color additive is used.

(c) *Labeling*. The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Exemption from certification*. Certification of this color additive is not necessary for the protection of the public health, and therefore the color additive is exempt from the certification requirements of section 721(c) of the act.

[48 FR 31376, July 8, 1983]

§ 73.3120 16,17-Dimethoxydinaphtho [1,2,3-cd:3′,2′,1′-lm] perylene-5,10-dione.

(a) *Identity*. The color additive is 16,17-dimethoydinaphtho[1,2,3,-*cd:3′*,2′,1′-*lm*]perylene-5,10-dione (CAS Reg. No. 128–58–5), Colour Index No. 59825.

(b) *Uses and restrictions*. (1) The substance listed in paragraph (a) of this section may be used as a color additive in contact lenses in amounts not to exceed the minimum reasonably required to accomplish the intended coloring effect.

(2) Authorization for this use shall not be construed as waiving any of the requirements of sections 510(k), 515, and 520(g) of the Federal Food, Drug, and Cosmetic Act with respect to the contact lens in which the color additive is used.

(c) *Labeling*. The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Exemption from certification*. Certification of this color additive is not necessary for the protection of the public health, and therefore the color additive is exempt from the certification requirements of section 721(c) of the act.

[48 FR 31376, July 8, 1983]

§ 73.3121 Poly(hydroxyethyl methacrylate)-dye copolymers.

(a) *Identity*. The color additives are formed by reacting one or more of the reactive dyes listed in this paragraph with poly(hydroxyethyl methacrylate), so that the sulfate group (or groups) or chlorine substituent of the dye is replaced by an ether linkage to poly(hydroxyethyl methacrylate). The dyes that may be used alone or in combination are

(1) Reactive Black 5 [2,7-naphthalenedisulfonic acid, 4-amino-5-hydroxy-3,6-bis((4-((2-(sulfooxy)ethyl)sulfonyl)phenyl)azo)-tetrasodium salt] (CAS Reg. No. 17095–24–8);

(2) Reactive Blue 21 [copper, (29*H*,31*H*-phthalocyaninato(2-)-N^{29},N^{30},N^{31},N^{32})-, sulfo((4-((2-sulfooxy)ethyl)sulfonyl)phenyl)amino) sulfonyl derivs] (CAS Reg. No. 73049–92–0);

(3) Reactive Orange 78 [2-naphthalenesulfonic acid, 7-(acetylamino)-4-hydroxy-3-((4-((2-(sulfooxy)ethyl) sulfonyl)phenyl)azo)-] CAS Reg. No. 68189–39–9);

(4) Reactive Yellow 15 [benzensulfonic acid, 4-(4,5-dihydro-4-((2-methoxy-5-methyl-4-((2-(sulfooxy)ethyl) sulfonyl)phenyl)azo)-3-methyl-5-oxo-1*H*-pyrazol-1-yl)-] (CAS Reg. No. 60958–41–0);

(5) Reactive Blue No. 19 [2-anthracene-sulfonic acid, 1-amino-9,10-dihydro-9,10-dioxo-4-((3-((2-(sulfooxy)ethyl)sulfonyl)phenyl)amino) -, disodium salt] (CAS Reg. No. 2580–78–1);

(6) Reactive Blue No. 4 [2-anthracenesulfonic acid, 1-amino-4-(3-((4,6-dichloro-s-triazin-2-yl)amino)-4-sulfoanilino)-9,10-dihydro-9,10-dioxo, disodium salt] (CAS Reg. No. 4499–01–8);

(7) C.I. Reactive Red 11 [5-((4,6-dichloro-1,3,5-triazin-2-yl)amino)-4-hydroxy-3-((1-sulfo-2-naphthalenyl)azo)-2,7-naphthalenedisulfonic acid, trisodium salt] (CAS Reg. No. 12226–08–3);

(8) C.I. Reactive Yellow 86 [1,3-benzenedisulfonic acid, 4-((5-aminocarbonyl-1-ethyl-1,6-dihydro-2-hydroxy-4-methyl-6-oxo-3-pyridinyl)azo)-6-(4,6-dichloro-1,3,5-triazin-2-yl)amino)-, disodium salt] (CAS Reg. No. 61951–86–8);

(9) C.I. Reactive Blue 163 [triphenodioxazinedisulfonic acid, 6,13-dichloro-3, 10-bis((4-((4.6-dichloro-1,3,5-triazin-2-yl)amino) sulfophenyl)amino)-, tetrasodium salt] (CAS Reg. No. 72847–56–4); and

(10) C.I. Reactive Red 180 [5-(benzoylamino)-4-hydroxy-3-((1-sulfo-6-((2-(sulfooxy)ethyl)sulfonyl)-2-naphthalenyl)azo)-2,7-naphthalenedisulfonic acid, tetrasodium salt] (CAS Reg. No. 98114–32–0).

(b) *Uses and restrictions.* (1) The substances listed in paragraph (a) of this section may be used to color contact lenses in amounts not to exceed the minimum reasonably required to accomplish the intended coloring effect.

(2) As part of the manufacturing process, the lenses containing the color additives are thoroughly washed to remove unbound reactive dyes.

(3) Authorization and compliance with this use shall not be construed as waiving any of the requirements of sections 510(k), 515, and 520(g) of the Federal Food, Drug, and Cosmetic Act (the act). A person intending to introduce a device containing a poly(hydroxyethyl methacrylate)-dye copolymer listed under this section into commerce shall submit to the Food and Drug Administration either a premarket notification in accordance with subpart E of part 807 of this chapter, if the device is not subject to premarket approval, or submit and receive approval of an original or supplemental premarket approval application if the device is subject to premarket approval.

(c) *Labeling.* The label of the color additives shall conform to the requirements of § 70.25 of this chapter.

(d) *Exemption from certification.* Certification of these color additives is not necessary for the protection of the public health, and therefore these color additives are exempt from the certification requirements of section 721(c) of the act.

[49 FR 373, Jan. 4, 1984; 49 FR 5094, Feb. 10, 1984, as amended at 50 FR 9425, Mar. 8, 1985; 50 FR 33338, Aug. 19, 1985; 50 FR 37845, Sept. 18, 1985; 50 FR 45993, Nov. 6, 1985; 58 FR 9541, Feb. 22, 1993]

§ 73.3122 4-[(2,4-dimethylphenyl)azo]-2,4-dihydro-5-methyl-2-phenyl-3H-pyrazol-3-one.

(a) *Identity.* The color additive is 4-[(2,4-dimethylphenyl)azo]-2,4-dihydro-5-methyl-2-phenyl-3*H*- pyrazol-3-one (CAS Reg. No. 6407–78–9).

(b) *Uses and restrictions.* (1) The substances listed in paragraph (a) of this section may be used as a color additive in contact lenses in amounts not to exceed the minimum reasonably required to accomplish the intended coloring effect.

(2) Authorization for this use shall not be construed as waiving any of the requirements of sections 510(k), 515, and 520(g) of the Federal Food, Drug, and Cosmetic Act with respect to the contact lens in which the color additive is used.

(c) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore the color additive is exempt from the certification requirements of section 721(c) of the act.

[51 FR 11432, Apr. 3, 1986]

§ 73.3123 6-Ethoxy-2-(6-ethoxy-3-oxobenzo[b]thien-2(3H)-ylidene) benzo[b]thiophen-3 (2H)-one.

(a) *Identity.* The color additive is 6-ethoxy-2-(6-ethoxy-3-oxobenzo [*b*]thien-2(3*H*)-ylidene)benzo[*b*]thiophen-3(2*H*)-one (CAS Reg. No. 3263–31–8), Colour Index No. 73335.

(b) *Uses and restrictions.* (1) The substance listed in paragraph (a) of this section may be used as a color additive in contact lenses in amounts not to exceed the minimum reasonably required to accomplish the intended coloring effect.

(2) Authorization for this use shall not be construed as waiving any of the requirements of sections 510(k), 515,

and 520(g) of the Federal Food, Drug, and Cosmetic Act with respect to the contact lens in which the color additive is used.

(c) *Labeling*. The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Exemption from certification*. Certification of this color additive is not necessary for the protection of the public health, and therefore the color additive is exempt from the certification requirements of section 721(c) of the act.

[51 FR 11436, Apr. 3, 1986]

§ 73.3124 Phthalocyanine green.

(a) *Identity*. The color additive is phthalocyanine green (CAS Reg. No. 1328–53–6), Colour Index No. 74260.

(b) *Uses and restrictions*. (1) The substance listed in paragraph (a) of this section may be used as a color additive in contact lenses in amounts not to exceed the minimum reasonably required to accomplish the intended coloring effect.

(2) Authorization for this use shall not be construed as waiving any of the requirements of sections 510(k), 515, and 520(g) of the Federal Food, Drug, and Cosmetic Act with respect to the contact lens in which the additive is used.

(c) *Labeling*. The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Exemption from certification*. Certification of this color additive is not necessary for the protection of the public health, and therefore the color additive is exempt from the certification requirements of section 721(c) of the act.

[51 FR 11433, Apr. 3, 1986]

§ 73.3125 Iron oxides.

(a) *Identity and specifications*. The color additive iron oxides (CAS Reg. No. 1332–37–2), Color Index No. 77491, shall conform in identity and specifications to the requirements of § 73.2250 (a) and (b).

(b) *Uses and restrictions*. (1) The substance listed in paragraph (a) of this section may be used as a color additive in contact lenses in amounts not to exceed the minimum reasonably required to accomplish the intended coloring effect.

(2) Authorization and compliance with this use shall not be construed as waiving any of the requirements of sections 510(k), 515, and 520(g) of the Federal Food, Drug, and Cosmetic Act with respect to the contact lens in which the additive is used.

(c) *Labeling*. The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Exemption from certification*. Certification of this color additive is not necessary for the protection of the public health, and therefore the color additive is exempt from the certification requirements of section 721(c) of the act.

[51 FR 24816, July 9, 1986, as amended at 69 FR 24511, May 4, 2004]

§ 73.3126 Titanium dioxide.

(a) *Identity and specifications*. The color additive titanium dioxide (CAS Reg. No. 13463–67–7), Color Index No. 77891, shall conform in identity and specifications to the requirements of § 73.575(a)(1) and (b).

(b) *Uses and restrictions*. (1) The substance listed in paragraph (a) of this section may be used as a color additive in contact lenses and intraocular lens orientation marks in amounts not to exceed the minimum reasonably required to accomplish the intended coloring effect.

(2) Authorization and compliance with this use shall not be construed as waiving any of the requirements of sections 510(k), 515, and 520(g) of the Federal Food, Drug, and Cosmetic Act with respect to the contact lenses in which the additive is used.

(c) *Labeling*. The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Exemption from certification*. Certification of this color additive is not necessary for the protection of the public health, and therefore the color additive is exempt from the certification requirements of section 721(c) of the act.

[51 FR 24816, July 9, 1986, as amended at 81 FR 75692, Nov. 1, 2016]

§ 73.3127 Vinyl alcohol/methyl methacrylate-dye reaction products.

(a) *Identity*. The color additives are formed by reacting the dyes, either alone or in combination, with a vinyl alcohol/methyl methacrylate copolymer, so that the sulfate groups of the dyes are replaced by ether linkages to the vinyl alcohol/methyl methacrylate copolymer. The dyes are:

(1) C.I. Reactive Red 180 [5-(benzoylamino)-4-hydroxy-3-((1-sulfo-6-((2-(sulfooxy)ethyl)sulfonyl)-2-naphthalenyl)azo)-2,7-naphthalenedisulfonic acid, tetrasodium salt] (CAS Reg. No. 98114–32–0).

(2) C.I. Reactive Black 5 [2,7-naphthalenedisulfonic acid, 4-amino-5-hydroxy-3,6-bis((4-((2-(sulfooxy)ethyl)sulfonyl)phenyl)azo)-, tetrasodium salt] (CAS Reg. No. 17095–24–8).

(3) C.I. Reactive Orange 78 [2-naphthalenesulfonic acid, 7-(acetylamino)-4-hydroxy-3-((4-((2-(sulfooxy)ethyl)sulfonyl)phenyl)azo)-] (CAS Reg. No. 68189–39–9).

(4) C.I. Reactive Yellow 15 [benzenesulfonic acid, 4-(4,5-dihydro-4-((2-methoxy-5-methyl-4-((2-(sulfooxy)ethyl)sulfonyl)phenyl)azo)-3-methyl-5-oxo-1*H*-pyrazol-1-yl)-] (CAS Reg. No. 60958–41–0).

(5) C.I. Reactive Blue No. 19 [2-anthracenesulfonic acid, 1-amino-9,10-dihydro-9,10-dioxo-4-((3-((2-(sulfooxy)ethyl)sulfonyl)phenyl)amino)-, disodium salt] (CAS Reg. No. 2580–78–1).

(6) C.I. Reactive Blue 21 [copper, (29*H*,31*H*-phthalocyaninato(2-)-N^{29}, N^{30}, N^{31}, N^{32})-, sulfo((4-((2-(sulfooxy)ethyl)sulfonyl)phenyl)amino)sulfonyl derivatives] (CAS Reg. No. 73049–92–0).

(b) *Uses and restrictions*. (1) The substances listed in paragraph (a) of this section may be used to color contact lenses in amounts not to exceed the minimum reasonably required to accomplish the intended coloring effect.

(2) As part of the manufacturing process, the lenses containing the color additives are thoroughly washed to remove unbound reactive dye.

(3) Authorization and compliance with this use shall not be construed as waiving any of the requirements of sections 510(k), 515, and 520(g) of the Federal Food, Drug, and Cosmetic Act (the act). A person intending to introduce a device containing a vinyl alcohol/methyl methacrylate-dye reaction product listed under this section into commerce shall submit to the Food and Drug Administration either a premarket notification in accordance with subpart E of part 807 of this chapter, if the device is not subject to premarket approval, or submit and receive approval of an original or supplemental premarket approval application if the device is subject to premarket approval.

(c) *Labeling*. The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Exemption from certification*. Certification of this color additive is not necessary for the protection of the public health, and therefore, this color additive is exempt from the certification requirements of section 721(c) of the act.

[58 FR 3227, Jan. 8, 1993, as amended at 58 FR 17510, Apr. 5, 1993]

§ 73.3128 Mica-based pearlescent pigments.

(a) *Identity and specifications*. The color additive is formed by depositing titanium or iron salts from a basic solution onto mica, followed by calcination to produce titanium dioxide or iron oxides on mica. Mica used to manufacture the color additive shall conform in identity and specifications to the requirements of § 73.1496(a)(1) and (b).

(b) *Uses and restrictions*. (1) Mica-based pearlescent pigments listed in paragraph (a) of this section may be used as a color additive in contact lenses in amounts not to exceed the minimum reasonably required to accomplish the intended coloring effect.

(2) Authorization and compliance with this use shall not be construed as waiving any of the requirements of sections 510(k), 515, and 520(g) of the Federal Food, Drug, and Cosmetic Act (the act) with respect to the contact lenses in which the additive is used.

(c) *Labeling*. The label of the color additive shall conform to the requirements in § 70.25 of this chapter.

(d) *Exemption from certification*. Certification of this color additive is not

necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 721(c) of the act.

[67 FR 65312, Oct. 24, 2002]

§ 73.3129 Disodium 1-amino-4-[[4-[(2-bromo-1-oxoallyl)amino]-2-sulfonatophenyl]amino]-9,10-dihydro-9,10-dioxoanthracene-2-sulfonate.

(a) *Identity*. The color additive is disodium 1-amino-4-[[4-[(2-bromo-1-oxoallyl)amino]-2-sulfonatophenyl]amino]-9,10-dihydro-9,10-dioxoanthracene-2-sulfonate (Reactive Blue 69) (CAS Reg. No. 70209–99–3, Colour Index No. 612037).

(b) *Uses and restrictions*. (1) The substance listed in paragraph (a) of this section may be used as a color additive in contact lenses in amounts not to exceed the minimum reasonably required to accomplish the intended coloring effect.

(2) Authorization and compliance with this use shall not be construed as waiving any of the requirements of sections 510(k), 515, and 520(g) of the Federal Food, Drug, and Cosmetic Act with respect to the contact lenses in which the additive is used.

(c) *Labeling*. The label of the color additive shall conform to the requirements in § 70.25 of this chapter.

(d) *Exemption from certification*. Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 721(c) of the Federal Food, Drug, and Cosmetic Act.

[76 FR 25235, May 4, 2011, as amended at 78 FR 14664, Mar. 7, 2013]

PART 74—LISTING OF COLOR ADDITIVES SUBJECT TO CERTIFICATION

Subpart A—Foods

Sec.
74.101 FD&C Blue No. 1.
74.102 FD&C Blue No. 2.
74.203 FD&C Green No. 3.
74.250 Orange B.
74.302 Citrus Red No. 2.
74.303 FD&C Red No. 3.
74.340 FD&C Red No. 40.
74.705 FD&C Yellow No. 5.
74.706 FD&C Yellow No. 6.

Subpart B—Drugs

74.1101 FD&C Blue No. 1.
74.1102 FD&C Blue No. 2.
74.1104 D&C Blue No. 4.
74.1109 D&C Blue No. 9.
74.1203 FD&C Green No. 3.
74.1205 D&C Green No. 5.
74.1206 D&C Green No. 6.
74.1208 D&C Green No. 8.
74.1254 D&C Orange No. 4.
74.1255 D&C Orange No. 5.
74.1260 D&C Orange No. 10.
74.1261 D&C Orange No. 11.
74.1303 FD&C Red No. 3.
74.1304 FD&C Red No. 4.
74.1306 D&C Red No. 6.
74.1307 D&C Red No. 7.
74.1317 D&C Red No. 17.
74.1321 D&C Red No. 21.
74.1322 D&C Red No. 22.
74.1327 D&C Red No. 27.
74.1328 D&C Red No. 28.
74.1330 D&C Red No. 30.
74.1331 D&C Red No. 31.
74.1333 D&C Red No. 33.
74.1334 D&C Red No. 34.
74.1336 D&C Red No. 36.
74.1339 D&C Red No. 39.
74.1340 FD&C Red No. 40.
74.1602 D&C Violet No. 2.
74.1705 FD&C Yellow No. 5.
74.1706 FD&C Yellow No. 6.
74.1707 D&C Yellow No. 7.
74.1707a Ext. D&C Yellow No. 7.
74.1708 D&C Yellow No. 8.
74.1710 D&C Yellow No. 10.
74.1711 D&C Yellow No. 11.

Subpart C—Cosmetics

74.2052 D&C Black No. 2.
74.2053 D&C Black No. 3.
74.2101 FD&C Blue No. 1.
74.2104 D&C Blue No. 4.
74.2151 D&C Brown No. 1.
74.2203 FD&C Green No. 3.
74.2205 D&C Green No. 5.
74.2206 D&C Green No. 6.
74.2208 D&C Green No. 8.
74.2254 D&C Orange No. 4.
74.2255 D&C Orange No. 5.
74.2260 D&C Orange No. 10.
74.2261 D&C Orange No. 11.
74.2304 FD&C Red No. 4.
74.2306 D&C Red No. 6.
74.2307 D&C Red No. 7.
74.2317 D&C Red No. 17.
74.2321 D&C Red No. 21.
74.2322 D&C Red No. 22.
74.2327 D&C Red No. 27.
74.2328 D&C Red No. 28.
74.2330 D&C Red No. 30.
74.2331 D&C Red No. 31.
74.2333 D&C Red No. 33.

74.2334 D&C Red No. 34.
74.2336 D&C Red No. 36.
74.2340 FD&C Red No. 40.
74.2602 D&C Violet No. 2.
74.2602a Ext. D&C Violet No. 2.
74.2705 FD&C Yellow No. 5.
74.2706 FD&C Yellow No. 6.
74.2707 D&C Yellow No. 7.
74.2707a Ext. D&C Yellow No. 7.
74.2708 D&C Yellow No. 8.
74.2710 D&C Yellow No. 10.
74.2711 D&C Yellow No. 11.

Subpart D—Medical Devices

74.3045 [Phthalocyaninato(2-)] copper.
74.3054 D&C Black No. 4.
74.3102 FD&C Blue No. 2.
74.3106 D&C Blue No. 6.
74.3206 D&C Green No. 6.
74.3230 D&C Red No. 17.
74.3602 D&C Violet No. 2.
74.3708 D&C Yellow No. 8.
74.3710 D&C Yellow No. 10.

AUTHORITY: 21 U.S.C. 321, 341, 342, 343, 348, 351, 352, 355, 361, 362, 371, 379e.

SOURCE: 42 FR 15654, Mar. 22, 1977, unless otherwise noted.

Subpart A—Foods

§ 74.101 FD&C Blue No. 1.

(a) *Identity*. (1) The color additive FD&C Blue No. 1 is principally the disodium salt of ethyl [4-[*p*-[ethyl (*m*-sulfobenzyl) amino]-α-(*o*-sulfophenyl) benzylidene] - 2,5 -cyclohexadien - 1 - ylidene] (*m*-sulfobenzyl) ammonium hydroxide inner salt with smaller amounts of the isomeric disodium salts of ethyl [4-[*p*-[ethyl(*p*-sulfobenzyl) amino]-α-(*o*-sulfophenyl) benzylidene]-2,5-cyclohexadien-1-ylidene] (*p*-sulfobenzyl) ammonium hydroxide inner salt and ethyl [4-[*p*-[ethyl (*o*-sulfobenzyl) amino] - α - (*o* -sulfophenyl) benzylidene]-2,5-cyclohexadien-1-ylidene] (*o*-sulfobenzyl) ammonium hydroxide inner salt.

(2) Color additive mixtures for food use (including dietary supplements) made with FD&C Blue No. 1 may contain only those diluents that are suitable and that are listed in part 73 of this chapter as safe for use in color additive mixtures for coloring foods.

(b) *Specifications*. FD&C Blue No. 1 shall conform to the following specifications and shall be free from impurities other than those named to the extent that such other impurities may be avoided by current good manufacturing practice:

Sum of volatile matter (at 135 °C) and chlorides and sulfates (calculated as sodium salts), not more than 15.0 percent.
Water-insoluble matter, not more than 0.2 percent.
Leuco base, not more than 5 percent.
Sum of *o*-, *m*-, and *p*-sulfobenzaldehydes, not more than 1.5 percent.
N-Ethyl,*N*-(*m*-sulfobenzyl)sulfanilic acid, not more than 0.3 percent.
Subsidiary colors, not more than 6.0 percent.
Chromium (as Cr), not more than 50 parts per million.
Manganese (as Mn), not more than 100 parts per million.
Arsenic (as As), not more than 3 parts per million.
Lead (as Pb), not more than 10 parts per million.
Total color, not less than 85.0 percent.

(c) *Uses and restrictions*. FD&C Blue No. 1 may be safely used for coloring foods (including dietary supplements) generally in amounts consistent with good manufacturing practice except that it may not be used to color foods for which standards of identity have been promulgated under section 401 of the act unless added color is authorized by such standards.

(d) *Labeling*. The label of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification*. All batches of FD&C Blue No. 1 shall be certified in accordance with regulations in part 80 of this chapter.

[42 FR 15654, Mar. 22, 1977, as amended at 58 FR 17511, Apr. 5, 1993]

§ 74.102 FD&C Blue No. 2.

(a) *Identity*. (1) The color additive FD&C Blue No. 2 is principally the disodium salt of 2-(1,3-dihydro-3-oxo-5-sulfo-2*H*-indol-2-ylidene)-2,3-dihydro-3-oxo-1*H*-indole-5-sulfonic acid (CAS Reg. No. 860–22–0) with smaller amounts of the disodium salt of 2-(1,3-dihydro-3-oxo-7-sulfo-2*H*-indol-2-ylidene)-2,3-dihydro-3-oxo-1*H*-indole-5-sulfonic acid (CAS Reg. No. 54947–75–0) and the sodium salt of 2-(1,3-dihydro-3-oxo-2*H*-indol-2-ylidene)-2,3-dihydro-3-oxo-1*H*-indole-5-sulfonic acid (CAS Reg. No. 605–18–5). Additionally, FD&C Blue No.

2 is obtained by heating indigo (or indigo paste) in the presence of sulfuric acid. The color additive is isolated and subjected to purification procedures. The indigo (or indigo paste) used above is manufactured by the fusion of *N*-phenylglycine (prepared from aniline and formaldehyde) in a molten mixture of sodamide and sodium and potassium hydroxides under ammonia pressure. The indigo is isolated and subjected to purification procedures prior to sulfonation.

(2) Color additive mixtures for food use (including dietary supplements) made with FD&C Blue No. 2 may contain only those diluents that are suitable and that are listed in part 73 of this chapter as safe for use in color additive mixtures for coloring foods.

(b) *Specifications*. The color additive FD&C Blue No. 2 shall conform to the following specifications and shall be free from impurities other than those named to the extent that such other impurities may be avoided by current good manufacturing practice:

Sum of volatile matter at 135 °C (275 °F) and chlorides and sulfates (calculated as sodium salts), not more than 15 percent.

Water insoluble matter, not more than 0.4 percent.

Isatin-5-sulfonic acid, not more than 0.4 percent.

5-Sulfoanthranilic acid, not more than 0.2 percent.

Disodium salt of 2-(1,3-dihydro-3-oxo-7-sulfo-2*H*-indol-2-ylidene)-2,3-dihydro-3-oxo-1*H*-indole-5-sulfonic acid, not more than 18 percent.

Sodium salt of 2-(1,3-dihydro-3-oxo-2*H*-indol-2-ylidene)-2,3-dihydro-3-oxo-1*H*-indole-5-sulfonic acid, not more than 2 percent.

Lead (as Pb), not more than 10 parts per million.

Arsenic (as As), not more than 3 parts per million.

Mercury (as Hg), not more than 1 part per million.

Total color, not less than 85 percent.

(c) *Uses and restrictions*. The color additive FD&C Blue No. 2 may be safely used for coloring foods (including dietary supplements) generally in amounts consistent with current good manufacturing practice except that it may not be used to color foods for which standards of identity have been promulgated under section 401 of the Federal Food, Drug, and Cosmetic Act unless added color is authorized by such standards.

(d) *Labeling*. The label of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification*. All batches of FD&C Blue No. 2 shall be certified in accordance with regulations in part 80 of this chapter.

[48 FR 5260, Feb. 4, 1983]

§ 74.203 FD&C Green No. 3.

(a) *Identity*. (1) The color additive FD&C Green No. 3 is principally the inner salt disodium salt of *N*-ethyl-*N*-[4-[[4-[ethyl[(3-sulfophenyl)methyl]amino]phenyl](4-hydroxy-2-sulfophenyl)methylene]-2,5-cyclohexadien-1-ylidene]-3-sulfobenzenemethanaminium hydroxide (CAS Reg. No. 2353–45–9); with smaller amounts of the isomeric inner salt disodium salt of *N*-ethyl-*N*-[4-[[4-[ethyl[(3-sulfophenyl)methyl] amino]phenyl](4-hydroxy-2-sulfophenyl)methylene]-2,5-cyclohexadien-1-ylidene]-4-sulfobenzenemethanaminium hydroxide; of *N*-ethyl-*N*-[4-[[4-[ethyl[(4-sulfophenyl)methyl]amino]phenyl](4-hydroxy-2-sulfophenyl)methylene]-2,5-cyclohexadien-1-ylidene]-4-sulfobenzenemethanaminium hydroxide and of *N*-ethyl-*N*-[4-[[4-[ethyl[(2-sulfophenyl)methyl]amino]phenyl](4-hydroxy-2-sulfophenyl)methylene]-2,5-cyclohexadien-1-ylidene]-3-sulfobenzenemethanaminium hydroxide. Additionally, FD&C Green No. 3 is manufactured by the acid catalyzed condensation of one molecule of 2-formyl-5-hydroxybenzenesulfonic acid with two molecules from a mixture consisting principally of 3-[(ethylphenylamino)methyl]

benzensulfonic acid, and smaller amounts of 4-[(ethylphenylamino)methyl]

benzenesulfonic acid and 2-[(ethylphenylamino)methyl]

benzenesulfonic acid to form the leuco base. The leuco base is then oxidized with lead dioxide and acid or with dichromate and acid to form the dye. The intermediate 2-formyl-5-

hydroxybenzenesulfonic acid is prepared by the potassium permanganate oxidation of 2,2′-(1,2-ethenediyl)-bis(5-aminobenzenesulfonic acid) to sodium 5-amino-2-formylbenzenesulfonate. This amine is diazotized and the resulting diazonium salt is hydrolyzed to the desired 2-formyl-5-hydroxybenzenesulfonic acid.

(2) Color additive mixtures for food use (including dietary supplements) made with FD&C Green No. 3 may contain only those diluents that are suitable and that are listed in part 73 of this chapter as safe for use in color additive mixtures for coloring food.

(b) *Specifications*. The color additive FD&C Green No. 3 shall conform to the following specifications and shall be free from impurities other than those named to the extent that such other impurities may be avoided by current good manufacturing practice:

Sum of volatile matter at 135 °C (275 °F) and chlorides and sulfates (calculated as sodium salts), not more than 15 percent.
Water-insoluble matter, not more than 0.2 percent.
Leuco base, not more than 5 percent.
Sum of 2-,3-,4-formylbenzenesulfonic acids, sodium salts, not more than 0.5 percent.
Sum of 3- and 4-[[ethyl(4-sulfophenyl)amino]methyl] benzenesulfonic acid, disodium salts, not more than 0.3 percent.
2-Formyl-5-hydroxybenzenesulfonic acid, sodium salt, not more than 0.5 percent.
Subsidiary colors, not more than 6 percent.
Chromium (as Cr), not more than 50 parts per million.
Arsenic (as As), not more than 3 parts per million.
Lead (as Pb), not more than 10 parts per million.
Mercury (as Hg), not more than 1 part per million.
Total color, not less than 85 percent.

(c) *Uses and restrictions*. The color additive FD&C Green No. 3 may be safely used for coloring foods (including dietary supplements) generally in amounts consistent with current good manufacturing practice except that it may not be used to color foods for which standards of identity have been promulgated under section 401 of the act unless added color is authorized by such standards.

(d) *Labeling*. The label of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification*. All batches of FD&C Green No. 3 shall be certified in accordance with regulations in part 80 of this chapter.

[47 FR 52143, Nov. 19, 1982; 47 FR 56489, Dec. 17, 1982]

§ 74.250 Orange B.

(a) *Identity*. (1) The color additive Orange B is principally the disodium salt of 1-(4-sulfophenyl)-3-ethylcarboxy-4-(4-sulfonaphthylazo)-5-hydro-xypyrazole.

(2) The diluents in color additive mixtures for food use containing Orange B are limited to those listed in part 73 of this chapter as safe and suitable in color additive mixtures for coloring foods.

(b) *Specifications*. Orange B shall conform to the following specifications:

Volatile matter (at 135 °C.), not more than 6.0 percent.
Chlorides and sulfates (calculated as the sodium salts), not more than 7.0 percent.
Water insoluble matter, not more than 0.2 percent.
1-(4-Sulfophenyl)-3-ethylcarboxy-5-hydroxypyrazolone and 1-(4-sulfophenyl)-3-carboxy-5-hydroxypyrazolone, not more than 0.7 percent.
Naphthionic acid, not more than 0.2 percent.
Phenylhydrazine-*p*-sulfonic acid, not more than 0.2 percent.
The trisodium salt of 1-(4-sulfophenyl)-3-carboxy-4-(4-sulfonaphthylazo)-5-hydroxypyrazole, not more than 6.0 percent.
Other subsidiary dyes, not more than 1.0 percent.
Lead (as Pb), not more than 10 parts per million.
Arsenic (as As), not more than 1 part per million.
Total color, not less than 87.0 percent.

(c) *Uses and restrictions*. Orange B may be safely used for coloring the casings or surfaces of frankfurters and sausages subject to the restriction that the quantity of the color additive does not exceed 150 parts per million by weight of the finished food.

(d) *Labeling requirements*. The label of the color additive and any mixtures intended solely or in part for coloring purposes prepared therefrom shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification*. All batches of Orange B shall be certified in accordance with

regulations promulgated under part 80 of this chapter.

§ 74.302 Citrus Red No. 2.

(a) *Identity*. (1) The color additive Citrus Red No. 2 is principally 1–(2,5–dimethoxyphenylazo)-2-naphthol.

(2) The following diluents may be used in aqueous suspension, in the percentages specified, to facilitate application to oranges in accordance with paragraph (c)(1) of this section:

(i) Suitable diluents used in accordance with § 73.1(a) of this chapter.

(ii) Volatile solvents that leave no residue after application to the orange.

(iii) Salts of fatty acids meeting the requirements of § 172.863 of this chapter.

(iv) Sodium tripolyphosphate, not more than 0.05 percent.

(b) *Specifications*. Citrus Red No. 2 shall conform to the following specifications and shall be free from impurities, other than those named, to the extent that such other impurities may be avoided by good manufacturing practice:

Volatile matter (at 100 °C.), not more than 0.5 percent.
Water-soluble matter, not more than 0.3 percent.
Matter insoluble in carbon tetrachloride, not more than 0.5 percent.
Uncombined intermediates, not more than 0.05 percent.
Subsidiary dyes, not more than 2.0 percent.
Lead (as Pb), not more than 10 parts per million.
Arsenic (as As), not more than 1 part per million.
Total color, not less than 98 percent.

(c) *Uses and restrictions*. (1) Citrus Red No. 2 shall be used only for coloring the skins of oranges that are not intended or used for processing (or if so used are designated in the trade as *Packinghouse elimination*) and that meet minimum maturity standards established by or under the laws of the States in which the oranges are grown.

(2) Oranges colored with Citrus Red No. 2 shall bear not more than 2.0 parts per million of such color additive, calculated on the basis of the weight of the whole fruit.

(d) *Labeling*. The label of the color additive and any mixtures prepared therefrom and intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter. To meet the requirements of § 70.25 (b) and (c) of this chapter the label shall bear:

(1) The statement (or its equivalent) ''To be used only for coloring skins of oranges.''

(2) Directions for use to limit the amount of the color additive to not more than 2.0 parts per million, calculated on the basis of the weight of the whole fruit.

(e) *Certification*. All batches of Citrus Red No. 2 shall be certified in accordance with regulations in part 80 of this chapter.

§ 74.303 FD&C Red No. 3.

(a) *Identity*. (1) The color additive FD&C Red No. 3 is principally the monohydrate of 9 (*o*- carboxyphenyl)-6-hydroxy - 2,4,5,7-tetraiodo-3H-xanthen-3-one, disodium salt, with smaller amounts of lower imdinated fluoresceins.

(2) Color additive mixtures for food use made with FD&C Red No. 3 may contain only those diluents that are suitable and that are listed in part 73 of this chapter as safe for use in color additive mixtures for coloring foods.

(b) *Specifications*. FD&C Red No. 3 shall conform to the following specifications and shall be free from impurities other than those named to the extent that such other impurities may be avoided by good manufacturing practice:

Volatile matter (at 135 °C.) and chlorides and sulfates (calculated as the sodium salts), total not more than 13 percent.
Water-insoluble matter, not more than 0.2 percent.
Unhalogenated intermediates, total not more than 0.1 percent.
Sodium iodide, not more than 0.4 percent.
Triiodoresorcinol, not more than 0.2 percent.
2(2′,4′-Dihydroxy-3′, 5′-diiodobenzoyl) benzoic acid, not more than 0.2 percent.
Monoiodofluoresceins not more than 1.0 percent.
Other lower iodinated fluoresceins, not more than 9.0 percent.
Lead (as Pb), not more than 10 parts per million.
Arsenic (as As), not more than 3 parts per million.
Total color, not less than 87.0 percent.

(c) *Uses and restrictions*. FD&C Red No. 3 may be safely used for coloring

foods generally (including dietary supplements) in amounts consistent with good manufacturing practice except that it may not be used to color foods for which standards of identity have been promulgated under section 401 of the act unless added color is authorized by such standards.

(d) *Labeling*. The label of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification*. All batches of FD&C Red No. 3 shall be certified in accordance with regulations in part 80 of this chapter.

§ 74.340 FD&C Red No. 40.

(a) *Identity*. (1) The color additive FD&C Red No. 40 is principally the disodium salt of 6-hydroxy-5-[(2-methoxy-5-methyl-4-sulfophenyl)azo]-2-naphthalenesulfonic acid.

(2) Color additive mixtures for food use (including dietary supplements) made with FD&C Red No. 40 may contain only those diluents that are suitable and that are listed in part 73 of this chapter as safe for use in color additive mixtures for coloring foods.

(3) The listing of this color additive includes lakes prepared as described in § 82.51 of this chapter, except that the color additive used is FD&C Red No. 40 and the resultant lakes meet the specification and labeling requirements prescribed by § 82.51 of this chapter.

(b) *Specifications*. FD&C Red No. 40 shall conform to the following specifications and shall be free from impurities other than those named to the extent that such other impurities may be avoided by good manufacturing practice:

Sum of volatile matter (at 135 °C.) and chlorides and sulfates (calculated as sodium salts), not more than 14.0 percent.

Water-insoluble matter, not more than 0.2 percent.

Higher sulfonated subsidiary colors (as sodium salts), not more than 1.0 percent.

Lower sulfonated subsidiary colors (as sodium salts), not more than 1.0 percent.

Disodium salt of 6-hydroxy-5-[(2-methoxy-5-methyl-4-sulfophenyl) azo] -8-(2-methoxy-5-methyl-4-sulfophenoxy)-2-naphthalenesulfonic acid, not more than 1.0 percent.

Sodium salt of 6-hydroxy-2-naphthalenesulfonic acid (Schaeffer's salt), not more than 0.3 percent.

4-Amino-5-methoxy-*o*- toluenesulfonic acid, not more than 0.2 percent.

Disodium salt of 6,6′-oxybis (2-naphthalenesulfonic acid), not more than 1.0 percent.

Lead (as Pb), not more than 10 parts per million.

Arsenic (as As), not more than 3 parts per million.

Total color, not less than 85.0 percent.

(c) *Uses and restrictions*. FD&C Red No. 40 may be safely used for coloring foods (including dietary supplements) generally in amounts consistent with good manufacturing practice except that it may not be used to color foods for which standards of identity have been promulgated under section 401 of the act unless added color is authorized by such standards.

(d) *Labeling*. The label of the color additive and any lakes or mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification*. All batches of FD&C Red No. 40 and lakes thereof shall be certified in accordance with regulations in part 80 of this chapter.

§ 74.705 FD&C Yellow No. 5.

(a) *Identity*. (1) The color additive FD&C Yellow No. 5 is principally the trisodium salt of 4,5-dihydro-5-oxo-1-(4-sulfophenyl)-4-[4-sulfophenyl-azo]-1*H*-pyrazole-3-carboxylic acid (CAS Reg. No. 1934–21–0). To manufacture the additive, 4-amino-benzenesulfonic acid is diazotized using hydrochloric acid and sodium nitrite. The diazo compound is coupled with 4,5-dihydro-5-oxo-1-(4-sulfophenyl)-1*H*-pyrazole-3-carboxylic acid or with the methyl ester, the ethyl ester, or a salt of this carboxylic acid. The resulting dye is purified and isolated as the sodium salt.

(2) Color additive mixtures for food use made with FD&C Yellow No. 5 may contain only those diluents that are suitable and that are listed in part 73 of this chapter as safe for use in color additive mixtures for coloring foods.

(b) *Specifications*. FD&C Yellow No. 5 shall conform to the following specifications and shall be free from impurities other than those named to the extent that such other impurities may be

avoided by good manufacturing practice:

Sum of volatile matter at 135 °C (275 °F) and chlorides and sulfates (calculated as sodium salts), not more than 13 percent.

Water-insoluble matter, not more than 0.2 percent.

4,4′-[4,5-Dihydro-5-oxo-4-[(4-sulfophenyl)hydrazono]-1*H*-pyrazol-1,3-diyl]bis[benzenesulfonic acid], trisodium salt, not more than 1 percent.

4-[(4′,5-Disulfo[1,1′-biphenyl]-2-yl)hydrazono]-4,5-dihydro-5-oxo-1-(4-sulfophenyl)-1*H*-pyrazole-3-carboxylic acid, tetrasodium salt, not more than 1 percent.

Ethyl or methyl 4,5-dihydro-5-oxo-1-(4-sulfophenyl)-4-[(4-sulfophenyl)hydrazono]-1*H*-pyrazole-3-carboxylate, disodium salt, not more than 1 percent.

Sum of 4,5-dihydro-5-oxo-1-phenyl-4-[(4-sulfophenyl)azo]-1*H*-pyrazole-3-carboxylic acid, disodium salt, and 4,5-dihydro-5-oxo-4-(phenylazo)-1-(4-sulfophenyl)-1*H*-pyrazole-3-carboxylic acid, disodium salt, not more than 0.5 percent.

4-Aminobenzenesulfonic acid, sodium salt, not more than 0.2 percent.

4,5-Dihydro-5-oxo-1-(4-sulfophenyl)-1*H*-pyrazole-3-carboxylic acid, disodium salt, not more than 0.2 percent.

Ethyl or methyl 4,5-dihydro-5-oxo-1-(4-sulfophenyl)-1*H*-pyrazole-3-carboxylate, sodium salt, not more than 0.1 percent.

4,4′-(1-Triazene-1,3-diyl)bis[benzenesulfonic acid], disodium salt, not more than 0.05 percent.

4-Aminoazobenzene, not more than 75 parts per billion.

4-Aminobiphenyl, not more than 5 parts per billion.

Aniline, not more than 100 parts per billion.

Azobenzene, not more than 40 parts per billion.

Benzidine, not more than 1 part per billion.

1,3-Diphenyltriazene, not more than 40 parts per billion.

Lead (as Pb), not more than 10 parts per million.

Arsenic (as As), not more than 3 parts per million.

Mercury (as Hg), not more than 1 part per million.

Total color, not less than 87 percent.

(c) *Uses and restrictions.* FD&C Yellow No. 5 may be safely used for coloring foods (including dietary supplements) generally in amounts consistent with good manufacturing practice, except that it may not be used to color foods for which standards of identity have been promulgated under section 401 of the act unless added color is authorized by such standards.

(d) *Labeling requirements.* (1) The label of the color additive and any mixtures intended solely or in part for coloring purposes prepared therefrom shall conform to the requirements of § 70.25 of this chapter.

(2) Foods for human use that contain FD&C Yellow No. 5, including butter, cheese, and ice cream, shall specifically declare the presence of FD&C Yellow No. 5 by listing the color additive as FD&C Yellow No. 5 among the list of ingredients.

(e) *Certification.* All batches of FD&C Yellow No. 5 shall be certified in accordance with regulations in part 80 of this chapter.

[42 FR 15654, Mar. 22, 1977; 44 FR 17658, Mar. 23, 1979, as amended at 44 FR 37220, June 26, 1979; 51 FR 24519, July 7, 1986]

§ 74.706 FD&C Yellow No. 6.

(a) *Identity.* (1) The color additive FD&C Yellow No. 6 is principally the disodium salt of 6-hydroxy-5-[(4-sulfophenyl)azo]-2-naphthalenesulfonic acid (CAS Reg. No. 2783–94–0). The trisodium salt of 3-hydroxy-4-[(4-sulfophenyl)azo]-2,7-naphthalenedisulfonic acid (CAS Reg. No. 50880–65–4) may be added in small amounts. The color additive is manufactured by diazotizing 4-aminobenzenesulfonic acid using hydrochloric acid and sodium nitrite or sulfuric acid and sodium nitrite. The diazo compound is coupled with 6-hydroxy-2-naphthalene-sulfonic acid. The dye is isolated as the sodium salt and dried. The trisodium salt of 3-hydroxy-4-[(4-sulfophenyl)azo]-2,7-naphthalenedisulfonic acid which may be blended with the principal color is prepared in the same manner except the diazo benzenesulfonic acid is coupled with 3-hydroxy-2,7-naphthalenedisulfonic acid.

(2) Color additive mixtures for food use made with FD&C Yellow No. 6 may contain only those diluents that are suitable and that are listed in part 73 of this chapter as safe for use in color additive mixtures for coloring foods.

(b) *Specifications.* The color additive FD&C Yellow No. 6 shall conform to the following specifications and shall be free from impurities other than those named to the extent that such

other impurities may be avoided by current good manufacturing practice:

Sum of volatile matter (at 135 °C) and chlorides and sulfates (calculated as sodium salts), not more than 13 percent.
Water insoluble matter, not more than 0.2 percent.
Sodium salt of 4-aminobenzenesulfonic acid, not more than 0.2 percent.
Sodium salt of 6-hydroxy-2-naphthalenesulfonic acid, not more than 0.3 percent.
Disodium salt of 6,6′-oxybis[2-naphthalenesulfonic acid], not more than 1 percent.
Disodium salt of 4,4′-(1-triazene-1,3-diyl)bis[benzenesulfonic acid], not more than 0.1 percent.
Sum of the sodium salt of 6-hydroxy-5-(phenylazo)-2-naphthalenesulfonic acid and the sodium salt of 4-[(2-hydroxy-1-naphthalenyl)azo]benzenesulfonic acid, not more than 1 percent.
Sum of the trisodium salt of 3-hydroxy-4-[(4-sulfophenyl)azo]-2,7-naphthalenedisulfonic acid and other higher sulfonated subsidiaries, not more than 5 percent.
4-Aminoazobenzene, not more than 50 parts per billion.
4-Aminobiphenyl, not more than 15 parts per billion.
Aniline, not more than 250 parts per billion.
Azobenzene, not more than 200 parts per billion.
Benzidine, not more than 1 part per billion.
1,3-Diphenyltriazene, not more than 40 parts per billion.
1-(Phenylazo)-2-naphthalenol, not more than 10 parts per million.
Lead (as Pb), not more than 10 parts per million.
Arsenic (as As), not more than 3 parts per million.
Mercury (as Hg), not more than 1 part per million.
Total color, not less than 87 percent.

(c) *Uses and restrictions.* The color additive FD&C Yellow No. 6 may be safely used for coloring foods (including dietary supplements) generally in amounts consistent with current good manufacturing practice, except that it may not be used to color foods for which standards of identity have been promulgated under section 401 of the act unless added color is authorized by such standards.

(d) *Labeling requirements.* (1) The label of the color additive and any mixtures intended solely or in part for coloring purposes prepared therefrom shall conform to the requirements of § 70.25 of this chapter.

(2) [Reserved]

(e) *Certification.* All batches of FD&C Yellow No. 6 shall be certified in accordance with regulations in part 80 of this chapter.

[51 FR 41782, Nov. 19, 1986, as amended at 52 FR 21508, June 8, 1987; 53 FR 49138, Dec. 6, 1988]

Subpart B—Drugs

§ 74.1101 FD&C Blue No. 1

(a) *Identity.* (1) For ingested drugs, the color additive FD&C Blue No. 1 shall conform in identity to the requirements of § 74.101(a)(1).

(2) For externally applied drugs, the color additive FD&C Blue No. 1 shall conform in identity to the requirements of § 74.2101(a).

(3) Color additive mixtures for drug use made with FD&C Blue No. 1 may contain only those diluents that are suitable and that are listed in part 73 of this chapter as safe for use in color additive mixtures for coloring drugs.

(b) *Specifications.* (1) The color additive FD&C Blue No. 1 for use in coloring drugs generally shall conform in specifications to the requirements of § 74.101(b).

(2) FD&C Blue No. 1 Aluminum Lake shall be prepared in accordance with the requirements of § 82.51 of this chapter.

(c) *Uses and restrictions.* (1) FD&C Blue No. 1 may be safely used for coloring drugs, including drugs intended for use in the area of the eye, in amounts consistent with current good manufacturing practice.

(2) FD&C Blue No. 1 Aluminum Lake may be safely used for coloring drugs intended for use in the area of the eye, in amounts consistent with current good manufacturing practice, subject to the restrictions on the use of color additives in § 70.5(b) and (c) of this chapter.

(d) *Labeling.* The label of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification*. All batches of FD&C Blue No. 1 shall be certified in accordance with regulations in part 80 of this chapter.

[47 FR 42565, Sept. 28, 1982, as amended at 59 FR 7638, Feb. 16, 1994]

§ 74.1102 FD&C Blue No. 2.

(a) *Identity*. (1) The color additive FD&C Blue No. 2 shall conform in identity to the requirements of § 74.102(a)(1).

(2) Color additive mixtures for use in ingested drugs made with FD&C Blue No. 2 may contain only those diluents that are suitable and that are listed in part 73 of this chapter as safe for use in color additive mixtures for coloring drugs.

(b) The color additive FD&C Blue No. 2 for use in coloring ingested drugs shall conform to the specifications in § 74.102(b).

(c) The color additive FD&C Blue No. 2 may be safely used for coloring ingested drugs in amounts consistent with current good manufacturing practice.

(d) *Labeling*. The label of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification*. All batches of FD&C Blue No. 2 shall be certified in accordance with regulations in part 80 of this chapter.

[48 FR 5260, Feb. 4, 1983, as amended at 49 FR 10090, Mar. 19, 1984; 64 FR 48290, Sept. 3, 1999]

§ 74.1104 D&C Blue No. 4.

(a) *Identity*. (1) The color additive D&C Blue No. 4 is principally the diammonium salt of ethyl[4-[*p*[ethyl(*m*-sulfobenzyl)ami-no]-α-(*o*-sulfophenyl)benzylidene]-2,5-cyclohexadien-1-ylidene] (*m*- sulfobenzyl) ammonium hydroxide inner salt with smaller amounts of the isomeric diammonium salts of ethyl [4-[*p*-[ethyl(*p*- sulfobenzyl) amino]-α-(*o*-sulfophenyl) benzylidene]-2,5-cyclohexadien - 1-ylidene](*p*-sulfobenzyl) ammonium hydroxide inner salt and ethyl[4-[*p*-[ethyl (*o*-sulfobenzyl)amino]-α-(*o*- sulfophenyl) benzylidene]-2,5-cyclohexadien-1-ylidene] (*o*- sulfobenzyl) ammonium hydroxide inner salt.

(2) Color additive mixtures for use in externally applied drugs made with D&C Blue No. 4 may contain only those diluents that are suitable and that are listed in part 73 of this chapter for use in color additive mixtures for coloring externally applied drugs.

(b) *Specifications*. D&C Blue No. 4 shall conform to the following specifications and shall be free from impurities other than those named to the extent that such impurities may be avoided by good manufacturing practice:

Sum of volatile matter (at 135 °C) and chlorides and sulfates (calculated as sodium salts), not more than 15 percent.
Water-insoluble matter, not more than 0.2 percent.
Leuco base, not more than 5 percent.
Sum of *o*-, *m*, and *p*- sulfobenzaldehydes, ammonium salt, not more than 1.5 percent.
N-ethyl, N-(*m*- sulfobenzyl) sulfanilic acid ammonium salt, not more than 0.3 percent.
Subsidiary colors, not more than 6 percent.
Chromium (as Cr), not more than 50 parts per million.
Lead (as Pb), not more than 20 parts per million.
Arsenic (as As), not more than 3 parts per million.
Mercury (as Hg), not more than 1 part per million.
Total color, not less than 85 percent.

(c) *Uses and restrictions*. D&C Blue No. 4 may be safely used in externally applied drugs in amounts consistent with good manufacturing practice.

(d) *Labeling*. The label of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification*. All batches of D&C Blue No. 4 shall be certified in accordance with regulations in part 80 of this chapter.

§ 74.1109 D&C Blue No. 9.

(a) *Identity*. The color additive D&C Blue No. 9 is principally 7,16-dichloro-6,15 - dihydro - 5,9,14,18 - anthrazinetetrone.

(b) *Specifications*. D&C Blue No. 9 shall conform to the following specifications and shall be free from impurities other than those named to the extent that such impurities may be

avoided by good manufacturing practice:

Volatile matter (at 135 °C.), not more than 3 percent.
Matter extractable by alcoholic HCl (0.1 ml of concentrated hydrochloric acid per 50 ml of 95 percent ethyl alcohol), not more than 1 percent.
2-Amino anthraquinone, not more than 0.2 percent.
Organically combined chlorine in pure dye, 13.0–14.8 percent.
Lead (as Pb), not more than 20 p/m.
Arsenic (as As), not more than 3 p/m.
Total color, not less than 97 percent.

(c) *Uses and restrictions.* D&C Blue No. 9 may be safely used for coloring cotton and silk surgical sutures, including sutures for ophthalmic use, subject to the following restrictions:

(1) The dyed suture shall conform in all respects to the requirements of the United States Pharmacopeia XX (1980).

(2) The quantity of the color additive does not exceed 2.5 percent by weight of the suture.

(3) When the sutures are used for the purposes specified in their labeling, the color additive does not migrate to the surrounding tissue.

(4) If the suture is a new drug, a new-drug application approved pursuant to section 505 of the act is in effect for it.

(d) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification.* All batches of D&C Blue No. 9 shall be certified in accordance with regulations in part 80 of this chapter.

[42 FR 15654, Mar. 22, 1977, as amended at 49 FR 10090, Mar. 19, 1984; 58 FR 17098, Apr. 1, 1993]

§ 74.1203 FD&C Green No. 3.

(a) *Identity and specifications.* (1) The color additive FD&C Green No. 3 shall conform in identity and specifications to the requirements of § 74.203(a)(1) and (b).

(2) Color additive mixtures for drug use made with FD&C Green No. 3 may contain only those diluents that are suitable and that are listed in part 73 of this chapter as safe for use in color additive mixtures for coloring drugs.

(b) *Uses and restrictions.* The color additive FD&C Green No. 3 may be safely used for coloring drugs generally in amounts consistent with current good manufacturing practice.

(c) *Labeling.* The label of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(d) *Certification.* All batches of FD&C Green No. 3 shall be certified in accordance with regulations in part 80 of this chapter.

[47 FR 52144, Nov. 19, 1982]

§ 74.1205 D&C Green No. 5.

(a) *Identity.* (1) The color additive D&C Green No. 5 is principally the disodium salt of 2,2′-[(9,10-dihydro-9,10-dioxo-1,4-anthracenediyl)diimino]bis-[5-methylbenzenesulfonic acid] (CAS Reg. No. 4403–90–1).

(2) Color additive mixtures for use in drugs made with D&C Green No. 5 may contain only those diluents that are suitable and those that are listed in part 73 of this chapter for use in color additive mixtures for coloring drugs.

(b) *Specifications.* (1) D&C Green No. 5 for use in coloring surgical sutures shall conform to the following specifications and shall be free from impurities other than those named to the extent that such impurities may be avoided by current good manufacturing practice:

Sum of volatile matter (at 135 °C) and chlorides and sulfates (calculated as sodium salts), not more than 20 percent.
Water insoluble matter, not more than 0.2 percent.
1,4-Dihydroxyanthraquinone, not more than 0.2 percent.
2-Amino-*m*-toluenesulfonic acid, not more than 0.2 percent.
Subsidiary colors, not more than 5 percent.
Lead (as Pb), not more than 10 parts per million.
Arsenic (as As), not more than 3 parts per million.
Total color, not less than 80 percent.

(2) D&C Green No. 5 for use in coloring drugs shall conform to the following specifications and shall be free from impurities other than those named to the extent that such other impurities may be avoided by current good manufacturing practice:

Sum of volatile matter (at 135 °C) and chlorides and sulfates (calculated as sodium salts), not more than 20 percent.

Water-insoluble matter, not more than 0.2 percent.
1,4-Dihydroxyanthraquinone, not more than 0.2 percent.
Sulfonated toluidines, total not more than 0.2 percent.
p-Toluidine, not more than 0.0015 percent.
Sum of monosulfonated D&C Green No. 6 and Ext. D&C Violet No. 2, not more than 3 percent.
Lead (as Pb), not more than 20 parts per million.
Arsenic (as As), not more than 3 parts per million.
Mercury (as Hg), not more than 1 part per million.
Total color, not less than 80 percent.

(c) *Use and restrictions.* (1) D&C Green No. 5 may be safely used to color nylon 66 (the copolymer of adipic acid and hexamethylenediamine) and/or nylon 6[poly-(*e*-caprolactam)]nonabsorbable surgical sutures for use in general surgery, subject to the following restrictions:

(i) The quantity of color additive does not exceed 0.6 percent by weight of the suture.

(ii) When the sutures are used for the purposes specified in their labeling, there is no migration of the color additive to the surrounding tissue.

(iii) If the suture is a new drug, an approved new drug application, under section 505 of the act, is in effect for it.

(2) D&C Green No. 5 may be safely used for coloring drugs generally, including drugs intended for use in the area of the eye, in amounts consistent with current good manufacturing practice.

(d) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification.* All batches of D&C Green No. 5 shall be certified in accordance with regulations in part 80 of this chapter.

[47 FR 24284, June 4, 1982; 47 FR 27551, June 25, 1982, as amended at 59 FR 40805, Aug. 10, 1994]

§ 74.1206 D&C Green No. 6.

(a) *Identity.* The color additive D&C Green No. 6 is 1,4-bis[(4-methylphenyl)amino]-9,10-anthracenedione (CAS. Reg. No. 128–80–3).

(b) *Specifications.* The color additive D&C Green No. 6 for use in coloring externally applied drugs shall conform to the following specifications and shall be free from impurities other than those named to the extent that such other impurities may be avoided by current good manufacturing practice:

Volatile matter (at 135 °C), not more than 2.0 percent.
Water-soluble matter, not more than 0.3 percent.
Matter insoluble in carbon tetrachloride, not more than 1.5 percent.
p-Toluidine, not more than 0.1 percent.
1,4-Dihydroxyanthraquinone, not more than 0.2 percent.
1-Hydroxy-4-[(4-methylphenyl)amino]-9, 10-anthracenedione, not more than 5.0 percent.
Lead (as Pb), not more than 20 parts per million.
Arsenic (as As), not more than 3 parts per million.
Mercury (as Hg), not more than 1 part per million.
Total color, not less than 96.0 percent.

(c) *Uses and restrictions.* The color additive D&C Green No. 6 may be safely used for coloring externally applied drugs in amounts consistent with current good manufacturing practice.

(d) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification.* All batches of D&C Green No. 6 shall be certified in accordance with regulations promulgated under part 80 of this chapter.

[42 FR 15654, Mar. 22, 1977, as amended at 47 FR 14146, Apr. 2, 1982; 47 FR 24278, June 4, 1982; 51 FR 9784, Mar. 21, 1986]

§ 74.1208 D&C Green No. 8.

(a) *Identity.* (1) The color additive D&C Green No. 8 is principally the trisodium salt of 8-hydroxy-1,3,6-pyrenetrisulfonic acid.

(2) Color additive mixtures for use in externally applied drugs made with D&C Green No. 8 may contain only those diluents that are suitable and that are listed in part 73 of this chapter for use in color additive mixtures for coloring externally applied drugs.

(b) *Specifications.* D&C Green No. 8 shall conform to the following specifications and shall be free from impurities other than those named to the extent that such impurities may be avoided by good manufacturing practices:

Volatile matter (at 135 °C), not more than 15 percent.
Water-insoluble matter, not more than 0.2 percent.
Chlorides and sulfates (calculated as sodium salt), not more than 20 percent.
The trisodium salt of 1,3,6-pyrenetrisulfonic acid, not more than 6 percent.
The tetrasodium salt of 1,3,6,8-pyrenetetrasulfonic acid, not more than 1 percent.
Pyrene, not more than 0.2 percent.
Lead (as Pb), not more than 20 parts per million.
Arsenic (as As), not more than 3 parts per million.
Mercury (as Hg), not more than 1 part per million.
Total color, not less than 65 percent.

(c) *Uses and restrictions*. D&C Green No. 8 may be safely used in externally applied drugs in amounts not exceeding 0.01 percent by weight of the finished product.

(d) *Labeling*. The label of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification*. All batches of D&C Green No. 8 shall be certified in accordance with regulations in part 80 of this chapter.

§ 74.1254 D&C Orange No. 4.

(a) *Identity*. (1) the color additive D&C Orange No. 4 is principally the sodium salt of 4-[(2-hydroxy-1-naphthalenyl)azo]benzenesulfonic acid.

(2) Color additive mixtures for use in externally applied drugs made with D&C Orange No. 4 may contain only those diluents that are suitable and that are listed in part 73 of this chapter for use in color additive mixtures for coloring externally applied drugs.

(b) *Specifications*. D&C Orange No. 4 shall conform to the following specifications and shall be free from impurities other than those named to the extent that such impurities may be avoided by good manufacturing practice.

Sum of volatile matter (at 135 °C) and chlorides and sulfates (calculated as sodium salts), not more than 13 percent.
Water-insoluble matter, not more than 0.2 percent.
2-Naphthol, not more than 0.4 percent.
Sulfanilic acid, sodium salt, not more than 0.2 percent.
Subsidiary colors, not more than 3 percent.
4,4′-(Diazoamino)-dibenzenesulfonic acid, not more than 0.1 percent.
Lead (as Pb), not more than 20 parts per million.
Arsenic (as As), not more than 3 parts per million.
Mercury (as Hg), not more than 1 part per million.
Total color, not less than 87 percent.

(c) *Uses and restrictions*. D&C Orange No. 4 may be safely used for coloring externally applied drugs in amounts consistent with good manufacturing practice.

(d) *Labeling*. The label of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification*. All batches of D&C Orange No. 4 shall be certified in accordance with regulations in part 80 of this chapter.

[42 FR 52396, Sept. 30, 1977, as amended at 43 FR 14642, Apr. 7, 1978; 46 FR 8461, Jan. 27, 1981]

§ 74.1255 D&C Orange No. 5.

(a) *Identity*. (1) the color additive D&C Orange No. 5 is a mixture consisting principally the sodium salt of 4′,5′-dibromofluorescein (CAS Reg. No. 596–03–2) and 2′,4′,5′-tribromofluorescein (CAS Reg. No. 25709–83–5) and 2′,4′,5′,7′-tetrabromofluorescein (CAS Reg. No. 15086–94–9). D&C Orange No. 5 is manufactured by brominating fluorescein with elemental bromine. The fluorescein is manufactured by the acid condensation of resorcinol and phthalic acid or its anhydride. The fluorescein is isolated and partially purified prior to bromination.

(2) Color additive mixtures for drug use made with D&C Orange No. 5 may contain only those diluents that are suitable and that are listed in part 73 of this chapter for use in color additive mixtures for coloring drugs.

(b) *Specifications*. D&C Orange No. 5 shall conform to the following specifications and shall be free from impurities other than those named to the extent that such impurities may be avoided by good manufacturing practice.

4′,5′-dibromofluorescein, not less than 50 percent and not more than 65 percent.

2′,4′,5′-tribromofluorescein, not less than 30 percent and not more than 40 percent.
2′,4′,5′,7′-tetrabromofluorescein, not more than 10 percent.
Sum of 2′,4′-dibromofluorescein and 2′,5′-dibromofluorescein, not more than 2 percent.
4′–Bromofluorescein, not more than 2 percent.
Fluorescein, not more than 1 percent.
Phthalic acid, not more than 1 percent.
2-(3,5-Dibromo-2,4-dihydroxybenzoyl) benzoic acid, not more than 0.5 percent.
Brominated resorcinol, not more than 0.4 percent.
Sum of volatile matter (at 135 °C) and halides and sulfates (calculated as sodium salts), not more than 10 percent.
Insoluble matter (alkaline solution), not more than 0.3 percent.
Lead (as Pb), not more than 20 parts per million.
Arsenic (as As), not more than 3 parts per million.
Mercury (as Hg), not more than 1 part per million.
Total color, not less than 90 percent.

(c) *Uses and restrictions*. D&C Orange No. 5 may be safely used for coloring mouthwashes and dentifrices that are ingested drugs in amounts consistent with current good manufacturing practice. D&C Orange No. 5 may be safely used in externally applied drugs in amounts not exceeding 5 milligrams per daily dose of the drug.

(d) *Labeling*. The label of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification*. All batches of D&C Orange No. 5 shall be certified in accordance with regulations in part 80 of this chapter.

[47 FR 44635, Nov. 2, 1982, as amended at 49 FR 13342, Apr. 4, 1984]

§ 74.1260 D&C Orange No. 10.

(a) *Identity*. (1) The color additive D&C Orange No. 10 is a mixture consisting principally of 4′,5′-diiodofluorescein, 2′,4′,5′-triiodofluorescein, and 2′,4′,5′,7′-tetraiodofluorescein.

(2) Color additive mixtures for drug use made with D&C Orange No. 10 may contain only those diluents listed in this subpart as safe and suitable for use in color additive mixtures for coloring externally applied drugs.

(b) *Specifications*. D&C Orange No. 10 shall conform to the following specifications and shall be free from impurities other than those named to the extent that such other impurities may be avoided by good manufacturing practice:

Sum of volatile matter (at 135 °C) and halides and sulfates (calculated as sodium salts), not more than 8 percent.
Insoluble matter (alkaline solution), not more than 0.5 percent.
Phthalic acid, not more than 0.5 percent.
2-[3′,5′-Diiodo-2′,4′-dihydroxybenzoyl] benzoic acid, not more than 0.5 percent.
Fluorescein, not more than 1 percent.
4′-Iodofluorescein, not more than 3 percent.
2′,4′-Diiodofluorescein and 2′,5′-diiodofluorescein, not more than 2 percent.
2′,4′,5′-Triiodofluorescein, not more than 35 percent.
2′,4′,5′,7′-Tetraiodofluorescein, not more than 10 percent.
4′,5′-Diiodofluorescein, not less than 60 percent and not more than 95 percent.
Lead (as Pb), not more than 20 parts per million.
Arsenic (as As), not more than 3 parts per million.
Mercury (as Hg), not more than 1 part per million.
Total color, not less than 92 percent.

(c) *Uses and restrictions*. D&C Orange No. 10 may be safely used for coloring externally applied drugs in amounts consistent with good manufacturing practice.

(d) *Labeling requirements*. The label of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification*. All batches of D&C Orange No. 10 shall be certified in accordance with regulations in part 80 of this chapter.

[46 FR 18953, Mar. 27, 1981]

§ 74.1261 D&C Orange No. 11.

(a) *Identity*. (1) The color additive D&C Orange No. 11 is a mixture consisting principally of the disodium salts of 4′,5′-diiodofluorescein, 2′,4′,5′-triiodofluorescein and 2′,4′,5′,7′-tetraiodofluorescein.

(2) Color additive mixtures for drug use made with D&C Orange No. 11 may contain only those diluents listed in this subpart as safe and suitable for use

in color additive mixtures for coloring externally applied drugs.

(b) *Specifications*. The color additive D&C Orange No. 11 shall conform to the following specifications and shall be free from impurities other than those named to the extent that such impurities may be avoided by good manufacturing practice:

Sum of volatile matter (at 135 °C) and halides and sulfates (calculated as sodium salts), not more than 8 percent.
Water-insoluble matter, not more than 0.5 percent.
Phthalic acid, not more than 0.5 percent.
2-[3′,5′-Diiodo-2′,4′-dihydroxybenzoyl] benzoic acid, sodium salt, not more than 0.5 percent.
Fluorescein, disodium salt, not more than 1 percent.
4′-Iodofluorescein, disodium salt, not more than 3 percent.
2′,4′-Diiodofluorescein and 2′,5′-diiodofluorescein, not more than 2 percent.
2′,4′,5′-Triiodofluorescein, not more than 35 percent.
2′,4′,5′,7′-Tetraiodofluorescein, disodium salt, not more than 10 percent.
4′,5′-Diiodofluorescein, disodium salt, not less than 60 percent and not more than 95 percent.
Lead (as Pb), not more than 20 parts per million.
Arsenic (as As), not more than 3 parts per million.
Mercury (as Hg), not more than 1 part per million.
Total color, not less than 92 percent.

(c) *Uses and restrictions*. D&C Orange No. 11 may be safely used for coloring externally applied drugs in amounts consistent with good manufacturing practice.

(d) *Labeling requirements*. The label of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification*. All batches of D&C Orange No. 11 shall be certified in accordance with regulations in part 80 of this chapter.

[46 FR 18953, Mar. 27, 1981]

§ 74.1303 FD&C Red No. 3.

(a) *Identity and specifications*. (1) The color additive FD&C Red No. 3 shall conform in identity and specifications to the requirements of § 74.303(a)(1) and (b).

(2) Color additive mixtures for ingested drug used made with FD&C Red No. 3 may contain only those diluents that are suitable and that are listed in part 73 of this chapter as safe for use in color additive mixtures for coloring ingested drugs.

(b) *Uses and restrictions*. FD&C Red No. 3 may be safely used for coloring ingested drugs in amounts consistent with good manufacturing practice.

(c) *Labeling*. The label of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(d) *Certification*. All batches of FD&C Red No. 3 shall be certified in accordance with regulations in part 80 of this chapter.

§ 74.1304 FD&C Red No. 4.

(a) *Identity*. (1) The color additive FD&C Red No. 4 is principally the disodium salt of 3-[(2,4-dimethyl-5-sulfophenyl)azo] -4-hydroxy-1-naphthalenesulfonic acid.

(2) Color additive mixtures for use in externally applied drugs made with FD&C Red No. 4 may contain only those diluents that are suitable and that are listed in part 73 of this chapter for use in color additive mixtures for coloring externally applied drugs.

(b) *Specifications*. FD&C Red No. 4 shall conform to the following specifications and shall be free from impurities other than those named to the extent that such impurities may be avoided by good manufacturing practice:

Sum of volatile matter (at 135 °C.) and chlorides and sulfates (calculated as sodium salts), not more than 13 percent.
Water-insoluble matter, not more than 0.2 percent.
5-Amino-2,4-dimethyl-1-benzenesulfonic acid, sodium salt, not more than 0.2 percent.
4-Hydroxy-1-naphthalenesulfonic acid, sodium salt, not more than 0.2 percent.
Subsidiary colors, not more than 2 percent.
Lead (as Pb), not more than 10 parts per million.
Arsenic (as As), not more than 3 parts per million.
Mercury (as Hg), not more than 1 part per million.
Total color, not less than 87 percent.

(c) *Uses and restrictions*. FD&C Red No. 4 may be safely used in externally

applied drugs in amounts consistent with good manufacturing practice.

(d) *Labeling*. The label of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification*. All batches of FD&C Red No. 4 shall be certified in accordance with regulations in part 80 of this chapter.

§ 74.1306 D&C Red No. 6.

(a) *Identity*. (1) The color additive D&C Red No. 6 is principally the disodium salt of 3-hydroxy-4-[(4-methyl-2-sulfophenyl)azo]-2-naphthalenecarboxylic acid (CAS Reg. No. 5858–81–1). To manufacture the additive, 2-amino-5-methylbenzenesulfonic acid is diazotized with hydrochloric acid and sodium nitrite. The diazo compound is coupled in alkaline medium with 3-hydroxy-2-naphthalenecarboxylic acid. The resulting dye precipitates as the disodium salt.

(2) Color additive mixtures for drug use made with D&C Red No. 6 may contain only those diluents that are suitable and that are listed in part 73 of this chapter as safe for use in color additive mixtures for coloring drugs.

(b) *Specifications*. The color additive D&C Red No. 6 shall conform to the following specifications and shall be free from impurities other than those named to the extent that such impurities may be avoided by current good manufacturing practice:

Sum of volatile matter (at 135 °C) and chlorides and sulfates (calculated as sodium salts), not more than 10 percent.

1-[(4-methylphenyl)azo]-2-naphthalenol, not more than 0.015 percent.

2-Amino-5-methylbenzenesulfonic acid, sodium salt, not more than 0.2 percent.

3-Hydroxy-2-naphthalenecarboxylic acid, sodium salt, not more than 0.4 percent.

3-Hydroxy-4-[(4-methylphenyl)azo]-2-naphthalenecarboxylic acid, sodium salt, not more than 0.5 percent.

p- Toluidine, not more than 15 parts per million.

Lead (as Pb), not more than 20 parts per million.

Arsenic (as As), not more than 3 parts per million.

Mercury (as Hg), not more than 1 part per million.

Total color, not less than 90 percent.

(c) *Uses and restrictions*. The color additive D&C Red No. 6 may be safely used for coloring drugs such that the combined total of D&C Red No. 6 and D&C Red No. 7 does not exceed 5 milligrams per daily dose of the drug.

(d) *Labeling*. The label of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification*. All batches of D&C Red No. 6 shall be certified in accordance with regulations in part 80 of this chapter.

[47 FR 57687, Dec. 28, 1982, as amended at 77 FR 39923, July 6, 2012]

§ 74.1307 D&C Red No. 7.

(a) *Identity*. (1) The color additive D&C Red No. 7 is principally the calcium salt of 3-hydroxy-4-[(4-methyl-2-sulfophenyl)azo]-2-naphthalenecarboxylic acid (CAS Reg. No. 5281–04–9). To manufacture the additive, 2-amino-5-methylbenzenesulfonic acid is diazotized with hydrochloric acid and sodium nitrite. The diazo compound is coupled in alkaline medium with 3-hydroxy-2-naphthalenecarboxylic acid and the resulting dye converted to the calcium salt with calcium chloride.

(2) Color additive mixtures for drug use made with D&C Red No. 7 may contain only those diluents that are suitable and that are listed in part 73 of this chapter as safe for use in color additive mixtures for coloring drugs.

(b) *Specifications*. The color additive D&C Red No. 7 shall conform to the following specifications and shall be free from impurities other than those named to the extent that such impurities may be avoided by current good manufacturing practice:

Sum of volatile matter (at 135 °C) and chlorides and sulfates (calculated as sodium salts), not more than 10 percent.

1-[(4-methylphenyl)azo]-2-naphthalenol, not more than 0.015 percent.

2-Amino-5-methylbenzenesulfonic acid, calcium salt, not more than 0.2 percent.

3-Hydroxy-2-naphthalenecarboxylic acid, calcium salt, not more than 0.4 percent.

3-Hydroxy-4-[(4-methylphenyl)azo]-2-naphthalenecarboxylic acid, calcium salt, not more than 0.5 percent.

p-Toluidine, not more than 15 parts per million.

Lead (as Pb), not more than 20 parts per million.
Arsenic (as As), not more than 3 parts per million.
Mercury (as Hg), not more than 1 part per million.
Total color, not less than 90 percent.

(c) *Uses and restrictions.* The color additive D&C Red No. 7 may be safely used for coloring drugs such that the combined total of D&C Red No. 6 and D&C Red No. 7 does not exceed 5 milligrams per daily dose of the drug.

(d) *Labeling.* The label of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification.* All batches of D&C Red No. 7 shall be certified in accordance with regulations in part 80 of this chapter.

[47 FR 57687, Dec. 28, 1982, as amended at 77 FR 39923, July 6, 2012]

§ 74.1317 D&C Red No. 17.

(a) *Identity.* (1) The color additive D&C Red No. 17 is principally 1-[[4-(phenylazo)phenyl]azo]-2-naphthalenol.

(2) Color additive mixtures for drug use made with D&C Red No. 17 may contain only those diluents that are suitable and that are listed in part 73 of this chapter as safe for use in color additive mixtures for coloring externally applied drugs.

(b) *Specifications.* D&C Red No. 17 shall conform to the following specifications and shall be free from impurities, other than those named, to the extent that such other impurities may be avoided by good manufacturing practice:

Volatile matter (at 135 °C), not more than 5 percent.
Matter insoluble in both toluene and water (color additive mixed in toluene and the resultant residue isolated and mixed with water to obtain the matter insoluble in both toluene and water), not more than 0.5 percent.
Chlorides and sulfates (calculated as sodium salts), not more than 3 percent.
Aniline, not more than 0.2 percent.
4-Aminoazobenzene, not more than 0.1 percent.
2-Naphthol, not more than 0.2 percent.
1-(Phenylazo)-2-naphthol, not more than 3 percent.
1-[[2-(phenylazo) phenyl]azo]-2-naphthalenol, not more than 2 percent.
Lead (as Pb), not more than 20 parts per million.
Arsenic (as As), not more than 3 parts per million.
Mercury (as Hg), not more than 1 part per million.
Total color, not less than 90 percent.

(c) *Uses and restrictions.* D&C Red No. 17 may be safely used in externally applied drugs in amounts consistent with good manufacturing practice.

(d) *Labeling.* The label of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification.* All batches of D&C Red No. 17 shall be certified in accordance with regulations in part 80 of this chapter.

[42 FR 15654, Mar. 22, 1977, as amended at 42 FR 27225, May 27, 1977]

§ 74.1321 D&C Red No. 21.

(a) *Identity.* (1) The color additive D&C Red No. 21 is principally 2′,4′,5′,7′-tetrabromofluorescein (CAS Reg. No. 15086–94–9), and may contain smaller amounts of 2′,4′,5′-tribromofluorescein (CAS Reg. No. 25709–83–5) and 2′,4′,7′-tribromofluorescein (CAS Reg. No. 25709–84–6). The color additive is manufactured by brominating fluorescein with elemental bromine. The fluorescein is manufactured by the acid condensation of resorcinol and phthalic acid or its anhydride. The fluorescein is isolated and partially purified prior to bromination.

(2) Color additive mixtures for drug use made with D&C Red No. 21 may contain only those diluents that are suitable and that are listed in part 73 of this chapter as safe for use in color additive mixtures for coloring drugs.

(b) *Specifications.* The color additive D&C Red No. 21 shall conform to the following specifications and shall be free from impurities other than those named to the extent that such impurities may be avoided by current good manufacturing practice:

Sum of volatile matter (at 135 °C) and halides and sulfates (calculated as sodium salts), not more than 10 percent.
Insoluble matter (alkaline solution), not more than 0.5 percent.
Phthalic acid, not more than 1 percent.
2-(3,5-Dibromo-2,4-dihydroxybenzoyl) benzoic acid, not more than 0.5 percent.

2′,4′,5′,7′-Tetrabromofluorescein, ethyl ester, not more than 1 percent.
Brominated resorcinol, not more than 0.4 percent.
Fluorescein, not more than 0.2 percent.
Sum of mono- and dibromofluoresceins, not more than 2 percent.
Tribromofluoresceins, not more than 11 percent.
2′,4′,5′,7′-Tetrabromofluorescein, not less than 87 percent.
Lead (as Pb), not more than 20 parts per million.
Arsenic (as As), not more than 3 parts per million.
Mercury (as Hg), not more than 1 part per million.
Total color, not less than 90 percent.

(c) *Uses and restrictions.* The color additive D&C Red No. 21 may be safely used for coloring drugs generally in amounts consistent with current good manufacturing practice.

(d) *Labeling.* The label of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification.* All batches of D&C Red No. 21 shall be certified in accordance with regulations in part 80 of this chapter.

[47 FR 53846, Nov. 30, 1982]

§ 74.1322 D&C Red No. 22.

(a) *Identity.* (1) The color additive D&C Red No. 22 is principally the disodium salt of 2′,4′,5′7′-tetrabromofluorescein (CAS Reg. No. 17372–87–1) and may contain smaller amounts of the disodium salts of 2′,4′,5′-tribromofluorescein and 2′,4′,7′-tribromofluorescein. The color additive is manufactured by alkaline hydrolysis of 2′,4′,5′,7′-tetrabromofluorescein. 2′,4′,5′,7′-Tetrabromofluorescein is manufactured by brominating fluorescein with elemental bromine. The fluorescein is manufactured by the acid condensation of resorcinol and phthalic acid or its anhydride. Fluorescein is isolated and partially purified prior to bromination.

(2) Color additive mixtures for drug use made with Red No. 22 may contain only those diluents that are suitable and that are listed in part 73 of this chapter as safe for use in color additive mixtures for coloring drugs.

(b) *Specifications.* The color additive D&C Red No. 22 shall conform to the following specifications and shall be free from impurities other than those named to the extent that such impurities may be avoided by current good manufacturing practice:

Sum of volatile matter (at 135 °C) and halides and sulfates (calculated as soduim salts), not more than 10 percent.
Water-insoluble matter not more than 0.5 percent.
Disodium salt of phthalic acid, not more than 1 percent.
Sodium salt of 2-(3,5-Dibromo-2,4-dihydroxybenzoyl)benzoic acid, not more than 0.5 percent.
2′,4′,5′,7′-Tetrabromofluorescein, ethyl ester, not more than 1 percent.
Brominated resorcinol, not more than 0.4 percent.
Sum of disodium salts of mono- and dibromofluoresceins, not more than 2 percent.
Sum of disodium salts of tribromofluoresceins, not more than 25 percent.
Disodium salt of 2′,4′,5′,7′-Tetrabromofluorescein, not less than 72 percent.
Lead (as Pb), not more than 20 parts per million.
Arsenic (as As), not more than 3 parts per million.
Mercury (as Hg), not more than 1 part per million.
Total color, not less than 90 percent.

(c) *Uses and restrictions.* The color additive D&C Red No. 22 may be safely used for coloring drugs generally in amounts consistent with current good manufacturing practice.

(d) *Labeling.* The label of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification.* All batches of D&C Red No. 22 shall be certified in accordance with regulations in part 80 of this chapter.

[47 FR 53846, Nov. 30, 1982]

§ 74.1327 D&C Red No. 27.

(a) *Identity.* (1) The color additive D&C Red No. 27 is principally 2′,4′,5′,7′-tetrabromo-4,5,6,7-tetrachlorofluorescein (CAS Reg. No. 13473-26-2). The color additive is manufactured by brominating 4,5,6,7-tetrachlorofluorescein with elemental

bromine. The 4,5,6,7-tetrachlorofluorescein is manufactured by the acid condensation of resorcinol and tetrachlorophthalic acid or its anhydride. The 4,5,6,7-tetrachlorofluorescein is isolated and partially purified prior to bromination.

(2) Color additive mixtures for drug use made with D&C Red No. 27 may contain only those diluents that are suitable and that are listed in part 73 of this chapter as safe for use in color additive mixtures for coloring drugs.

(b) *Specifications*. D&C Red No. 27 shall conform to the following specifications and shall be free from impurities other than those named to the extent that such impurities may be avoided by current good manufacturing practice:

Sum of volatile matter (at 135 °C) and halides and sulfates (calculated as sodium salts), not more than 10 percent.
Insoluble matter (alkaline solution), not more than 0.5 percent.
Tetrachlorophthalic acid, not more than 1.2 percent.
Brominated resorcinol, not more than 0.4 percent.
2,3,4,5-Tetrachloro-6-(3,5-dibromo-2,4-dihydroxybenzoyl) benzoic acid, not more than 0.7 percent.
2′,4′,5′,7′-Tetrabromo-4,5,6,7-tetrachlorofluorescein, ethyl ester, not more than 2 percent.
Lower halogenated subsidiary colors, not more than 4 percent.
Lead (as Pb), not more than 20 parts per million.
Arsenic (as As), not more than 3 parts per million.
Mercury (as Hg), not more than 1 part per million.
Total color, not less than 90 percent.

(c) *Uses and restrictions*. D&C Red No. 27 may be safely used for coloring drugs generally in amounts consistent with current good manufacturing practice.

(d) *Labeling*. The label of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification*. All batches of D&C Red No. 27 shall be certified in accordance with regulations in part 80 of this chapter.

[47 FR 42567, Sept. 28, 1982; 47 FR 51106, Nov. 12, 1982]

§ 74.1328 D&C Red No. 28.

(a) *Identity*. (1) The color additive D&C Red No. 28 is principally the disodium salt of 2′,4′,5′,7′-tetrabromo-4,5,6,7-tetrachlorofluorescein (CAS Reg. No. 18472–87–2) formed by alkaline hydrolysis of the parent tetrabromotetrachlorofluorescein.

(2) Color additive mixtures for drug use made with D&C Red No. 28 may contain only those diluents that are suitable and that are listed in part 73 of this chapter as safe for use in color additive mixtures for coloring drugs.

(b) *Specifications*. D&C Red No. 28 shall conform to the following specifications and shall be free from impurities other than those named to the extent that such impurities may be avoided by current good manufacturing practice:

Sum of volatile matter (at 135 °C) and halides and sulfates (calculated as sodium salts), not more than 15 percent.
Insoluble matter (alkaline solution), not more than 0.5 percent.
Tetrachlorophthalic acid, not more than 1.2 percent.
Brominated resorcinol, not more than 0.4 percent.
2,3,4,5-Tetrachloro-6-(3,5-dibromo-2,4-dihydroxybenzoyl)benzoic acid, not more than 0.7 percent.
2′,4′,5′,7′-Tetrabromo-4,5,6,7-tetrachlorofluorescein, ethyl ester, not more than 2 percent.
Lower halogenated subsidiary colors, not more than 4 percent.
Lead (as Pb), not more than 20 parts per million.
Arsenic (as As), not more than 3 parts per million.
Mercury (as Hg), not more than 1 part per million.
Total color, not less than 85 percent.

(c) *Uses and restrictions*. D&C Red No. 28 may be safely used for coloring drugs generally in amounts consistent with current good manufacturing practice.

(d) *Labeling*. The label of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification*. All batches of D&C Red No. 28 shall be certified in accordance with regulations in part 80 of this chapter.

[47 FR 42568, Sept. 28, 1982]

§ 74.1330 D&C Red No. 30.

(a) *Identity*. (1) The color additive D&C Red No. 30 is principally 6-chloro-2-(6-chloro-4-methyl-3-oxobenzo[*b*]thien-2(3*H*)-ylidene)-4-methyl-benzo[*b*]thiophen-3(2*H*)-one (CAS Reg. No. 2379–74–0).

(2) Color additive mixtures for drug use made with D&C Red No. 30 may contain only those diluents that are suitable and that are listed in part 73 of this chapter as safe for use in color additive mixtures for coloring drugs.

(b) *Specifications*. D&C Red No. 30 shall conform to the following specifications and shall be free from impurities other than those named to the extent that such impurities may be avoided by current good manufacturing practice:

Volatile matter (at 135 °C), not more than 5 percent.
Chlorides and sulfates (calculated as sodium salts), not more than 3 percent.
Matter soluble in acetone, not more than 5 percent.
Total color, not less than 90 percent.
Lead (as Pb), not more than 20 parts per million.
Arsenic (as As), not more than 3 parts per million.
Mercury (as Hg), not more than 1 part per million.

(c) *Uses and restrictions*. D&C Red No. 30 may be safely used for coloring drugs generally in amounts consistent with current good manufacturing practice.

(d) *Labeling*. The label of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification*. All batches of D&C Red No. 30 shall be certified in accordance with regulations in part 80 of this chapter.

[47 FR 22510, May 25, 1982]

§ 74.1331 D&C Red No. 31.

(a) *Identity*. (1) The color additive D&C Red No. 31 is principally the calcium salt of 3-hydroxy-4-(phenylazo)-2-naphthalenecarboxylic acid.

(2) Color additive mixtures for drug use made with D&C Red No. 31 may contain only those diluents that are suitable and that are listed in part 73 of this chapter as safe for use in color additive mixtures for coloring externally applied drugs.

(b) *Specifications*. D&C Red No. 31 shall conform to the following specifications and shall be free from impurities, other than those named, to the extent that such other impurities may be avoided by good manufacturing practice:

Sum of volatile matter (at 135 °C) and chlorides and sulfates (calculated as sodium salts), not more than 10 percent.
Aniline, not more than 0.2 percent.
3-Hydroxy-2-naphthoic acid, calcium salt, not more than 0.4 percent.
Subsidiary colors, not more than 1 percent.
Lead (as Pb), not more than 20 parts per million.
Arsenic (as As), not more than 3 parts per million.
Mercury (as Hg), not more than 1 part per million.
Total color, not less than 90 percent.

(c) *Uses and restrictions*. D&C Red No. 31 may be safely used in externally applied drugs in amounts consistent with good manufacturing practice.

(d) *Labeling*. The label of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification*. All batches of D&C Red No. 31 shall be certified in accordance with regulations in part 80 of this chapter.

§ 74.1333 D&C Red No. 33.

(a) *Identity*. (1) The color additive D&C Red No. 33 is principally the disodium salt of 5-amino-4-hydroxy-3-(phenylazo)-2,7-naphthalenedisulfonic acid (CAS Reg. No. 3567–66–6). To manufacture the additive, the product obtained from the nitrous acid diazotization of aniline is coupled with 4-hydroxy-5-amino-2,7-naphthalenedisulfonic acid in an alkaline aqueous medium. The color additive is isolated as the sodium salt.

(2) Color additive mixtures for drug use made with D&C Red No. 33 may contain only those diluents that are suitable and that are listed in part 73 of this chapter as safe for use in color additive mixtures for coloring drugs.

(b) *Specifications.* D&C Red No. 33 shall conform to the following specifications and shall be free from impurities other than those named to the extent that such impurities may be avoided by current good manufacturing practices:

Sum of volatile matter at 135 °C (275 °F) and chlorides and sulfates (calculated as sodium salts), not more than 18 percent.
Water-insoluble matter, not more than 0.3 percent.
4-Amino-5-hydroxy-2,7-naphthalenedisulfonic acid, disodium salt, not more than 0.3 percent.
4,5-Dihydroxy-3-(phenylazo)-2,7-naphthalenedisulfonic acid, disodium salt, not more than 3.0 percent.
Aniline, not more than 25 parts per million.
4-Aminoazobenzene, not more than 100 parts per billion.
1,3-Diphenyltriazene, not more than 125 parts per billion.
4-Aminobiphenyl, not more than 275 parts per billion.
Azobenzene, not more than 1 part per million.
Benzidine, not more than 20 parts per billion.
Lead (as Pb), not more than 20 parts per million.
Arsenic (as As), not more than 3 parts per million.
Mercury (as Hg), not more than 1 part per million.
Total color, not less than 82 percent.

(c) *Uses and restrictions.* The color additive D&C Red. No 33 may be safely used for coloring ingested drugs, other than mouthwashes and dentifrices, in amounts not to exceed 0.75 milligram per daily dose of the drug. D&C Red No. 33 may be safely used for coloring externally applied drugs, mouthwashes, and dentifrices in amounts consistent with current good manufacturing practice.

(d) *Labeling requirements.* The label of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification.* All batches of D&C Red No. 33 shall be certified in accordance with regulations in part 80 of this chapter.

[53 FR 33120, Aug. 30, 1988]

§ 74.1334 D&C Red No. 34.

(a) *Identity.* (1) The color additive D&C Red No. 34 is principally the calcium salt of 3-hydroxy-4-[(1-sulfo-2-naphthalenyl)azo]-2-naphthalene-carboxylic acid.

(2) Color additive mixtures for drug use made with D&C Red No. 34 may contain only those diluents that are suitable and that are listed in part 73 of this chapter as safe for use in color additive mixtures for coloring externally applied drugs.

(b) *Specifications.* D&C Red No. 34 shall conform to the following specifications and shall be free from impurities, other than those named, to the extent that such other impurities may be avoided by good manufacturing practice:

Sum of volatile matter (at 135 °C) and chlorides and sulfates (calculated at sodium salts), not more than 15 percent.
2-Amino-1-naphthalenesulfonic acid, calcium salt, not more than 0.2 percent.
3-Hydroxy-2-naphthoic acid, not more than 0.4 percent.
Subsidiary colors, not more than 4 percent.
Lead (as Pb), not more than 20 parts per million.
Arsenic (as As), not more than 3 parts per million.
Mercury (as Hg), not more than 1 part per million.
Total color not less than 85 percent.

(c) *Uses and restrictions.* The color additive D&C Red No. 34 may be safely used for coloring externally applied drugs in amounts consistent with good manufacturing practice.

(d) *Labeling.* The label of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification.* All batches of D&C Red No. 34 shall be certified in accordance with regulations in part 80 of this chapter.

§ 74.1336 D&C Red No. 36.

(a) *Identity.* (1) The color additive D&C Red No. 36 is 1-[(2-chloro-4-nitrophenyl)azo]-2-naphthalenol (CAS Reg. No. 2814–77–9). The color additive is manufactured by diazotization of 2-chloro-4-nitrobenzenamine in acid medium and coupling with 2-naphthalenol in acid medium.

(2) Color additive mixtures for drug use made with D&C Red No. 36 may contain only those diluents that are suitable and that are listed in part 73

of this chapter as safe for use in color additive mixtures for coloring drugs.

(b) *Specifications.* D&C Red No. 36 shall conform to the following specifications and shall be free from impurities other than those named to the extent that such impurities may be avoided by current good manufacturing practice:

Volatile matter at 135 °C (275 °F), not more than 1.5 percent.
Matter insoluble in toluene, not more than 1.5 percent.
2-Chloro-4-nitrobenzenamine, not more than 0.3 percent.
2-Naphthalenol, not more than 1 percent.
2,4-Dinitrobenzenamine, not more than 0.02 percent.
1-[(2,4-Dinitrophenyl)azo]-2-naphthalenol, not more than 0.5 percent.
4-[(2-Chloro-4-nitrophenyl)azo]-1-naphthalenol, not more than 0.5 percent.
1-[(4-Nitrophenyl)azo]-2-naphthalenol, not more than 0.3 percent.
1-[(4-Chloro-2-nitrophenyl)azo]-2-naphthalenol, not more than 0.3 percent.
Lead (as Pb), not more than 20 parts per million.
Arsenic (as As), not more than 3 parts per million.
Mercury (as Hg), not more than 1 part per million.
Total color, not less than 95 percent.

(c) *Uses and restrictions.* The color additive D&C Red No. 36 may be safely used for coloring ingested drugs, other than mouthwashes and dentifrices, in amounts not to exceed 1.7 milligrams per daily dose of the drug for drugs that are taken continuously only for less than 1 year. For drugs taken continuously for longer than 1 year, the color additive shall not be used in amounts to exceed 1.0 milligram per daily dose of the drug. D&C Red No. 36 may be safely used for coloring externally applied drugs in amounts consistent with current good manufacturing practice.

(d) *Labeling requirements.* The label of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification.* All batches of D&C Red No. 36 shall be certified in accordance with regulations in part 80 of this chapter.

[53 FR 29031, Aug. 2, 1988; 53 FR 35255, Sept. 12, 1988, as amended at 53 FR 52130, Dec. 27, 1988]

§ 74.1339 D&C Red No. 39.

(a) *Identity.* (1) The color additive D&C Red No. 39 is *o*-[*p*(β,β′-dihydroxydiethylamino)-phenylazo]-benzoic acid.

(2) Color additive mixtures made with D&C Red No. 39 may contain the following diluents: Water, acetone, isopropyl alcohol, and specially denatured alcohols used in accordance with 26 CFR part 212.

(b) *Specifications.* D&C Red No. 39 shall conform to the following specifications and shall be free from impurities other than those named to the extent that such other impurities may be avoided by good manufacturing practice:

Volatile matter (at 100 °C.), not more than 2.0 percent.
Matter insoluble in acetone, not more than 1.0 percent.
Anthranilic acid, not more than 0.2 percent.
N,*N*-(β,β′-Dihydroxy-diethyl) aniline, not more than 0.2 percent.
Subsidiary colors, not more than 3.0 percent.
Lead (as Pb), not more than 20 parts per million.
Arsenic (as As), not more than 3 parts per million.
Total color, not less than 95.0 percent.

(c) *Uses and restrictions.* The color additive D&C Red No. 39 may be safely used for the coloring of quaternary ammonium type germicidal solutions intended for external application only, and subject to the further restriction that the quantity of the color additive does not exceed 0.1 percent by weight of the finished drug product.

(d) *Labeling.* The label of the color additive and any mixtures prepared therefrom and intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification.* All batches of D&C Red No. 39 shall be certified in accordance with regulations promulgated under part 80 of this chapter.

§ 74.1340 FD&C Red No. 40.

(a) *Identity and specifications.* (1) The color additive FD&C Red No. 40 shall

conform in identity and specifications to the requirements of § 74.340(a)(1) and (b).

(2) Color additive mixtures for drug use made with FD&C Red No. 40 may contain only those diluents that are suitable and that are listed in part 73 of this chapter as safe for use in color additive mixtures for coloring drugs.

(3) The listing of this color additive includes lakes prepared as described in §§ 82.51 and 82.1051 of this chapter, except that the color additive used is FD&C Red No. 40 and the resultant lakes meet the specification and labeling requirements prescribed by §§ 82.51 or 82.1051 of this chapter.)

(b) *Uses and restrictions.* (1) FD&C Red No. 40 and FD&C Red No. 40 Aluminum Lake may be safely used in coloring drugs, including those intended for use in the area of the eye, subject to the restrictions on the use of color additives in § 70.5(b) and (c) of this chapter, in amounts consistent with current good manufacturing practice.

(2) Other lakes of FD&C Red No. 40 may be safely used in coloring drugs, subject to the restrictions on the use of color additives in § 70.5 of this chapter, in amounts consistent with current good manufacturing practice.

(c) *Labeling.* The label of the color additive and any lakes or mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(d) *Certification.* All batches of FD&C Red No. 40 and lakes thereof shall be certified in accordance with regulations, in part 80 of this chapter.

[42 FR 15654, Mar. 22, 1977, as amended at 59 FR 7636, Feb. 16, 1994]

§ 74.1602 D&C Violet No. 2.

(a) *Identity.* (1) The color additive D&C Violet No. 2 is principally 1-hydroxy -4-[(4-methylphenyl)amino]-9,10-anthracenedione.

(2) Color additive mixtures for use in externally applied drugs made with D&C Violet No. 2 may contain only those diluents that are suitable and that are listed in part 73 of this chapter as safe for use in color additive mixtures for coloring externally applied drugs.

(b) *Specifications.* D&C Violet No. 2 shall conform to the following specifications and shall be free from impurities, other than those named, to the extent that such other impurities can be avoided by good manufacturing practice:

Volatile matter (at 135 °C.), not more than 2.0 percent.

Matter insoluble in both carbon tetrachloride and water, not more than 0.5 percent.

p- Toluidine, not more than 0.2 percent.

1-Hydroxy-9,10-anthracenedione, not more than 0.5 percent.

1,4-Dihydroxy-9,10-anthracenedione, not more than 0.5 percent.

Subsidiary colors, not more than 1.0 percent.

Lead (as Pb), not more than 20 parts per million.

Arsenic (as As), not more than 3 parts per million.

Total color, not less than 96.0 percent.

(c) *Uses and restrictions.* The color additive D&C Violet No. 2 may be safely used for coloring externally applied drugs in amounts consistent with good manufacturing practice.

(d) *Labeling.* The label of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification.* All batches of D&C Violet No. 2 shall be certified in accordance with regulations in part 80 of this chapter.

[42 FR 15654, Mar. 22, 1977, as amended at 45 FR 62978, Sept. 23, 1980; 55 FR 18868, May 7, 1990]

§ 74.1705 FD&C Yellow No. 5.

(a) *Identity and specifications.* (1) The color additive FD&C Yellow No. 5 shall conform in identity and specifications to the requirements of § 74.705 (a)(1) and (b).

(2) FD&C Yellow No. 5 Aluminum Lake shall be prepared in accordance with the requirements of § 82.51 of this chapter.

(3) Color additive mixtures for drug use made with FD&C Yellow No. 5 may contain only those diluents that are suitable and are listed in part 73 of this chapter as safe for use in color additive mixtures for coloring drugs.

(b) *Uses and restrictions.* (1) FD&C Yellow No. 5 may be safely used for coloring drugs generally, including drugs intended for use in the area of the eye, in amounts consistent with current good manufacturing practice.

(2) FD&C Yellow No. 5 Aluminum Lake may be safely used for coloring drugs intended for use in the area of the eye, when prepared in accordance with § 82.51 of this chapter.

(c) *Labeling requirements.* (1) The label of the color additive and any mixtures intended solely or in part for coloring purposes prepared therefrom shall conform to the requirements of § 70.25 of this chapter.

(2) The label of OTC and prescription drug products intended for human use administered orally, nasally, rectally, or vaginally, or for use in the area of the eye, containing FD&C Yellow No. 5 shall specifically declare the presence of FD&C Yellow No. 5 by listing the color additive using the names FD&C Yellow No. 5 and tartrazine. The label shall bear a statement such as ''Contains FD&C Yellow No. 5 (tartrazine) as a color additive'' or ''Contains color additives including FD&C Yellow No. 5 (tartrazine).'' The labels of certain drug products subject to this labeling requirement that are also cosmetics, such as: antibacterial mouthwashes and fluoride toothpastes, need not comply with this requirement provided they comply with the requirements of § 701.3 of this chapter.

(3) For prescription drugs for human use containing FD&C Yellow No. 5 that are administered orally, nasally, vaginally, or rectally, or for use in the area of the eye, the labeling required by § 201.100(d) of this chapter shall, in addition to the label statement required under paragraph (c)(2) of this section, bear the warning statement ''This product contains FD&C Yellow No. 5 (tartrazine) which may cause allergic-type reactions (including bronchial asthma) in certain susceptible persons. Although the overall incidence of FD&C Yellow No. 5 (tartrazine) sensitivity in the general population is low, it is frequently seen in patients who also have aspirin hypersensitivity.'' This warning statement shall appear in the ''Precautions'' section of the labeling.

(d) *Certification.* All batches of FD&C Yellow No. 5 shall be certified in accordance with regulations in part 80 of this chapter.

[42 FR 15654, Mar. 22, 1977, as amended at 44 FR 37220, June 26, 1979; 50 FR 35782, Sept. 4, 1985; 51 FR 24519, July 7, 1986; 59 FR 60897, Nov. 29, 1994]

§ 74.1706 FD&C Yellow No. 6.

(a) *Identity and specifications.* (1) The color additive FD&C Yellow No. 6 shall conform in identity and specifications to the requirements of § 74.706(a)(1) and (b).

(2) Color additive mixtures for drug use made with FD&C Yellow No. 6 may contain only those diluents that are suitable and that are listed in part 73 of this chapter as safe for use in color additive mixtures for coloring drugs.

(b) *Uses and restrictions.* FD&C Yellow No. 6 may be safely used for coloring drugs generally in amounts consistent with current good manufacturing practice.

(c) *Labeling requirements.* (1) The label of the color additive and any mixtures intended solely or in part for coloring purposes prepared therefrom shall conform to the requirements of § 70.25 of this chapter.

(2) [Reserved]

(d) *Certification.* All batches of FD&C Yellow No. 6 shall be certified in accordance with regulations in part 80 of this chapter.

[51 FR 41782, Nov. 19, 1986, as amended at 52 FR 21508, June 8, 1987; 53 FR 49138, Dec. 6, 1988]

§ 74.1707 D&C Yellow No. 7.

(a) *Identity.* (1) The color additive D&C Yellow No. 7 is principally fluorescein.

(2) Color additive mixtures for use in externally applied drugs made with D&C Yellow No. 7 may contain only those diluents that are suitable and that are listed in part 73 of this chapter for use in color additive mixtures for coloring externally applied drugs.

(b) *Specifications.* D&C Yellow No. 7 shall conform to the following specifications and shall be free from impurities other than those named to the extent that such impurities may be avoided by good manufacturing practice:

Sum of water and chlorides and sulfates (calculated as sodium salts), not more than 6 percent.
Matter insoluble in alkaline water, not more than 0.5 percent.
Resorcinol, not more than 0.5 percent.
Phthalic acid, not more than 0.5 percent.
2-2,4-(Dihydroxybenzoyl) benzoic acid, not more than 0.5 percent.
Lead (as Pb), not more than 20 parts per million.
Arsenic (as As), not more than 3 parts per million.
Mercury (as Hg), not more than 1 part per million.
Total color, not less than 94 percent.

(c) *Uses and restrictions*. D&C Yellow No. 7 may be safely used in externally applied drugs in amounts consistent with good manufacturing practice.

(d) *Labeling*. The label of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification*. All batches of D&C Yellow No. 7 shall be certified in accordance with regulations in part 80 of this chapter.

§ 74.1707a Ext. D&C Yellow No. 7.

(a) *Identity*. (1) The color additive Ext. D&C Yellow No. 7 is principally the disodium salt of 8-hydroxy-5,7-dinitro-2-naphthalenesulfonic acid.

(2) Color additive mixtures for drug use made with Ext. D&C Yellow No. 7 may contain only those diluents that are suitable and that are listed in part 73 of this chapter as safe for use in color additive mixtures for coloring externally applied drugs.

(b) *Specifications*. Ext. D&C Yellow No. 7 shall conform to the following specifications and shall be free from impurities, other than those named, to the extent that such other impurities may be avoided by good manufacturing practice:

Sum of volatile matter (at 135 °C) and chlorides and sulfates (calculated as sodium salts), not more than 15 percent.
Water-insoluble matter, not more than 0.2 percent.
1-Naphthol, not more than 0.2 percent.
2,4-Dinitro-1-naphthol, not more than 0.03 percent.
Lead (as Pb), not more than 20 parts per million.
Arsenic (as As), not more than 3 parts per million.
Mercury (as Hg), not more than 1 part per million.
Total color, not less than 85 percent.

(c) *Uses and restrictions*. Ext. D&C Yellow No. 7 may be safely used in externally applied drugs in amounts consistent with good manufacturing practice.

(d) *Labeling*. The label of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification*. All batches of Ext. D&C Yellow No. 7 shall be certified in accordance with regulations in part 80 of this chapter.

§ 74.1708 D&C Yellow No. 8.

(a) *Identity*. (1) The color additive D&C Yellow No. 8 is principally the disodium salt of fluorescein.

(2) Color additive mixtures for use in externally applied drugs made with D&C Yellow No. 8 may contain only those diluents that are suitable and that are listed in part 73 of this chapter for use in color additive mixtures for coloring externally applied drugs.

(b) *Specifications*. D&C Yellow No. 8 shall be free from impurities other than those named to the extent that such impurities may be avoided by good manufacturing practice:

Sum of water and chlorides and sulfates (calculated as sodium salts), not more than 15 percent.
Matter insoluble in alkaline water, not more than 0.3 percent.
Resorcinol, not more than 0.5 percent.
Phthalic acid, not more than 1 percent.
2-(2,4-Dihydroxybenzoyl) benzoic acid, not more than 0.5 percent.
Lead (as Pb), not more than 20 parts per million.
Arsenic (as As), not more than 3 parts per million.
Mercury (as Hg), not more than 1 part per million.
Total color, not less than 85 percent.

(c) *Uses and restrictions*. D&C Yellow No. 8 may be safely used in externally applied drugs in amounts consistent with good manufacturing practice.

(d) *Labeling*. The label of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification*. All batches of D&C Yellow No. 8 shall be certified in accordance with regulations in part 80 of this chapter.

§ 74.1710 D&C Yellow No. 10.

(a) *Identity*. (1) The color additive D&C Yellow No. 10 is a mixture of the sodium salts of the mono- and disulfonic acids of 2-(2-quinolinyl)-1*H*-indene-1,3 (2*H*)-dione consisting principally of the sodium salts of 2-(2,3-dihydro-1,3-dioxo-1*H*-indene-2-yl)-6-quinolinesulfonic acid and 2-(2,3-dihydro-1,3-dioxo-1*H*-indene-2-yl)-8-quinolinesulfonic acid with lesser amounts of the disodium salts of the disulfonic acids of 2-(2-quinolinyl)-1*H*-indene-1,3(2*H*)-dione (CAS Reg. No. 8004–92–0). D&C Yellow No. 10 is manufactured by condensing quinaldine with phthalic anhydride to give the unsulfonated dye, which is then sulfonated with oleum.

(2) Color additive mixtures made with D&C Yellow No. 10 for drug use may contain only those diluents that are suitable and that are listed in part 73 of this chapter as safe for use in color additive mixtures for coloring drugs.

(b) *Specifications*. The color additive D&C Yellow No. 10 shall conform to the following specifications and shall be free from impurities other than those named to the extent that such other impurities may be avoided by current good manufacturing practice:

Sum of volatile matter at 135 °C (275 °F) and chlorides and sulfates (calculated as sodium salts), not more than 15 percent.

Matter insoluble in both water and chloroform, not more than 0.2 percent.

Total sulfonated quinaldines, sodium salts, not more than 0.2 percent.

Total sulfonated phthalic acids, sodium salts, not more than 0.2 percent.

2-(2-Quinolinyl)-1*H*-indene-1,3 (2*H*)-dione, not more than 4 parts per million.

Sum of sodium salts of the monosulfonates of 2-(2-quinolinyl)-1*H*-indene-1,3 (2*H*)-dione, not less than 75 percent.

Sum of sodium salts of the disulfonates of 2-(2-quinolinyl)-1*H*-indene-1,3 (2*H*)-dione, not more than 15 percent.

2-(2,3-Dihydro-1,3-dioxo-1*H*-indene-2-yl)-6, 8-quinolinedisulfonic acid, disodium salt, not more than 3 percent.

Diethyl ether soluble matter other than that specified, not more than 2 parts per million, using added 2-(2-quinolinyl)-1*H*-indene-1,3 (2*H*)-dione for calibration.

Lead (as Pb), not more than 20 parts per million.

Arsenic (as As), not more than 3 parts per million.

Mercury (as Hg), not more than 1 part per million.

Total color, not less than 85 percent.

(c) *Uses and restrictions*. The color additive D&C Yellow No. 10 may be safely used for coloring drugs generally in amounts consistent with current good manufacturing practice.

(d) *Labeling*. The label of the color additive and any mixtures prepared therefrom and intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification*. All batches of D&C Yellow No. 10 shall be certified in accordance with regulations in part 80 of this chapter.

[48 FR 39219, Aug. 30, 1983, as amended at 49 FR 8432, Mar. 7, 1984]

§ 74.1711 D&C Yellow No. 11.

(a) *Identity*. (1) The color additive D&C Yellow No. 11 is principally 2-(2-quinolyl)-1,3-indandione.

(2) Color additive mixtures, for drug use made with D&C Yellow No. 11 may contain only those diluents that are suitable and that are listed in part 73 of this chapter as safe for use in color additive mixtures for coloring externally applied drugs.

(b) *Specifications*. D&C Yellow No. 11 shall conform to the following specifications and shall be free from impurities, other than those named, to the extent that such other impurities may be avoided by good manufacturing practice:

Volatile matter (at 135 °C), not more than 1 percent.

Ethyl alcohol-insoluble matter, not more than 0.4 percent.

Phthalic acid, not more than 0.3 percent.

Quinaldine, not more than 0.2 percent.

Subsidiary colors, not more than 5 percent.

Lead (as Pb), not more than 20 parts per million.

Arsenic (as As), not more than 3 parts per million.

Mercury (as Hg), not more than 1 part per million.

Total color, not less than 96 percent.

(c) *Uses and restrictions*. D&C Yellow No. 11 may be safely used in externally applied drugs in amounts consistent with good manufacturing practice.

(d) *Labeling*. The label of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification*. All batches of D&C Yellow No. 11 shall be certified in accordance with regulations in part 80 of this chapter.

Subpart C—Cosmetics

§ 74.2052 D&C Black No. 2.

(a) *Identity*. The color additive D&C Black No. 2 is a high-purity carbon black prepared by the oil furnace process. It is manufactured by the combustion of aromatic petroleum oil feedstock and consists essentially of pure carbon, formed as aggregated fine particles with a surface area range of 200 to 260 meters $(m)^2$/gram.

(b) *Specifications*. D&C Black No. 2 shall conform to the following specifications and shall be free from impurities other than those named to the extent that such other impurities may be avoided by good manufacturing practice:

(1) Surface area by nitrogen BET (Brunauer, Emmett, Teller) method, 200 to 260 m^2/gram.

(2) Weight loss on heating at 950 °C for 7 minutes (predried for 1 hour at 125 °C), not more than 2 percent.

(3) Ash content, not more than 0.15 percent.

(4) Arsenic (total), not more than 3 milligrams per kilogram (mg/kg) (3 parts per million).

(5) Lead (total), not more than 10 mg/kg (10 parts per million).

(6) Mercury (total), not more than 1 mg/kg (1 part per million).

(7) Total sulfur, not more than 0.65 percent.

(8) Total PAHs, not more than 0.5 mg/kg (500 parts per billion).

(9) Benzo[*a*]pyrene, not more than 0.005 mg/kg (5 parts per billion).

(10) Dibenz[*a*,*h*]anthracene, not more than 0.005 mg/kg (5 parts per billion).

(11) Total color (as carbon), not less than 95 percent.

(c) *Uses and restrictions*. D&C Black No. 2 may be safely used for coloring the following cosmetics in amounts consistent with current good manufacturing practice: Eyeliner, brush-on-brow, eye shadow, mascara, lipstick, blushers and rouge, makeup and foundation, and nail enamel.

(d) *Labeling*. The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification*. All batches of D&C Black No. 2 shall be certified in accordance with regulations in part 80 of this chapter.

[69 FR 44930, July 28, 2004, as amended at 72 FR 10357]

§ 74.2053 D&C Black No. 3.

(a) *Identity*. The color additive D&C Black No. 3 is a washed bone char prepared from calcined cattle bones. The bones are twice heated in excess of 700 °C for at least 6 hours.

(b) *Specifications*. D&C Black No. 3 shall conform to the following specifications and shall be free from impurities other than those named, to the extent that such other impurities may be avoided by current good manufacturing practices:

(1) Calcium hydroxyapatite (CaO and P_2O_5), not less than 75 percent and not more than 84 percent;

(2) Elemental carbon, not less than 7 percent;

(3) Moisture, not more than 7 percent;

(4) Silica (SiO_2), not more than 5 percent;

(5) Arsenic, not more than 3 milligrams (mg)/kilogram (kg) (3 parts per million (ppm));

(6) Lead, not more than 10 mg/kg (10 ppm); and

(7) Total polycyclic aromatic hydrocarbons (PAHs), not more than 5 mg/kg (5 ppm).

(c) *Uses and restrictions*. Cosmetics containing D&C Black No. 3 must comply with § 700.27 of this chapter with respect to prohibited cattle materials in cosmetic products. D&C Black No. 3 may be safely used for coloring the following cosmetics in amounts consistent with current good manufacturing practice: Eyeliner, eye shadow, mascara, and face powder.

(d) *Labeling*. The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification*. All batches of D&C Black No. 3 shall be certified in accordance with regulations in part 80 of this chapter.

[72 FR 33666, June 19, 2007]

§ 74.2101 FD&C Blue No. 1.

(a) *Identity*. The color additive FD&C Blue No. 1 is principally the disodium salt of ethyl[4-[*p*-[ethyl(*m*-sulfobenzyl)amino]-α-(*o*-sulfophenyl)benzylidene]-2,5-cyclohexadien-1-ylidene](*m*-sulfobenzyl)ammonium hydroxide inner salt with smaller amounts of the isomeric disodium salts of ethyl[4-[*p*-[ethyl(*p*-sulfobenzyl)amino]-α-(*o*-sulfophenyl)benzylidene]-2,5-cyclohexadien-1-ylidene](*p*-sulfobenzyl)ammonium hydroxide inner salt and ethyl[4-[*p*-[ethyl(*o*-sulfobenzyl)amino]-α-(*o*-sulfophenyl)benzylidene]-2,5-cyclohexadien-1-ylidene](*o*-sulfobenzyl)ammonium hydroxide inner salt. Additionally, FD&C Blue No. 1 is manufactured by the acid catalyzed condensation of one mole of sodium 2-formylbenzenesulfonate with two moles from a mixture consisting principally of 3-[(ethylphenylamino)methyl] benzenesulfonic acid, and smaller amounts of 4-[(ethylphenylamino)methyl] benzenesulfonic acid and 2-[(ethylphenylamino)methyl] benzenesulfonic acid to form the leuco base. The leuco base is then oxidized with lead dioxide and acid, or with dichromate and acid, or with manganese dioxide and acid to form the dye. The intermediate sodium 2-formylbenzenesulfonate is prepared from 2-chlorobenzaldehyde and sodium sulfite.

(b) *Specifications*. (1) The color additive FD&C Blue No. 1 shall conform in specifications to the requirements of § 74.101(b).

(2) FD&C Blue No. 1 Aluminum Lake shall be prepared in accordance with the requirements of § 82.51 of this chapter.

(c) *Uses and restrictions*. (1) FD&C Blue No. 1 may be safely used for coloring cosmetics generally, including cosmetics intended for use in the area of the eye, in amounts consistent with current good manufacturing practice.

(2) FD&C Blue No. 1 Aluminum Lake may be safely used for coloring cosmetics intended for use in the area of the eye, in amounts consistent with current good manufacturing practice.

(d) *Labeling*. The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification*. All batches of FD&C Blue No. 1 shall be certified in accordance with regulations in part 80 of this chapter.

[47 FR 42565, Sept. 28, 1982, as amended at 58 FR 17511, Apr. 5, 1993; 59 FR 7638, Feb. 16, 1994]

§ 74.2104 D&C Blue No. 4.

(a) *Identity and specifications*. The color additive D&C Blue No. 4 shall conform in identity and specifications to the requirements of § 74.1104(a)(1) and (b).

(b) *Uses and restrictions*. D&C Blue No. 4 may be safely used for coloring externally applied cosmetics in amounts consistent with good manufacturing practice.

(c) *Labeling*. The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Certification*. All batches of D&C Blue No. 4 shall be certified in accordance with regulations in part 80 of this chapter.

§ 74.2151 D&C Brown No. 1.

(a) *Identity*. The color additive D&C Brown No. 1 is a mixture of the sodium salts of 4[[5-[(dialkylphenyl)- azo]-2,4-dihydroxyphenyl]azo]-benzene sulfonic acid. The alkyl group is principally the methyl group.

(b) *Specifications*. D&C Brown No. 1 shall conform to the following specifications and shall be free from impurities other than those named to the extent that such other impurities may be avoided by good manufacturing practice:

Sum of volatile matter (at 135 °C) and chlorides and sulfates (calculated as sodium salts), not more than 16 percent.

Water-insoluble matter, not more than 0.2 percent.

Sulfanilic acid, sodium salt, not more than 0.2 percent.
Resorcinol, not more than 0.2 percent.
Xylidines, not more than 0.2 percent.
Disodium salt of 4[[5-[(4-sulfophenyl)-azo]-2,4-dihydroxyphenyl]azo] benzenesulfonic acid, not more than 3 percent.
Monosodium salt of 4[[5-[(2,4-dimethylphenyl)azo] -2,4-dihydroxyphenyl]azo] benzenesulfonic acid, not less than 29 percent and not more than 39 percent.
Monosodium salt of 4[[5-[(2,5-dimethylphenyl)azo] -2,4-dihydroxyphenyl]azo] benzenesulfonic acid, not less than 12 percent and not more than 17 percent.
Monosodium salt of 4[[5-[(2,3-dimethylphenyl)azo] - 2,4-dihydroxyphenyl]azo] benzenesulfonic acid, not less than 6 percent and not more than 13 percent.
Monosodium salt of 4[[5-[(2-ethylphenyl)-azo]-2,4-dihydroxyphenyl]-azo] benzenesulfonic acid, not less than 5 percent and not more than 12 percent.
Monosodium salt of 4[[5-[(3,4-dimethylphenyl)azo] -2,4-dihydroxyphenyl]azo] benzenesulfonic acid, not less than 3 percent and not more than 9 percent.
Monosodium salt of 4[[5-[(2,6-dimethylphenyl)azo] -2,4-dihydroxyphenyl]azo] benzenesulfonic acid, not less than 3 percent and not more than 8 percent.
Monosodium salt of 4[[5-[(4-ethylphenyl) azo]-2,4-dihydroxyphenyl]-azo] benzenesulfonic acid, not less than 2 percent and not more than 8 percent.
Lead (as Pb), not more than 20 parts per million.
Arsenic (as As), not more than 3 parts per million.
Mercury (as Hg), not more than 1 part per million.
Total color, not less than 84 percent.

(c) *Uses and restrictions*. D&C Brown No. 1 may be safely used for coloring externally applied cosmetics in amounts consistent with good manufacturing practice.

(d) *Labeling*. The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification*. All batches of D&C Brown No. 1 shall be certified in accordance with regulations in part 80 of this chapter.

§ 74.2203 FD&C Green No. 3.

(a) *Identity and specifications*. The color additive FD&C Green No. 3 shall conform in identity and specifications to the requirements of § 74.203(a)(1) and (b).

(b) *Uses and restrictions*. The color additive FD&C Green No. 3 may be safely used for coloring cosmetics generally in amounts consistent with current good manufacturing practice.

(c) *Labeling*. The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Certification*. All batches of FD&C Green No. 3 shall be certified in accordance with regulations in part 80 of this chapter.

[47 FR 52144, Nov. 19, 1982]

§ 74.2205 D&C Green No. 5.

(a) *Identity and specifications*. The color additive D&C Green No. 5 shall conform in identity and specifications to the requirements of § 74.1205 (a)(1) and (b)(2).

(b) *Uses and restrictions*. D&C Green No. 5 may be safely used for coloring cosmetics generally, including cosmetics intended for use in the area of the eye, in amounts consistent with current good manufacturing practice.

(c) *Labeling requirements*. The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Certification*. All batches of D&C Green No. 5 shall be certified in accordance with regulations in part 80 of this chapter.

[47 FR 24285, June 4, 1982, as amended at 59 FR 40805, Aug. 10, 1994]

§ 74.2206 D&C Green No. 6.

(a) *Identity and specifications*. The color additive D&C Green No. 6 shall conform in identity and specifications to the requirements of § 74.1206 (a) and (b).

(b) *Uses and restrictions*. D&C Green No. 6 may be safely used for coloring externally applied cosmetics in amounts consistent with good manufacturing practice.

(c) *Labeling requirements*. The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Certification*. All batches of D&C Green No. 6 shall be certified in accordance with regulations in part 80 of this chapter.

[47 FR 14146, Apr. 4, 1982, as amended at 51 FR 9784, Mar. 21, 1986]

§ 74.2208 D&C Green No. 8.

(a) *Identity and specifications*. The color additive D&C Green No. 8 shall conform in identity and specifications

to the requirements of § 74.1208(a)(1) and (b).

(b) *Uses and restrictions.* D&C Green No. 8 may be safely used for coloring externally applied cosmetics in amounts not exceeding 0.01 percent by weight of the finished cosmetic product.

(c) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Certification.* All batches of D&C Green No. 8 shall be certified in accordance with regulations in part 80 of this chapter.

§ 74.2254 D&C Orange No. 4.

(a) *Identity and specifications.* The color additive D&C Orange No. 4 shall conform in identity and specifications to the requirements of § 74.1254 (a)(1) and (b).

(b) *Uses and restrictions.* D&C Orange No. 4 may be safely used for coloring externally applied cosmetics in amounts consistent with good manufacturing practice.

(c) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Certification.* All batches of D&C Orange No. 4 shall be certified in accordance with regulations in part 80 of this chapter.

[42 FR 52396, Sept. 30, 1977]

§ 74.2255 D&C Orange No. 5.

(a) *Identity and specifications.* The color additive D&C Orange No. 5 shall conform in identity and specifications to the requirements of § 74.1255 (a)(1) and (b).

(b) *Uses and restrictions.* D&C Orange No. 5 may be safely used for coloring mouthwashes and dentifrices that are ingested cosmetics in amounts consistent with current good manufacturing practice. D&C Orange No. 5 may be safely used for coloring lipsticks and other cosmetics intended to be applied to the lips in amounts not exceeding 5.0 percent by weight of the finished cosmetic products. D&C Orange No. 5 may be safely used for coloring externally applied cosmetics in amounts consistent with current good manufacturing practice.

(c) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Certification.* All batches of D&C Orange No. 5 shall be certified in accordance with regulations in part 80 of this chapter.

[47 FR 49635, Nov. 2, 1982, as amended at 49 FR 13342, Apr. 4, 1984]

§ 74.2260 D&C Orange No. 10.

(a) *Identity and specifications.* The color additive D&C Orange No. 10 shall conform in identity and specifications to the requirements of § 74.1260(a)(1) and (b).

(b) *Uses and restrictions.* D&C Orange No. 10 may be safely used for coloring externally applied cosmetics in amounts consistent with good manufacturing practice.

(c) *Labeling requirements.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Certification.* All batches of D&C Orange No. 11 shall be certified in accordance with regulations in part 80 of this chapter.

[46 FR 18954, Mar. 27, 1981]

§ 74.2261 D&C Orange No. 11.

(a) *Identity and specifications.* The color additive D&C Orange No. 11 shall conform in identity and specifications to the requirements of § 74.1261(a)(1) and (b).

(b) *Uses and restrictions.* D&C Orange No. 11 may be safely used for coloring externally applied cosmetics in amounts consistent with good manufacturing practice.

(c) *Labeling requirements.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Certification.* All batches of D&C Orange No. 11 shall be certified in accordance with regulations in part 80 of this chapter.

[46 FR 18954, Mar. 27, 1981]

§ 74.2304 FD&C Red No. 4.

(a) *Identity and specifications.* The color additive FD&C Red No. 4 shall conform in identity and specifications to the requirements of § 74.1304(a)(1) and (b).

(b) *Uses and restrictions.* FD&C Red No. 4 may be safely used for coloring

externally applied cosmetics in amounts consistent with good manufacturing practice.

(c) *Labeling*. The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Certification*. All batches of FD&C Red No. 4 shall be certified in accordance with regulations in part 80 of this chapter.

§ 74.2306 D&C Red No. 6.

(a) *Identity and specifications*. The color additive D&C Red No. 6 shall conform in identity and specifications to the requirements of § 74.1306 (a)(1) and (b).

(b) *Uses and restrictions*. The color additive D&C Red No. 6 may be safely used for coloring cosmetics generally in amounts consistent with current good manufacturing practice.

(c) *Labeling requirements*. The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Certification*. All batches of D&C Red No. 6 shall be certified in accordance with regulations in part 80 of this chapter.

[47 FR 57688, Dec. 28, 1982]

§ 74.2307 D&C Red No. 7

(a) *Identity and specifications*. The color additive D&C Red No. 7 shall conform in identity and specifications to the requirements of § 74.1307 (a)(1) and (b).

(b) *Uses and restrictions*. The color additive D&C Red No. 7 may be safely used for coloring cosmetics generally in amounts consistent with current good manufacturing practice.

(c) *Labeling requirements*. The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Certification*. All batches of D&C Red No. 7 shall be certified in accordance with regulations in part 80 of this chapter.

[47 FR 57688, Dec. 28, 1982]

§ 74.2317 D&C Red No. 17.

(a) *Identity and specifications*. The color additive D&C Red No. 17 shall conform in identity and specifications to the requirements of § 74.1317(a)(1) and (b).

(b) *Uses and restrictions*. D&C Red No. 17 may be safely used for coloring externally applied cosmetics in amounts consistent with good manufacturing practice.

(c) *Labeling*. The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Certification*. All batches of D&C Red No. 17 shall be certified in accordance with regulations in part 80 of this chapter.

§ 74.2321 D&C Red No. 21.

(a) *Identity and specifications*. The color additive D&C Red No. 21 shall conform in identity and specifications to the requirements of § 74.1321(a)(1) and (b).

(b) *Uses and restrictions*. The color additive D&C Red No. 21 may be safely used for coloring cosmetics generally in amounts consistent with current good manufacturing practice.

(c) *Labeling requirements*. The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Certification*. All batches of D&C Red No. 21 shall be certified in accordance with regulations in part 80 of this chapter.

[47 FR 53846, Nov. 30, 1982]

§ 74.2322 D&C Red No. 22.

(a) *Identity and specifications*. The color additive D&C Red No. 22 shall conform in identity and specifications to the requirements of § 74.1322(a)(1) and (b).

(b) *Uses and restrictions*. The color additive D&C Red No. 22 may be safely used for coloring cosmetics generally in amounts consistent with current good manufacturing practice.

(c) *Labeling requirements*. The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Certification*. All batches of D&C Red No. 22 shall be certified in accordance with regulations in part 80 of this chapter.

[47 FR 53846, Nov. 30, 1982]

§ 74.2327 D&C Red No. 27.

(a) *Identity and specifications*. The color additive D&C Red No. 27 shall conform in identity and specifications

to the requirements of § 74.1327 (a)(1) and (b).

(b) *Uses and restrictions.* D&C Red No. 27 may be safely used for coloring cosmetics generally in amounts consistent with current good manufacturing practice.

(c) *Labeling requirements.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Certification.* All batches of D&C Red No. 27 shall be certified in accordance with regulations in part 80 of this chapter.

[47 FR 42568, Sept. 28, 1982]

§ 74.2328 D&C Red No. 28.

(a) *Identity and specifications.* The color additive D&C Red No. 28 shall conform in identity and specifications to the requirements of § 74.1328 (a)(1) and (b).

(b) *Uses and restrictions.* D&C Red No. 28 may be safely used for coloring cosmetics generally in amounts consistent with current good manufacturing practice.

(c) *Labeling requirements.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Certification.* All batches of D&C Red No. 28 shall be certified in accordance with regulations in part 80 of this chapter.

[47 FR 42568, Sept. 28, 1982]

§ 74.2330 D&C Red No. 30.

(a) *Identity and specifications.* The color additive D&C Red No. 30 shall conform in identity and specifications to the requirements of § 74.1330 (a)(1) and (b).

(b) *Uses and restrictions.* D&C Red No. 30 may be safely used for coloring cosmetics generally in amounts consistent with current good manufacturing practice.

(c) *Labeling requirements.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Certification.* All batches of D&C Red No. 30 shall be certified in accordance with regulations in part 80 of this chapter.

[47 FR 22511, May 25, 1982]

§ 74.2331 D&C Red No. 31.

(a) *Identity and specifications.* The color additive D&C Red No. 31 shall conform in identity and specifications to the requirements of § 74.1331(a)(1) and (b).

(b) *Uses and restrictions.* D&C Red No. 31 may be safely used for coloring externally applied cosmetics in amounts consistent with good manufacturing practice.

(c) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Certification.* All batches of D&C Red No. 31 shall be certified in accordance with regulations in part 80 of this chapter.

§ 74.2333 D&C Red No. 33.

(a) *Identity and specifications.* The color additive D&C Red No. 33 shall conform in identity and specifications to the requirements of § 74.1333(a) (1) and (b).

(b) *Uses and restrictions.* The color additive D&C Red No. 33 may be safely used for coloring cosmetic lip products in amounts not to exceed 3 percent total color by weight of the finished cosmetic products. D&C Red No. 33 may be safely used for coloring mouthwashes (including breath fresheners), dentifrices, and externally applied cosmetics in amounts consistent with current good manufacturing practice.

(c) *Labeling requirements.* The label of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(d) *Certification.* All batches of D&C Red No. 33 shall be certified in accordance with regulations in part 80 of this chapter.

[53 FR 33120, Aug. 30, 1988]

§ 74.2334 D&C Red No. 34.

(a) *Identity and specifications.* The color additive D&C Red No. 34 shall conform in identity and specifications to the requirements of § 74.1334(a)(1) and (b).

(b) *Uses and restrictions.* D&C Red No. 34 may be safely used for coloring externally applied cosmetics in amounts

consistent with good manufacturing practice.

(c) *Labeling*. The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Certification*. All batches of D&C Red No. 34 shall be certified in accordance with regulations in part 80 of this chapter.

§ 74.2336 D&C Red No. 36.

(a) *Identity and specifications*. The color additive D&C Red No. 36 shall conform in identity and specifications to the requirements of § 74.1336 (a)(1) and (b).

(b) *Uses and restrictions*. The color additive D&C Red No. 36 may be safely used for coloring cosmetic lip products in amounts not to exceed 3 percent total color by weight of the finished cosmetic products. D&C Red No. 36 may be safely used for coloring externally applied cosmetics in amounts consistent with current good manufacturing practice.

(c) *Labeling requirements*. The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Certification*. All batches of D&C Red No. 36 shall be certified in accordance with regulations in part 80 of this chapter.

[53 FR 29031, Aug. 2, 1988]

§ 74.2340 FD&C Red No. 40.

(a) *Identity and specifications*. (1) The color additive FD&C Red No. 40 shall conform in identity and specifications to the requirements of § 74.340(a)(1) and (b) of this chapter.

(2) The listing of this color additive includes lakes prepared as described in §§ 82.51 and 82.1051 of this chapter, except that the color additive used is FD&C Red No. 40 and the resultant lakes meet the specification and labeling requirements prescribed by § 82.51 or § 82.1051 of this chapter.

(b) *Uses and restrictions*. FD&C Red No. 40 may be safely used in coloring cosmetics generally, except that only FD&C Red No. 40 and FD&C Red No. 40 Aluminum Lake may be safely used in coloring cosmetics intended for use in the area of the eye. These uses are subject to the following restrictions:

(1) The color additive may be used in amounts consistent with current good manufacturing practice.

(2) The color additive shall not be exposed to oxidizing or reducing agents that may affect the integrity of the color additives or any other condition that may affect their integrity.

(c) *Labeling*. The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Certification*. All batches of FD&C Red No. 40 shall be certified in accordance with regulations in part 80 of this chapter.

[42 FR 15654, Mar. 22, 1977, as amended at 59 FR 7636, Feb. 16, 1994]

§ 74.2602 D&C Violet No. 2.

(a) *Identity and specifications*. The color additive D&C Violet No. 2 shall conform in identity and specifications to the requirements of § 74.1602(a)(1) and (b).

(b) *Uses and restrictions*. The color additive D&C Violet No. 2 may be safely used for coloring externally applied cosmetics in amounts consistent with good manufacturing practice.

(c) *Labeling*. The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Certification*. All batches of D&C Violet No. 2 shall be certified in accordance with regulations in part 80 of this chapter.

§ 74.2602a Ext. D&C Violet No. 2.

(a) *Identity*. The color additive Ext. D&C Violet No. 2 is principally the monosodium salt of 2-[(9,10-dihydro-4-hydroxy -9,10-dioxo-1-anthracenyl) amino]-5-methyl-benzenesulfonic acid.

(b) *Specifications*. Ext. D&C Violet No. 2 shall conform to the following specifications and shall be free from impurities, other than those named, to the extent that such other impurities may be avoided by good manufacturing practice:

Sum of volatile matter (at 135 °C) and chlorides and sulfates (calculated as sodium salts), not more than 18 percent.

Water-insoluble matter, not more than 0.4 percent.

1-Hydroxy-9,10-anthracenedione, not more than 0.2 percent.

1,4-Dihydroxy-9,10-anthracenedione, not more than 0.2 percent.

p- Toluidine, not more than 0.1 percent.
p- Toluidine sulfonic acids, sodium salts, not more than 0.2 percent.
Subsidiary colors, not more than 1 percent.
Lead (as Pb), not more than 20 parts per million.
Arsenic (as As), not more than 3 parts per million.
Mercury (as Hg), not more than 1 part per million.
Total color, not less than 80 percent.

(c) *Uses and restrictions*. The color additive Ext. D&C Violet No. 2 may be safely used for coloring externally applied cosmetics in amounts consistent with good manufacturing practice.

(d) *Labeling*. The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification*. All batches of Ext. D&C Violet No. 2 shall be certified in accordance with regulations in part 80 of this chapter.

§ 74.2705 FD&C Yellow No. 5.

(a) *Identity*. The color additive FD&C Yellow No. 5 is principally the trisodium salt of 4,5-dihydro-5-oxo-(1-4-sulfophenyl)-4-[(4-sulfophenyl)azo]-1*H*-pyrazole-3-carboxylic acid (CAS Reg. No. 1934–21–0). To manufacture the additive, 4-aminobenzenesulfonic acid is diazotized using hydrochloric acid and sodium nitrite. The diazo compound is coupled with 4,5-dihydro-5-oxo-1-(4-sulfophenyl)-1*H*-pyrazole-3-carboxylic acid or with the methyl ester, the ethyl ester, or a salt of this carboxylic acid. The resulting dye is purified and isolated as the sodium salt.

(b) *Specifications*. (1) FD&C Yellow No. 5 shall conform to the following specifications and shall be free from impurities other than those named to the extent that such other impurities may be avoided by good manufacturing practice:

Sum of volatile matter at 135 °C (275 °F) and chlorides and sulfates (calculated as sodium salts), not more than 13 percent.
Water-insoluble matter, not more than 0.2 percent.
4,4′-[4,5-Dihydro-5-oxo-4-[(4-sulfophenyl)hydrazono]-1*H*-pyrazol-1,3-diyl]bis[benzenesulfonic acid], trisodium salt, not more than 1 percent.
4-[(4′,5-Disulfo[1,1′-biphenyl]-2-yl)hydrazono]-4,5-dihydro-5-oxo-1-(4-sulfophenyl)-1*H*-pyrazole-3-carboxylic acid, tetrasodium salt, not more than 1 percent.
Ethyl or methyl 4,5-dihydro-5-oxo-1-(4-sulfophenyl)-4-[(4-sulfophenyl)hydrazono]-1*H*-pyrazole-3-carboxylate, disodium salt, not more than 1 percent.
Sum of 4,5-dihydro-5-oxo-1-phenyl-4-[(4-sulfophenyl)azo]-1*H*-pyrazole-3-carboxylic acid, disodium salt, and 4,5-dihydro-5-oxo-4-(phenylazo)-1-(4-sulfophenyl)-1*H*-pyrazole-3-carboxylic acid, disodium salt, not more than 0.5 percent.
4-Aminobenzenesulfonic acid, sodium salt, not more than 0.2 percent.
4,5-Dihydro-5-oxo-1-(4-sulfophenyl)-1*H*-pyrazole-3-carboxylic acid, disodium salt, not more than 0.2 percent.
Ethyl or methyl 4,5-dihydro-5-oxo-1-(4-sulfophenyl)-1*H*-pyrazole-3-carboxylate, sodium salt, not more than 0.1 percent.
4,4′-(1-Triazene-1,3-diyl)bis[benzenesulfonic acid], disodium salt, not more than 0.05 percent.
4-Aminoazobenzene, not more than 75 parts per billion.
4-Aminobiphenyl, not more than 5 parts per billion.
Aniline, not more than 100 parts per billion.
Azobenzene, not more than 40 parts per billion.
Benzidine, not more than 1 part per billion.
1,3-Diphenyltriazene, not more than 40 parts per billion.
Lead (as Pb), not more than 10 parts per million.
Arsenic (as As), not more than 3 parts per million.
Mercury (as Hg), not more than 1 part per million.
Total color, not less than 87 percent.

(2) FD&C Yellow No. 5 Aluminum Lake shall be prepared in accordance with the requirements of § 82.51 of this chapter.

(c) *Uses and restrictions*. (1) FD&C Yellow No. 5 may be safely used for coloring cosmetics generally, including cosmetics intended for use in the area of the eye, in amounts consistent with current good manufacturing practice.

(2) FD&C Yellow No. 5 Aluminum Lake may be safely used for coloring cosmetics intended for use in the area of the eye, subject to the restrictions on use of color additives in § 70.5(b) and (c) of this chapter, in amounts consistent with current good manufacturing practice.

(d) *Labeling*. The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification*. All batches of FD&C Yellow No. 5 shall be certified in accordance with regulations in part 80 of this chapter.

[50 FR 35782, Sept. 4, 1985, as amended at 51 FR 24524, July 7, 1986; 59 FR 60898, Nov. 29, 1994]

§ 74.2706 FD&C Yellow No. 6.

(a) *Identity and specifications*. The color additive FD&C Yellow No. 6 shall conform in identity and specifications to the requirements of § 74.706 (a)(1) and (b).

(b) *Uses and restrictions*. FD&C Yellow No. 6 may be safely used for coloring cosmetics generally in amounts consistent with current good manufacturing practice.

(c) *Labeling*. The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Certification*. All batches of FD&C Yellow No. 6 shall be certified in accordance with regulations in part 80 of this chapter.

[51 FR 41782, Nov. 19, 1986]

§ 74.2707 D&C Yellow No. 7.

(a) *Identity and specifications*. The color additive D&C Yellow No. 7 shall conform in identity and specifications to the requirements of § 74.1707(a)(1) and (b).

(b) *Uses and restrictions*. D&C Yellow No. 7 may be safely used for coloring externally applied cosmetics in amounts consistent with good manufacturing practice.

(c) *Labeling*. The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Certification*. All batches of D&C Yellow No. 7 shall be certified in accordance with regulations in part 80 of this chapter.

§ 74.2707a Ext. D&C Yellow No. 7.

(a) *Identity and specifications*. The color additive Ext. D&C Yellow No. 7 shall conform in identity and specifications to the requirements of § 74.1707a (a)(1) and (b).

(b) *Uses and restrictions*. Ext. D&C Yellow No. 7 may be safely used for coloring externally applied cosmetics in amounts consistent with good manufacturing practice.

(c) *Labeling*. The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Certification*. All batches of Ext. D&C Yellow No. 7 shall be certified in accordance with regulations in part 80 of this chapter.

§ 74.2708 D&C Yellow No. 8.

(a) *Identity and specifications*. The color additive D&C Yellow No. 8 shall conform in identity and specifications to the requirements of § 74.1708(a)(1) and (b).

(b) *Uses and restrictions*. D&C Yellow No. 8 may be safely used for coloring externally applied cosmetics in amounts consistent with good manufacturing practice.

(c) *Labeling*. The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Certification*. All batches of D&C Yellow No. 8 shall be certified in accordance with regulations in part 80 of this chapter.

§ 74.2710 D&C Yellow No. 10.

(a) *Identity and specifications*. The color additive D&C Yellow No. 10 shall conform in identity and specifications to the requirements of § 74.1710(a)(1) and (b).

(b) *Uses and restrictions*. The color additive D&C Yellow No. 10 may be safely used for coloring cosmetics generally in amounts consistent with current good manufacturing practice.

(c) *Labeling*. The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Certification*. All batches of D&C Yellow No. 10 shall be certified in accordance with regulations in part 80 of this chapter.

[48 FR 39220, Aug. 30, 1983, as amended at 49 FR 8432, Mar. 7, 1984]

§ 74.2711 D&C Yellow No. 11.

(a) *Identity and specifications*. The color additive D&C Yellow No. 11 shall conform in identity and specifications to the requirements of § 74.1711(a)(1) and (b).

(b) *Uses and restrictions*. D&C Yellow No. 11 may be safely used for coloring externally applied cosmetics in amounts consistent with good manufacturing practice.

(c) *Labeling*. The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Certification*. All batches of D&C Yellow No. 11 shall be certified in accordance with regulations in part 80 of this chapter.

Subpart D—Medical Devices

§ 74.3045 [Phthalocyaninato(2-)] copper.

(a) *Identity*. The color additive is [phthalocyaninato(2-)] copper (CAS Reg. No. 147–14–8) having the structure shown in Colour Index No. 74160.

(b) *Specifications*. The color additive [phthalocyaninato(2-)] copper shall conform to the following specifications and shall be free from impurities other than those named to the extent that such impurities may be avoided by current good manufacturing practice:

Volatile matter 135 °C (275 °F), not more than 0.3 percent.
Salt content (as NaC1), not more than 0.3 percent.
Alcohol soluble matter, not more than 0.5 percent.
Organic chlorine, not more than 0.5 percent.
Aromatic amines, not more than 0.05 percent.
Lead (as Pb), not more than 40 parts per million.
Arsenic (as As), not more than 3 parts per million.
Mercury (as Hg), not more than 1 part per million.
Total color, not less than 98.5 percent.

(c) *Uses and restrictions*. (1) The color additive [phthalocyaninato(2-)] copper may be safely used to color polypropylene sutures, polybutester (the generic designation for the suture fabricated from 1,4-benzenedicarboxylic acid, polymer with 1,4-butanediol and *alpha*-hydro-*omega*-hydroxypoly(oxy-1,4-butanediyl), CAS Reg. No. 37282–12–5) nonabsorbable sutures for use in general and ophthalmic surgery, polybutylene terephthalate nonabsorbable monofilament sutures for general and ophthalmic surgery, nonabsorbable sutures made from poly(vinylidene fluoride) and poly(vinylidene fluoride-co-hexafluoropropylene) for general and ophthalmic surgery, polymethylmethacrylate monofilament used as supporting haptics for intraocular lenses, and polymers used in orientation marks for intraocular lenses, subject to the following restrictions:

(i) The quantity of the color additive does not exceed 0.5 percent by weight of the suture, haptic material, or orientation mark.

(ii) The dyed suture shall conform in all respects to the requirements of the U.S. Pharmacopeia.

(2) The color additive [phthalocyaninato(2-)] copper may be safely used for coloring contact lenses in amounts not to exceed the minimum reasonably required to accomplish the intended coloring effect.

(3) Authorization for these uses shall not be construed as waiving any of the requirements of section 510(k), 515, or 520(g) the Federal Food, Drug, and Cosmetic Act with respect to the medical device in which [phthalocyaninato(2-)] copper is used.

(d) *Labeling*. The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification*. All batches of [phthalocyaninato (2-)] copper shall be certified in accordance with regulations in part 80 of this chapter.

[48 FR 34947, Aug. 2, 1983, as amended at 50 FR 16228, Apr. 25, 1985; 51 FR 22929, June 24, 1986; 51 FR 28930, Aug. 13, 1986; 51 FR 39371, Oct. 28, 1986; 52 FR 15945, May 1, 1987; 55 FR 19620, May 10, 1990; 64 FR 23186, Apr. 30, 1999; 81 FR 75692, Nov. 1, 2016]

§ 74.3054 D&C Black No. 4.

(a) *Identity*. The color additive D&C Black No. 4 is a high-purity carbon black prepared by the oil furnace process. It is manufactured by the combustion of aromatic petroleum oil feedstock and consists essentially of pure carbon, formed as aggregated fine particles with a surface area range of 50 to 260 meters $(m)^2$/gram.

(b) *Specifications*. D&C Black No. 4 must conform to the following specifications and must be free from impurities other than those named to the extent that such other impurities may be avoided by good manufacturing practice:

(1) Surface area by nitrogen BET (Brunauer, Emmett, Teller) method, 50 to 260 m^2/gram.

(2) Weight loss on heating at 950 °C for 7 minutes (predried for 1 hour at 125 °C), not more than 2 percent.

(3) Ash content, not more than 0.15 percent.

(4) Arsenic (total), not more than 3 milligrams per kilogram (mg/kg) (3 parts per million).

(5) Lead (total), not more than 10 mg/kg (10 parts per million).

(6) Mercury (total), not more than 1 mg/kg (1 part per million).

(7) Total sulfur, not more than 0.65 percent.

(8) Total polycyclic aromatic hydrocarbons (PAHs), not more than 0.5 mg/kg (500 parts per billion).

(9) Benzo[*a*]pyrene, not more than 0.005 mg/kg (5 parts per billion).

(10) Dibenz[*a*,*h*]anthracene, not more than 0.005 mg/kg (5 parts per billion).

(11) Total color (as carbon), not less than 95 percent.

(c) *Uses and restrictions.* (1) D&C Black No. 4 may be safely used at a level not to exceed 1.0 percent by weight of the suture material for coloring ultra-high molecular weight polyethylene non-absorbable sutures for general surgical use.

(2) Authorization and compliance with this use must not be construed as waiving any of the requirements of sections 510(k), 515, and 520(g) of the Federal Food, Drug, and Cosmetic Act with respect to the ultra-high molecular weight polyethylene surgical sutures in which D&C Black No. 4 is used.

(d) *Labeling.* The label of the color additive must conform to the requirements of § 70.25 of this chapter.

(e) *Certification.* All batches of D&C Black No. 4 must be certified in accordance with regulations in part 80 of this chapter.

[83 FR 26359, June 7, 2018]

§ 74.3102 FD&C Blue No. 2.

(a) *Identity.* The color additive FD&C Blue No. 2 shall conform in identity to the requirements of § 74.102(a)(1).

(b) *Specifications.* (1) The color additive FD&C Blue No. 2 for use in coloring surgical sutures shall conform to the following specifications and shall be free from impurities other than those named to the extent that such impurities may be avoided by current good manufacturing practice:

Sum of volatile matter at 135 °C (275 °F) and chlorides and sulfates (calculated as sodium salts), not more than 15 percent.

Water insoluble matter, not more than 0.4 percent.

Isatin-5-sulfonic acid, not more than 0.4 percent.

Isomeric colors, not more than 18 percent.

Lower sulfonated subsidiary colors, not more than 5 percent.

Lead (as Pb), not more than 10 parts per million.

Arsenic (as As), not more than 3 parts per million.

Total color, not less than 85 percent.

(2) The color additive FD&C Blue No. 2–Aluminum Lake on alumina for use in bone cement shall be prepared in accordance with the requirements of § 82.51 of this chapter.

(c) *Uses and restrictions.* (1) The color additive FD&C Blue No. 2 may be safely used for coloring nylon (the copolymer of adipic acid and hexamethylene diamine) surgical sutures for use in general surgery subject to the following restrictions:

(i) The quantity of color additive does not exceed 1 percent by weight of the suture;

(ii) The dyed suture shall conform in all respects to the requirements of the United States Pharmacopeia XX (1980); and

(iii) When the sutures are used for the purposes specified in their labeling, the color additive does not migrate to the surrounding tissues.

(2) The color additive FD&C Blue No. 2–Aluminum Lake on alumina may be safely used for coloring bone cement at a level not to exceed 0.1 percent by weight of the bone cement.

(3) Authorization and compliance with these uses shall not be construed as waiving any of the requirements of sections 510(k), 515, and 520(g) of the Federal Food, Drug, and Cosmetic Act with respect to the medical device in which the color additive FD&C Blue No. 2 and the color additive FD&C Blue No. 2–Aluminum Lake on alumina are used.

(d) *Labeling.* The labels of the color additive FD&C Blue No. 2 and the color additive FD&C Blue No. 2–Aluminum Lake on alumina shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification*. All batches of FD&C Blue No. 2 and its lake shall be certified in accordance with regulations in part 80 of this chapter.

[64 FR 48290, Sept. 3, 1999]

§ 74.3106 D&C Blue No. 6.

(a) *Identity*. The color additive D&C Blue No. 6 is principally [Δ2,2′-biindoline]-3,3′ dione (CAS Reg. No. 482–89–3).

(b) *Specifications*. D&C Blue No. 6 shall conform to the following specifications and shall be free from impurities other than those named to the extent that such impurities may be avoided by good manufacturing practice:

Volatile matter at 135 °C (275 °F), not more than 3 percent.
Matter insoluble in *N,N*-dimethylformamide, not more than 1 percent.
Isatin, not more than 0.3 percent.
Anthranilic acid, not more than 0.3 percent.
Indirubin, not more than 1 percent.
Lead (as Pb), not more than 10 parts per million.
Arsenic (as As), not more than 3 parts per million.
Mercury (as Hg), not more than 1 part per million.
Total color, not less than 95 percent.

(c) *Uses and restrictions*. (1) D&C Blue No. 6 may be safely used at a level—

(i) Not to exceed 0.2 percent by weight of the suture material for coloring polyethylene terephthalate surgical sutures for general surgical use;

(ii) Not to exceed 0.25 percent by weight of the suture material for coloring plain or chromic collagen absorbable sutures for general surgical use;

(iii) Not to exceed 0.5 percent by weight of the suture material for coloring plain or chromic collagen absorbable sutures for ophthalmic surgical use;

(iv) Not to exceed 0.5 percent by weight of the suture material for coloring polypropylene surgical sutures for general surgical use; and

(v) Not to exceed 0.5 percent by weight of the suture material for coloring polydioxanone synthetic absorbable sutures for ophthalmic and general surgical use.

(2) Authorization for these uses shall not be construed as waiving any of the requirements of sections 510(k), 515, and 520(g) of the Federal Food, Drug, and Cosmetic Act with respect to the medical device in which the color additive is used.

(d) *Labeling*. The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification*. All batches of D&C Blue No. 6 shall be certified in accordance with regulations in part 80 of this chapter.

[49 FR 29956, July 25, 1984; 49 FR 34447, Aug. 31, 1984, as amended at 50 FR 30698, July 29, 1985]

§ 74.3206 D&C Green No. 6.

(a) *Identity*. The color additive D&C Green No. 6 shall conform in identity to the requirements of § 74.1206(a).

(b) *Specifications*. The color additive D&C Green No. 6 for use in medical devices shall conform to the specifications of § 74.1206(b).

(c) *Uses and restrictions*. (1) The color additive D&C Green No. 6 may be safely used at a level

(i) Not to exceed 0.03 percent by weight of the lens material for coloring contact lenses;

(ii) Not to exceed 0.75 percent by weight of the suture material for coloring polyethylene terephthalate surgical sutures, including sutures for ophthalmic use;

(iii) Not to exceed 0.1 percent by weight of the suture material for coloring polyglycolic acid surgical sutures with diameter greater than U.S.P. size 8–0, including sutures for ophthalmic use;

(iv) Not to exceed 0.5 percent by weight of the suture material for coloring polyglycolic acid surgical sutures with diameter not greater than U.S.P. size 8–0, including sutures for ophthalmic use;

(v) Not to exceed 0.21 percent by weight of the suture material for coloring poly(glycolic acid-*co*-trimethylene carbonate) sutures (also referred to as 1,4-dioxan-2,5-dione polymer with 1,3-dioxan-2-one) for general surgical use; and

(vi) Not to exceed 0.10 percent by weight of the haptic material for coloring polymethylmethacrylate support haptics of intraocular lenses.

(2) Authorization for these uses shall not be construed as waiving any of the requirements of sections 510(k), 515, and 520(g) of the Federal Food, Drug, and Cosmetic Act with respect to the medical device in which D&C Green No. 6 is used.

(d) *Labeling*. The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification*. All batches of D&C Green No. 6 shall be certified in accordance with regulations in part 80 of this chapter.

[48 FR 13022, Mar. 29, 1983, as amended at 51 FR 9784, Mar. 21, 1986; 51 FR 37909, Oct. 27, 1986; 58 FR 21542, Apr. 22, 1993]

§ 74.3230 D&C Red No. 17.

(a) *Identity and specifications*. The color additive D&C Red No. 17 shall conform in identity and specifications to the requirements of § 74.1317(a)(1) and (b).

(b) *Uses and restrictions*. (1) The substance listed in paragraph (a) of this section may be used as a color additive in contact lens in amounts not to exceed the minimum reasonably required to accomplish the intended coloring effect.

(2) Authorization for this use shall not be construed as waiving any of the requirements of section 510(k), 515, and 520(g) of the Federal Food, Drug, and Cosmetic Act with respect to the contact lens in which the color additive is used.

(c) *Labeling*. The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Certification*. All batches of D&C Red No. 17 shall be certified in accordance with regulations in part 80 of this chapter.

[55 FR 22898, June 5, 1990]

§ 74.3602 D&C Violet No. 2.

(a) *Identity and specifications*. The color additive D&C Violet No. 2 shall conform in identity and specifications to the requirements of § 74.1602(a)(1) and (b).

(b) *Uses and restrictions*. (1) The color additive, D&C Violet No. 2, may be safely used for coloring contact lenses in amounts not to exceed the minimum reasonably required to accomplish the intended coloring effect.

(2) D&C Violet No. 2 may be safely used for coloring sutures for use in surgery subject to the following conditions:

(i) At a level not to exceed 0.2 percent by weight of the suture material for coloring copolymers of 90 percent glycolide and 10 percent L-lactide synthetic absorbable sutures for use in general and ophthalmic surgery; and

(ii) At a level not to exceed 0.3 percent by weight of the suture material for coloring polydioxanone synthetic absorbable sutures for use in general and ophthalmic surgery.

(iii) At a level not to exceed 0.25 percent by weight of the suture material for coloring poliglecaprone 25 (ε-caprolactone/glycolide copolymer) synthetic absorbable sutures for use in general surgery.

(iv) At a level not to exceed 0.1 percent by weight of the suture material for coloring poly(ε-caprolactone) absorbable sutures for use in general surgery.

(v) At a level not to exceed 0.2 percent by weight of the suture material for coloring glycolide/dioxanone/trimethylene carbonate tripolymer absorbable sutures for use in general surgery.

(vi) At a level not to exceed 0.2 percent by weight of the suture material for coloring absorbable sutures prepared from homopolymers of glycolide for use in general surgery.

(3) The color additive, D&C Violet No. 2, may be safely used for coloring polymethylmethacrylate intraocular lens haptics at a level not to exceed 0.2 percent by weight of the haptic material.

(4) The color additive, D&C Violet No. 2, may be safely used for coloring absorbable meniscal tacks made from poly (L-lactic acid) at a level not to exceed 0.15 percent by weight of the tack material.

(5) Authorization for these uses shall not be construed as waiving any of the requirements of sections 510(k), 515, and 520(g) of the Federal Food, Drug, and Cosmetic Act with respect to the medical devices in which the color additive is used.

(c) *Labeling*. The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Certification*. All batches of D&C Violet No. 2 shall be certified in accordance with regulations in part 80 of this chapter.

[52 FR 19722, May 27, 1987, as amended at 55 FR 18868, May 7, 1990; 58 FR 60109, Nov. 15, 1993; 59 FR 11720, Mar. 14, 1994; 63 FR 20098, Apr. 23, 1998; 64 FR 32805, June 18, 1999; 65 FR 46344, July 28, 2000]

§ 74.3708 D&C Yellow No. 8.

(a) *Identity and specifications*. The color additive D&C Yellow No. 8 shall conform in identity and specifications to the requirements of § 74.1708(a)(1) and (b).

(b) *Uses and restrictions*. (1) D&C Yellow No. 8 may be safely used for coloring contact lens solution for coloring disposable daily-wear hydrogel-based soft (hydrophilic) contact lenses at a level not to exceed 0.044 percent in the contact lens solution. Following excitation by ultraviolet light, the colored contact lenses fluoresce a yellow-green color. The contact lens solution colored with D&C Yellow No. 8 is distributed by prescription only and used in accordance with the supplied directions for use. Contact lens solutions containing D&C Yellow No. 8 are intended for use only for coloring contact lenses that are worn for infrequent, celebratory occasions, and not for regular or daily use.

(2) Authorization for this use shall not be construed as waiving any of the requirements of sections 510(k), 515, and 520(g) of the Federal Food, Drug, and Cosmetic Act with respect to the contact lens solution in which the color additive is used.

(c) *Labeling*. The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Certification*. All batches of D&C Yellow No. 8 shall be certified in accordance with regulations in part 80 of this chapter.

[83 FR 48375, Sept. 25, 2018]

§ 74.3710 D&C Yellow No. 10.

(a) *Identity*. The color additive D&C Yellow No. 10 shall conform to the identity requirements of § 74.1710(a).

(b) *Specifications*. The color additive D&C Yellow No. 10 for use in contact lenses shall conform to the specifications of § 74.1710(b).

(c) *Uses and restrictions*. (1) The color additive D&C Yellow No. 10 may be used for coloring contact lenses in amounts not to exceed the minimum reasonably required to accomplish the intended coloring effect.

(2) Authorization for this use shall not be construed as waiving any of the requirements of sections 510(k), 515, and 520(g) of the Federal Food, Drug, and Cosmetic Act with respect to the contact lens in which the color additive is used.

(d) *Labeling*. The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification*. All batches of D&C Yellow No. 10 shall be certified in accordance with regulations in part 80 of this chapter.

[52 FR 28690, Aug. 3, 1987]

PART 80—COLOR ADDITIVE CERTIFICATION

Subpart A—General Provisions

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80.10 Fees for certification services.

Subpart B—Certification Procedures

80.21 Request for certification.
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80.37 Treatment of batch pending certification.
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AUTHORITY: 21 U.S.C. 371, 379e.

SOURCE: 42 FR 15662, Mar. 22, 1977, unless otherwise noted.

Subpart A—General Provisions

§ 80.10 Fees for certification services.

(a) *Fees for straight colors including lakes*. The fee for the services provided by the regulations in this part in the case of each request for certification

submitted in accordance with § 80.21(j)(1) and (j)(2) shall be $0.35 per pound of the batch covered by such requests, but no such fee shall be less than $224.

(b) *Fees for repacks of certified color additives and color additive mixtures.* The fees for the services provided under the regulations in this part in the case of each request for certification submitted in accordance with § 80.21(j)(3) and (j)(4) shall be:

(1) 100 pounds or less—$35.

(2) Over 100 pounds but not over 1,000 pounds—$35 plus $0.06 for each pound over 100 pounds.

(3) Over 1,000 pounds—$89 plus $0.02 for each pound over 1,000 pounds.

(c) *Advance deposits.* Any person regularly requesting certification services may deposit funds in advance of requests as prepayment of fees required by this section.

(d) *Method of payment.* All deposits and fees required by this section shall be paid by money order, bank draft, or certified check, drawn to the order of the Food and Drug Administration, collectible at par at Washington, DC. All such deposits and fees shall be forwarded to the Center for Food Safety and Applied Nutrition (HFS–100), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, whereupon after making appropriate records thereof, they will be transmitted to the Treasurer of the United States for deposit to the special account ''Salaries and Expenses, Certification, Inspection, and Other Services, Food and Drug Administration.''

(e) *Refunds from advance deposits.* Whenever in the judgment of the Commissioner the ratio between fees collected (which are based upon experience and the best estimate of costs and the best estimate of earnings) and the costs of providing the service during an elapsed period of time, in the light of all circumstances and contingencies, warrants a refund from the fund collected during such period, he shall make ratable refunds to those persons to whom the services were rendered and charged, except that no refund shall be made where the computed ratable amount for the elapsed period is less than $5.00.

[42 FR 15662, Mar. 22, 1977, as amended at 47 FR 24692, June 8, 1982; 54 FR 24890, June 12, 1989; 59 FR 60899, Nov. 29, 1994; 61 FR 3572, Feb. 1, 1996; 61 FR 14479, Apr. 2, 1996; 66 FR 56035, Nov. 6, 2001; 70 FR 15756, Mar. 29, 2005; 71 FR 70875, Dec. 7, 2006; 81 FR 49895, July 29, 2016]

Subpart B—Certification Procedures

§ 80.21 Request for certification.

A request for certification of a batch of color additive shall:

(a) Be addressed to the Commissioner of Food and Drugs.

(b) Be prepared in the manner set forth in paragraph (j) of this section.

(c) Be submitted in duplicate.

(d) Be signed by a responsible officer of the person requesting certification of the batch. In the case of a foreign manufacturer, the request for certification must be signed by a responsible officer of such firm, and, by his agent who resides in the United States.

(e) Show the name and post office address of the actual manufacturer in case such manufacturer is not the person requesting certification of the batch.

(f) Be accompanied by the fee prescribed in § 80.10 unless the person has established with the Food and Drug Administration an advanced deposit to be used for prepayment of such fees. In no case shall the Commissioner consider a request for certification of a batch of color additive if the fee accompanying such request is less than that required by § 80.10 or if such fee exceeds the amount held in the advance deposit account of the manufacturer submitting such request for certification.

(g) Be accompanied by the sample prescribed in § 80.22 consisting of:

(1) Four ounces in the case of straight colors and lakes.

(2) Two ounces in the case of repacks and mixtures.

A sample accompanying a request for certification must be submitted under separate cover and should be addressed to the Color Certification Branch.

(h) The name of a color additive shall be given in the following manner:

(1) The name of a straight color shall be the name of the color as listed in parts 74 and 81 of this chapter.

(2) The name of a lake shall be the name derived in the manner described in part 82 of this chapter.

(3) The name of a mixture shall be the name given to such mixture by the person requesting certification.

(4) The name of a repack shall be the name described in paragraph (h)(1), (2), or (3) of this section, whichever is applicable.

(i) The information and samples enumerated in paragraphs (a) to (h), inclusive, of this section are the minimum required. Additional information and samples shall be submitted at the request of the Food and Drug Administration when such additional information and samples are necessary to determine compliance with the requirements of § 80.31 for the issuance of a certificate.

(j) The form for submission of the application shall be one of the following, depending upon whether the color additive is a straight color, a lake, a repack of a previously certified color additive, or a color additive mixture.

(1) *Request for certification of a batch of straight color additive.*

Date _____

Office of Cosmetics and Colors (HFS–100),
Center for Food Safety and Applied Nutrition,
Food and Drug Administration,
5001 Campus Dr.,
College Park, MD 20740

In accordance with the regulations promulgated under the Federal Food, Drug, and Cosmetic Act, we hereby make application for the certification of a batch of straight color additive.

Name of color _____
(As listed in 21 CFR part 74)

Batch number _____
(Manufacturer's number)

Batch weighs ____ pounds
Batch manufactured by _____ at _____ (Name and address of actual manufacturer)

How stored pending certification _____
_____
(State conditions of storage, with kind and size of containers, location, etc.)

Certification requested of this color for use in _____
_____
_____
(State proposed uses)

Required fee, $____ (drawn to the order of Food and Drug Administration).

The accompanying sample was taken after the batch was mixed in accordance with 21 CFR 80.22 and is accurately representative thereof.

(Signed) _____
By _____
_____
(Title)

(2) *Request for certification of a batch of color additive lake.*

Date _____

Office of Cosmetics and Colors (HFS–100),
Center for Food Safety and Applied Nutrition,
Food and Drug Administration,
5001 Campus Dr.,
College Park, MD 20740

In accordance with the regulations promulgated under the Federal Food, Drug, and Cosmetic Act, we hereby make application for the certification of a batch of color additive lake.

Name of color _____
Batch number _____
(Manufacturer's number)

Batch weighs ____ pounds

Name of color used _____

Quantity ____ pounds

Lot number _____
(When certification of the lake for use in foods is requested)

Precipitant used _____
Substratum used _____

Quantity ____ pounds
Batch manufactured by _____ at _____ (Name and address of actual manufacturer)

How stored pending certification _____
_____
(State conditions of storage, with kind and size of containers, location, etc.)

Certification requested of this color for use in _____
_____
_____
(State proposed uses)

Required fee, $____ (drawn to the order of Food and Drug Administration).

The accompanying sample was taken after the batch was mixed in accordance with 21 CFR 80.22 and is accurately representative thereof.

(Signed) _____
By _____
_____
(Title)

(3) *Request for certification of a repack of a batch of certified color additive.*

Date _____

Office of Cosmetics and Colors (HFS–100),
Center for Food Safety and Applied Nutrition,
Food and Drug Administration,
5001 Campus Dr.,
College Park, MD 20740

In accordance with the regulations promulgated under the Federal Food, Drug, and Cosmetic Act, we hereby make application for the certification of a batch of color additive repack.

Name of color _____
(As listed in regulations and as certified; or repacker's name, if a mixture)
Original lot number _____
Certified color content _____
This color obtained from _____
Batch number _____

Batch weighs ____ pounds

How stored pending certification _____
_____
(State conditions of storage, with kind and size of containers, location, etc.)
Certification requested for use in _____
_____
_____
(State proposed uses)

Required fee, $____ (drawn to the order of Food and Drug Administration).

The accompanying sample was taken after the batch was mixed in accordance with 21 CFR 80.22 and is accurately representative thereof.

(Signed) _____
By _____
_____
(Title)

(4) *Request for certification of a batch of color additive mixture.*

Date _____

Office of Cosmetics and Colors (HFS–100),
Center for Food Safety and Applied Nutrition,
Food and Drug Administration,
5001 Campus Dr.,
College Park, MD 20740

In accordance with the regulations promulgated under the Federal Food, Drug, and Cosmetic Act, we hereby make application for the certification of a batch of color additive mixture.

Name of mixture _____
(Manufacturer's trade name)
Batch number _____
(Manufacturer's number)

Weight of batch ____ pounds
Volume of batch ____ (If liquid) gallons

Batch manufactured by _____

Constituents of the mixture:

1. Color(s). (List separately each color and each lot number.)

Name of color as certified	Lot number

Quantity used (*in pounds*)	*Obtained from*

2. List of diluents. (List separately each diluent.)

Name of diluent

Quantity used	
By weight	By volume (*if liquid*)

Batch mixed as follows _____
(Describe in detail)
How stored pending certification _____
_____
(State conditions of storage, with kind and size of containers, location, etc.)
Certification requested for use in _____
_____
_____
(State proposed uses)

Required fee, $____ (drawn to the order of Food and Drug Administration).

The accompanying sample was taken after the batch was mixed in accordance with 21 CFR 80.22 and is accurately representative thereof.

(Signed) _____
By _____
_____
(Title)

[42 FR 15662, Mar. 22, 1977; 44 FR 17658, Mar. 23, 1979; 44 FR 22053, Apr. 13, 1979, as amended at 54 FR 24890, June 12, 1989; 61 FR 14479, Apr. 2, 1996; 66 FR 56035, Nov. 6, 2001; 81 FR 49895, July 29, 2016]

§ 80.22 Samples to accompany requests for certification.

A sample of a batch of color additive which is to accompany a request for certification shall:

(a) Be taken only after such batch has been so thoroughly mixed as to be of uniform composition throughout.

(b) Held under the control of the person requesting certification until certified.

(c) Be labeled to show:

(1) The name of the color additive.

(2) The manufacturer's batch number.

(3) The quantity of such batch.

(4) The name and post-office address of the person requesting certification of such batch.

(5) Be accompanied by any label or labeling intended to be used.

§ 80.31 Certification.

(a) If the Commissioner determines, after such investigations as he considers to be necessary, that:

(1) A request submitted in accordance with § 80.21 appears to contain no untrue statement of a material fact;

(2) Such color additive conforms to the specifications and any other conditions set forth therefor in parts 81 and 82 of this chapter.

(3) The batch covered by such request otherwise appears to comply with the regulations in this chapter, the Commissioner shall issue to the person who submitted such request a certificate showing the lot number assigned to such batch and that such batch, subject to the terms, conditions, and restrictions prescribed by part 74, 81, and 82 of this chapter, is a certified batch.

(b) If the Commissioner determines, after such investigation as he considers to be necessary, that a request submitted in accordance with § 80.21, or the batch of color additive covered by such request, does not comply with the requirements prescribed by paragraph (a) of this section for the issuance of a certificate, the Commissioner shall refuse to certify such batch and shall give notice thereof to the person who submitted such request, stating his reasons for refusal. Any person who contests such refusal shall have an opportunity for a regulatory hearing before the Food and Drug Administration pursuant to part 16 of this chapter.

§ 80.32 Limitations of certificates.

(a) If a certificate is obtained through fraud or misrepresentation of a material fact, such certificate shall not be effective, and a color additive from the batch on which such certificate was issued shall be considered to be from a batch that has not been certified in accordance with the regulations in this part. Whenever, the Commissioner learns that any certificate has been obtained through fraud or material misrepresentation, he shall notify the holder of the certificate that it is of no effect.

(b) If between the time a sample of color additive accompanying a request for certification is taken and the time a certificate covering the batch of such color additive is received by the person to whom it is issued, any such color additive becomes changed in composition, such certificates shall not be effective with respect to such changed color additive and such changed color additive shall be considered to be from a batch that has not been certified in accordance with the regulations in this part.

(c) If at any time after a certificate is received by the person to whom it is issued any color additive from the batch covered by such certificate becomes changed in composition, such certificate shall expire with respect to such changed color additive. After such expiration, such color additive shall be considered to be from a batch that has not been certified in accordance with this part; except that such color additive shall not be so considered when used for coloring a food, drug, or cosmetic, or for the purpose of certifying a batch of a mixture in which such color additive was used as an ingredient, or for use in preparing a batch of a mixture for which exemption from certification has been authorized, if such change resulted solely from such use.

(d) A certificate shall expire with respect to any color additive covered thereby if the package in which such color additive was closed for shipment or delivery is opened. After such expiration such color additive shall be considered to be from a batch that has not been certified, except that such color additive shall not be so considered when the package is opened;

(1) and such color additive is used, subject to the restrictions prescribed by paragraphs (f), (g), and (h) of this section, in coloring a food, drug, or cosmetic;

(2) for the purpose of certifying a batch made by repacking such color;

(3) for the purpose of certifying a batch of a mixture in which such color is used as an ingredient; or

(4) for the purpose of preparing a batch of a mixture for which exemption from certification has been authorized; or

(5) when the package is reopened solely for repackaging by the person to whom such certificate was issued.

(e) A certificate shall not be effective with respect to a package of color additive and such color additive shall be considered to be from a batch that has not been certified if such package is shipped or delivered under a label which does not bear all words, statements, and other information required by § 70.25 of this chapter to appear thereon.

(f) A certificate shall not be effective with respect to a package of color additive, and such color additive shall be considered to be from a batch that has not been certified if:

(1) Such package has not been sealed in accordance with § 70.20 of this chapter.

(2) Such package has been sealed in accordance with § 70.20 of this chapter and the seal has been broken, intentionally or accidentally, unless such seal has been broken for the purpose of using color additive in accordance with § 80.38, or, such package has been opened by a duly authorized representative of the Administration or Department in the performance of his official duties, and he has immediately resealed the package in conformance with § 70.20 of this chapter.

(g) A certificate shall not be effective with respect to a package of color additive and such color additive shall be considered to be from a batch that has not been certified if such color additive is used in any manner other than that for which it was certified.

(h) When the listing or the specifications for a color additive are revoked or amended, the final order effecting the revocation or amendment may specify, in addition to its own effective date, a date on which all certificates for existing batches and portions of batches of such a color additive theretofore issued under such revoked or amended regulations shall cease to be effective; and any such lots of the color additive shall be regarded as uncertified after the date specified unless a new certificate can be and is obtained in conformance with the new regulations. When a certificate thus ceases to be effective for a color additive, any certificates previously issued for a color additive mixture containing that color additive shall cease to be effective on the same date. Use of such color additive or color additive mixture after such specified date without the new certificate in preparing foods, drugs, or cosmetics will result in such food, drugs, or cosmetics being adulterated. When a certified color additive has been used in food, drugs, or cosmetics and the status of the color additive is thereafter changed by amendment or revocation of its listing or specification regulations, such food, drugs, and cosmetics will not be regarded as adulterated by reason of the use of such color additive, unless the hazard to health is such that existing stocks of the foods, drugs, or cosmetics cannot be safely used, in which cases findings to that effect will be made and regulations appropriate for such special cases will be issued.

§ 80.34 Authority to refuse certification service.

(a) When it appears to the Commissioner that a person has:

(1) Obtained, or attempted to obtain, a certificate through fraud or misrepresentation of a material fact.

(2) Falsified the records required to be kept by § 80.39; or

(3) Failed to keep such records, or to make them available, or to accord full opportunity to make inventory of stocks on hand or otherwise to check the correctness of such records, as required by § 80.39; or

(4) Refused to permit duly authorized employees of the Food and Drug Administration free access to all manufacturing facilities, processes, and formulae involved in the manufacture of color additives and intermediates from which such color additives are derived; he may immediately suspend certification service to such person and may continue such suspension until adequate corrective action has been taken.

(b) Any person who contests suspension of service shall have an opportunity for a regulatory hearing before the Food and Drug Administration pursuant to part 16 of this chapter.

§ 80.35 Color additive mixtures; certification and exemption from certification.

(a) *Color additive mixtures to be certified.* Any color additive mixture that contains one or more straight colors listed in part 74 of this chapter, together with any diluents listed in such subparts for use with such straight colors, shall be certified if intended for use in foods, drugs, or cosmetics, or in coloring the human body, as the case may be, subject to any restriction prescribed in parts 70 and 71 of this chapter.

(b) *Color additive mixtures exempted from certification.* A color additive mixture prepared from a previously certified batch of one or more straight colors, with or without any diluent that has been listed in part 73 of this chapter for use in mixtures, shall be exempt from batch certification if the straight color used has not changed in composition in any manner whatsoever since its certification and if it is simply mixed with the approved diluents for exempt mixtures. The label of such color additive mixtures shall not bear the lot number assigned by the Food and Drug Administration to the certified straight color components, but shall bear the manufacturer's control number through which the history of the straight color can be determined.

(c) *Additions to the list of diluents.* A person requesting additions to the list of diluents authorized for the purposes described in paragraphs (a) and (b) of this section shall submit a petition in accordance with the provisions of § 71.1 of this chapter. Each such petition shall be accompanied by the fee prescribed in § 70.19 of this chapter, unless there is an advance deposit to be used for prepayment of such fees.

NOTE: The provisions of § 80.35 with respect only to diluents for use in cosmetic color additive mixtures were stayed, until a regulation is effected listing safe diluents for cosmetic use, including cosmetics which color the human body, 29 FR 18495, Dec. 29, 1964.

§ 80.37 Treatment of batch pending certification.

Immediately after the sample that is to accompany a request for certification of a batch of color additive is taken, the batch shall be:

(a) Stored in containers of such kind as to prevent change in composition.

(b) Held under the control of the person requesting certification until certified.

(c) Marked, by labeling or otherwise, in a manner such that there can be no question as to the identity of the batch and no question that it is not to be used until the requested certificate has been issued.

§ 80.38 Treatment of batch after certification.

(a) Immediately upon notification that a batch of color additive has been certified, the person requesting certification thereof shall identify such batch, by labeling, with the certified lot number.

(b) The person requesting certification shall maintain storage in such manner as to prevent change in composition until such batch has been packaged and labeled as required by §§ 70.20 and 70.25 of this chapter, except that the person requesting certification may use such color additive for the purpose of coloring a food, drug, or cosmetic.

§ 80.39 Records of distribution.

(a) The person to whom a certificate is issued shall keep complete records showing the disposal of all the color additive from the batch covered by such certificate. Upon the request of any officer or employee of the Food and Drug Administration or of any other officer or employee acting on behalf of the Secretary of Health and Human Services, such person, at all reasonable hours until at least 2 years after disposal of all such color additive, shall make such records available to any such officer or employee, and shall accord to such officer or employee full opportunity to make inventory of stocks of such color additive on hand and otherwise to check the correctness of such records.

(b) The records required to be kept by paragraph (a) of this section shall show:

(1) Each quantity used by such person from such batch and the date and kind of such use.

(2) The date and quantity of each shipment or delivery from such batch, and the name and post-office address of the person to whom such shipment or delivery was made.

(c) The records required to be kept by paragraph (a) of this section shall be kept separately from all other records.

PART 81—GENERAL SPECIFICATIONS AND GENERAL RESTRICTIONS FOR PROVISIONAL COLOR ADDITIVES FOR USE IN FOODS, DRUGS, AND COSMETICS

Sec.
81.1 Provisional lists of color additives.
81.10 Termination of provisional listings of color additives.
81.30 Cancellation of certificates.
81.32 Limitation of certificates.

AUTHORITY: 21 U.S.C. 371, 379e, 379e note.

§81.1 Provisional lists of color additives.

The Commissioner of Food and Drugs finds that the following lists of color additives are provisionally listed under section 203(b) of the Color Additive Amendments of 1960 (sec. 203(b), 74 Stat. 405 (21 U.S.C. 379e note)). Except for color additives for which petitions have been filed, progress reports are required by January 1, 1968, and at 6-month intervals thereafter. Specifications for color additives listed in paragraphs (a), (b), and (c) of this section appear in the respective designated sections. The listing of color additives in this section is not to be construed as a listing for surgical suture use unless color additive petitions have been submitted for such use or the Commissioner has been notified of studies underway to establish the safety of the color additive for such use. The color additives listed in paragraphs (a), (b), and (c) of this section may not be used in products which are intended to be used in the area of the eye. The color additives listed in paragraphs (a), (b), and (c) of this section are provisionally listed until the closing dates set forth therein.

(a) *Color additives previously and presently subject to certification and provisionally listed for food, drug, and cosmetic use.*

Color additive	Closing date		Restrictions
	Food use	Drug and cosmetic use	
Lakes (FD&C) (sec. 82.51 of this chapter).			

(b) *Color additives previously and presently subject to certification and provisionally listed for drug and cosmetic use.*

	Closing date	Restrictions
Lakes (D&C) (Sec. 82.2051 of this chapter).		

(c) *Color additives previously and presently subject to certification and provisionally listed for use in externally applied drugs and cosmetics.*

	Closing date	Restrictions
Lakes (Ext. D&C) (sec. 82.105(1) of this chapter)		

[42 FR 15665, Mar. 22, 1977]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting §81.1, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at *www.govinfo.gov*.

§81.10 Termination of provisional listings of color additives.

(a) *Ext. D&C Yellow Nos. 9 and 10.* These colors cannot be produced with any assurance that they do not contain β-naphthylamine as an impurity. While it has been asserted that the two colors can be produced without the impurity named, no method of analysis has been suggested to establish the fact. β-Naphthylamine is a known carcinogen; therefore, there is no scientific evidence that will support a safe tolerance for these colors in products to be used in contact with the skin. The Commissioner of Food and Drugs, having concluded that such action is necessary to protect the public health, hereby terminated the provisional listing of Ext.

D&C Yellow No. 9 and Ext. D&C Yellow No. 10.

(b) [Reserved]

(c) *FD&C Red No. 1.* Results of recent feeding tests of this color additive have demonstrated it to be toxic upon ingestion:

(1) Groups of 50 rats are being fed diets containing FD&C Red No. 1 at levels of 5 percent, 2 percent, 1 percent, 0.5 percent, and 0 percent. At this stage of the tests, which have now been in progress for from 15 months to 18 months, 116 animals from the 250 being fed FD&C Red No. 1 at various levels and 27 of the 100 controls have died. Of these, 11 being fed at the 5 percent level, 16 being fed at the 2 percent level, 11 being fed at the 1 percent level, and 2 being fed at the 0.5 percent level, have shown liver damage. None of the controls that have died have shown liver damage.

(2) Groups of 100 mice are being fed diets containing 2 percent, 1 percent, 0.5 percent, and 0.1 percent FD&C Red No. 1, with 400 mice as controls. All mice on dosage levels of 2 percent and 1 percent died before the seventieth week. Gross liver damage has been observed in all groups fed at the 0.5 percent diet and above.

(3) Groups of 4 dogs are being fed diets containing 2 percent, 1 percent, 0.25 percent, and 0 percent FD&C Red No. 1. Three of the dogs on the 2 percent dosage level died before 32 weeks; the other is living. Three of the dogs on the 1 percent dosage level died or were sacrificed within 13 months. All deceased or sacrificed dogs have shown liver damage grossly and/or microscopically. Deceased dogs on the 1 percent and 2 percent dosage level showed poor physical condition.

The Commissioner of Food and Drugs having concluded that ingestion of this color additive over a long period of time would be unsafe, and in order to protect the public health, hereby terminates the provisional listing of FD&C Red No. 1 for use in foods, drugs, and cosmetics.

(d) *FD&C Red No. 4.* Feeding tests of this color additive have been conducted with three species:

(1) Rats of the Osborne-Mendel and Sprague-Dawley strains were fed FD&C Red No. 4 for 2 years at levels of 5 percent, 2 percent, 1 percent, and 0.5 percent of the diet. No effect was found.

(2) Mice of the C3Hf and C57BL strains were fed FD&C Red No. 4 for 2 years at levels of 2 percent and 1 percent of the diet. No effect was found.

(3) Dogs were fed FD&C Red No. 4 at levels of 2 percent and 1 percent of the diet. Adverse effects were found at both levels in the urinary bladder and in the adrenals. Three dogs of five fed on the 2-percent level died after 6 months, 9 months, and 5½ years on the test. Two of the dogs on the 2-percent level and all five of the dogs on the 1-percent level survived to the completion of the 7 year study.

The Commissioner of Food and Drugs has concluded that available data do not permit the establishment of a safe level of use of this color additive in food, ingested drugs and ingested cosmetics. In order to protect the public health, the Commissioner hereby terminates the provisional listing of FD&C Red No. 4 for use in food and ingested drugs. The Commissioner has previously terminated the provisional listing of FD&C Red No. 4 for use in ingested cosmetics. FD&C Red No. 4 is listed for use in externally applied drugs and cosmetics by §§ 74.1304 and 74.2304 of this chapter, respectively. Section 82.304 of this chapter is retained in part 82 of this chapter to permit the use of lakes of FD&C Red No. 4 in externally applied drugs and cosmetics.

(e) *FD&C Violet No. 1.* The Commissioner of Food and Drugs, in order to protect the public health, hereby terminates the provisional listing of FD&C Violet No. 1 for use in foods, drugs, and cosmetics.

(f) *FD&C Red No. 2.* The Commissioner of Food and Drugs, in order to protect the public health, hereby terminates the provisional listing of FD&C Red No. 2 for use in food, drugs, and cosmetics.

(g) *Carbon black (prepared by the ''impingement'' or ''channel'' process).* The Commissioner of Food and Drugs, in order to protect the public health, hereby terminates the provisional listing of carbon black (prepared by the *impingement* or *channel* process) for use in food, drugs, and cosmetics.

(h) *D&C Red Nos. 10, 11, 12, and 13.* The petition for these color additives was withdrawn so that there no longer exists a basis for their continued provisional listing. In addition, the Commissioner has learned of the possible contamination of D&C Red No. 10, D&C Red No. 11, D&C Red No. 12, and D&C Red No. 13 with β-naphthyl-amine. The Commissioner concludes that these colors cannot be produced with any reasonable assurance that they will not contain β-naphthylamine as an impurity or not yield β-naphthylamine from the metabolism of subsidiary colors present in them. β-Naphthylamine is a known carcinogen; therefore, there is no scientific evidence that will support a safe tolerance for these colors in drugs or cosmetics. The Commissioner of Food and Drugs, upon withdrawal of the petition for their use and in order to protect the public health, hereby terminates the provisional listing of D&C Red No. 10, D&C Red No. 11, D&C Red No. 12, and D&C Red No. 13 for use in drugs and cosmetics, effective December 13, 1977.

(i) *Ext. D&C Yellow No. 1.* The Commissioner has learned of the contamination of Ext. D&C Yellow No. 1 with 4-aminobiphenyl. The Commissioner concludes that this color cannot be produced with any reasonable assurance that it will not contain 4-aminobiphenyl as an impurity or not yield benzidine from the decomposition of a subsidiary reaction product that might be present in the color. 4-Aminobiphenyl and benzidine are known carcinogens; therefore, there is no scientific evidence that will support a safe tolerance for these colors in drugs or cosmetics. In addition, insufficient data have been submitted to permit establishment of appropriate specifications for the batch certification of the color. The Commissioner of Food and Drugs, in order to protect the public health, hereby terminates the provisional listing of Ext. D&C Yellow No. 1 for use in externally applied drugs and cosmetics, effective December 13, 1977.

(j) *Graphite.* Data have been developed that show the contamination of graphite with polynuclear aromatic hydrocarbons (PNA's). There is no reasonable assurance this color can be produced so that it will not contain PNA's as an impurity. The presence of certain PNA's in graphite would indicate that PNA's known to be carcinogenic to animals and humans may also be present. Therefore, there is no scientific evidence that will support a safe tolerance for this color in drugs or cosmetics. The Commissioner of Food and Drugs, in order to protect the public health, hereby terminates the provisional listing of graphite for use in externally applied cosmetics, effective November 29, 1977.

(k) *Ext. D&C Green No. 1.* The Commissioner concludes that there are inadequate analytical methods to permit certification of the color additive Ext. D&C Green No. 1. In addition, the Commissioner has found that there was a failure to comply with the conditions attached to the postponement of the closing date in accordance with section 203(a)(2) of the transitional provisions of the Color Additive Amendments of 1960. The Commissioner of Food and Drugs hereby terminates the provisional listing of Ext. D&C Green No. 1 for use in externally applied drugs and cosmetics, effective November 29, 1977.

(l) [Reserved]

(m) *D&C Orange Nos. 10 and 11.* In the absense of a petition to list D&C Orange No. 10 and D&C Orange No. 11 for use in ingested drugs and cosmetics, there no longer exists a basis for provisional listing for such uses. Therefore, FDA is terminating the provisional listing of D&C Orange No. 10 and D&C Orange No. 11 for use in ingested drugs and cosmetics, effective April 28, 1981.

(n) *D&C Blue No. 6.* The Commissioner of Food and Drugs, having concluded that unresolved questions remain concerning the chemistry of unidentified minor components, hereby terminates the provisional listing of D&C Blue No. 6 for use in drugs and cosmetics.

(o) *D&C Green No. 6.* In the absence of a petition to list D&C Green No. 6 for use in ingested drugs and cosmetics, there no longer exists a basis for provisional listing for such uses. Accordingly, the Commissioner of Food and Drugs hereby terminates the provisional listing of D&C Green No. 6 for use in ingested drugs and cosmetics, effective March 27, 1981.

(p) [Reserved]

(q)(1) *D&C Red No. 19 and D&C Red No. 37.* Having concluded that, when ingested, D&C Red No. 19 causes cancer in rats and mice, the agency hereby terminates the provisional listings of D&C Red No. 19 and chemically related D&C Red No. 37 for use in ingested drugs and ingested cosmetics, effective February 4, 1983.

(2) *D&C Red No. 37.* In the absence of a petition to list D&C Red No. 37 for external uses, there no longer exists a basis for provisional listing for such uses. Accordingly, the Commissioner of Food and Drugs hereby terminates the provisional listings of D&C Red No. 37 for use in externally applied drugs and cosmetics, effective June 6, 1986.

(r) [Reserved]

(s) *D&C Orange No. 17.* Having concluded that, when ingested, D&C Orange No. 17 causes cancer in rats and mice, the agency has terminated the provisional listing of D&C Orange No. 17 for use in ingested drugs and ingested cosmetics, effective March 31, 1983.

(t) *D&C Red No. 8 and D&C Red No. 9.* In the absence of a petition to list D&C Red No. 8 and D&C Red No. 9 for mouthwash, dentifrices, and ingested drugs, except ingested drug lip products, there no longer exists a basis for provisional listing for such uses. Accordingly, the Commissioner of Food and Drugs hereby terminates the provisional listings of D&C Red No. 8 and D&C Red No. 9 for use in mouthwash, dentifrices, and ingested drugs, except ingested drug lip products, effective January 6, 1987.

(u) *FD&C Red No. 3.* Having concluded that FD&C Red No. 3 causes cancer in rats, the agency hereby terminates the provisional listing of FD&C Red No. 3 for use in cosmetics and externally applied drugs and the provisional listing of the lakes of FD&C Red No. 3 for use in food, drug, and cosmetic products, effective January 29, 1990.

[42 FR 15665, Mar. 22, 1977]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 81.10, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at *www.govinfo.gov.*

§ 81.30 Cancellation of certificates.

(a) Certificates issued heretofore for colors being removed from the provisional list (§ 81.10(a)) are cancelled and of no effect after December 1, 1960, and use of such color additives in drugs or cosmetics after that date will result in adulteration.

(b)(1) Certificates issued heretofore for the color additive designated FD&C Red No. 1 are cancelled as of the date of the publication of this Order, and use of this color additive in the manufacture of foods, drugs, or cosmetics after that date will result in adulteration.

(2) The Commissioner finds that no action needs to be taken to remove foods, drugs, and cosmetics containing this color additive from the market on the basis of the scientific evidence before him, taking into account that the additive is not an acute toxic substance and that it is only used in small amounts in foods, drugs, and cosmetics.

(c) Certificates issued for FD&C Red No. 4 and all mixtures containing this color additive are cancelled and have no effect after September 23, 1976 insofar as food, ingested drugs, and ingested cosmetics are concerned, and use of this color additive in the manufacture of food, ingested drugs, and ingested cosmetics after this date will result in adulteration. The certificates shall continue in effect for the use of FD&C Red No. 4 in externally applied drugs and cosmetics. The Commissioner finds, on the basis of the scientific evidence before him that no action has to be taken to remove from the market food, ingested drugs and ingested cosmetics containing the color additive.

(d) Certificates issued for the following color additives and all mixtures containing these color additives are canceled and have no effect after October 4, 1966, and use of such color additives in the manufacture of foods, drugs, or cosmetics after that date will result in adulteration:

FD&C Green No. 1.
FD&C Green No. 2.
D&C Green No. 7.
D&C Red No. 5.
D&C Red No. 14.
D&C Red No. 18.

D&C Red No. 24.
D&C Red No. 29.
D&C Red No. 35.
D&C Red No. 38.
D&C Orange No. 3.
D&C Orange No. 8.
D&C Orange No. 14.
D&C Orange No. 15.
D&C Orange No. 16.
D&C Blue No. 7.
D&C Black No. 1.
Ext. D&C Yellow No. 5.
Ext. D&C Yellow No. 6.
Ext. D&C Red No. 1.
Ext. D&C Red No. 2.
Ext. D&C Red No. 3.
Ext. D&C Red No. 10.
Ext. D&C Red No. 11.
Ext. D&C Red No. 13.
Ext. D&C Red No. 14.
Ext. D&C Red No. 15.
Ext. D&C Blue No. 1.
Ext. D&C Blue No. 4.
Ext. D&C Orange No. 1.
Ext. D&C Orange No. 4.

(e) Certificates issued for the following color additives and all mixtures containing these color additives are canceled and have no effect after July 1, 1968, and use of such color additives in the manufacture of drugs or cosmetics after that date will result in adulteration:

Ext. D&C Yellow No. 3.
Ext. D&C Red No. 8
Ext. D&C Orange No. 3.

(f) Certificates issued for D&C Yellow No. 11 and all mixtures containing this color additive are canceled and have no effect after April 30, 1968, insofar as ingested use is concerned. Use of this color additive in the manufacture of ingested drugs or cosmetics subject to ingestion after that date will result in adulteration.

(g) Certificates issued for D&C Red No. 17, D&C Red No. 31, D&C Red No. 34, D&C Orange No. 4, and D&C Violet No. 2, and all mixtures containing these color additives, are canceled and have no effect after December 31, 1968, insofar as ingested use is concerned. Use of these color additives in the manufacture of ingested drugs or cosmetics subject to ingestion after that date will result in adulteration.

(h)(1) Certificates issued for FD&C Violet No. 1 and all mixtures containing this color additive are canceled and have no effect after April 10, 1973, and use of such color additive in the manufacture of foods, drugs, or cosmetics after that date will result in adulteration.

(2) The Commissioner finds that no action needs to be taken to remove foods, drugs, and cosmetics containing this color additive from the market on the basis of the scientific evidence before him.

(i) Certificates issued prior to July 1, 1968, for D&C Brown No. 1 and Ext. D&C Violet No. 2 and all mixtures containing these colors are canceled and have no effect. This cancellation does not apply to certificates issued after March 15, 1973, for D&C Brown No. 1 and Ext. D&C Violet No. 2, which are provisionally listed in §81.1(b) and (c) respectively for coloring externally applied cosmetics.

(j)(1) Certificates issued for FD&C Red No. 2 and all mixtures containing this color additive are canceled and have no effect after January 28, 1976, and use of this color additive in the manufacture of food, drugs, or cosmetics after this date will result in adulteration.

(2) The Commissioner finds, on the basis of the scientific evidence before him, that no action has to be taken to remove from the market food, drugs, and cosmetics containing the color additive.

(k)(1) Certificates issued for D&C Red No. 10, D&C Red No. 11, D&C Red No. 12, and D&C Red No. 13, their lakes and all mixtures containing these color additives or their lakes are cancelled and have no effect after December 13, 1977, and use of these color additivies in the manufacture of drugs or cosmetics after this date will result in adulteration.

(2) The Commissioner finds, on the basis of the scientific evidence before him, that no action has to be taken to remove from the market, drug and cosmetic products containing the color additives.

(l)(1) Certificates issued for Ext. D&C Yellow No. 1 and all mixtures containing this color additive are cancelled and have no effect after December 13, 1977, and use of this color additive in the manufacture of drugs or cosmetics after this date will result in adulteration.

(2) The Commissioner finds, on the basis of the scientific evidence before him, that no action has to be taken to remove from the market drugs and cosmetics containing the color additive.

(m)(1) Certificates issued for Ext. D&C Green No. 1 and all mixtures containing this color additive are cancelled and have no effect after November 29, 1977, and use of the color additive in the manufacture of drugs or cosmetics after this date will result in adulteration.

(2) The Commissioner finds, on the basis of the scientific evidence before him, that no action has to be taken to remove from the market drugs and cosmetics containing the color additive.

(n)(1) Certificates issued for D&C Orange No. 10, D&C Orange No. 11, their lakes, and all mixtures containing these color additives are cancelled and have no effect as pertains to their use in ingested drugs and cosmetics after April 28, 1981 and use of these color additives in the manufacture of ingested drugs or cosmetics after this date will result in adulteration.

(2) The agency finds, on the basis of the scientific evidence before it, that no action has to be taken to remove from the market drugs and cosmetics to which the color additives were added on or before April 28, 1981.

(o)(1) Certificates issued for D&C Blue No. 6 and all mixtures containing this color additive are cancelled insofar as its use in drugs and cosmetics is concerned and have no effect after December 13, 1977, and use of the color additive in the manufacture of drugs or cosmetics after this date will result in adulteration. The color will continue to be certified for use in the coloring of surgical sutures.

(2) The Commissioner finds, on the basis of the scientific evidence before him, that no action has to be taken to remove from the market drugs and cosmetics containing the color additive.

(p)(1) Certificates issued for D&C Green No. 6, its lakes and all mixtures containing this color additive are cancelled and have no effect as pertains to their use in ingested drugs and cosmetics after May 4, 1982 and use of the color additive in the manufacture of ingested drugs or cosmetics after this date will result in adulteration.

(2) The agency finds, on the basis of the scientific evidence before it, that no action has to be taken to remove from the market ingested drugs and cosmetics containing the color additive.

(q) [Reserved]

(r)(1) Certificates issued for D&C Red No. 19 and D&C Red No. 37, their lakes, and all mixtures containing these color additives are cancelled and have no effect as pertains to their use in ingested drugs and cosmetics after February 4, 1983, and use of these color additives in the manufacture of ingested drugs or cosmetics after this date will result in adulteration.

(2) The agency finds, on the scientific evidence before it, that no action has to be taken to remove from the market ingested drugs and cosmetics to which D&C Red No. 19 and D&C Red No. 37 were added on or before February 4, 1983, or externally applied drugs and cosmetics to which D&C Red No. 37 was added on or before June 6, 1986.

(3) Certificates issued for D&C Red No. 37, its lakes, and all mixtures containing this color additive are cancelled and have no effect as pertains to its use in externally applied drugs and cosmetics after June 6, 1986, and use of this color additive in the manufacture of externally applied drugs or cosmetics after this date will result in adulteration.

(4) Certificates issued for D&C Red No. 19, its lakes, and all mixtures containing this color additive are cancelled and have no effect as pertains to its use in externally applied drugs and cosmetics after July 15, 1988, and use of this color in the manufacture of externally applied drugs or cosmetics after this date will result in adulteration.

(5) The agency finds, on the scientific evidence before it, that no action has to be taken to remove from the market externally applied drugs and cosmetics to which D&C Red No. 19 was added on or before July 15, 1988.

(s)(1) Certificates issued for D&C Red No. 8 and D&C Red No. 9, their lakes, and all mixtures containing these color additives are canceled and have no effect as pertains to their use in mouthwash, dentifrices, and ingested drugs, except ingested drug lip products, after January 6, 1987, and use of these color

additives in the manufacture of mouthwash, dentifrices, and ingested drugs, except ingested drug lip products, after this date will result in adulteration.

(2) The agency finds, on the basis of the scientific evidence before it, that no action has to be taken to remove from the market mouthwash, dentifrices, and ingested drugs to which the color additives were added on or before January 6, 1987. Ingested drug lip products, however, are regulated for use in §§ 74.1308 and 74.1309.

(3) Certificates issued for D&C Red No. 8, and D&C Red No. 9, their lakes, and all mixtures containing these color additives are cancelled and have no effect as pertains to their use in ingested drug and cosmetic lip products and in externally applied drugs and cosmetics after July 15, 1988, and use of these color additives in the manufacture of ingested drugs and cosmetic lip products and in externally applied drugs and cosmetics after this date will result in adulteration.

(4) The agency finds, on the basis of the scientific evidence before it, that no action has to be taken to remove from the market ingested drug and cosmetic lip products and externally applied drugs and cosmetics to which the color additives were added on or before July 15, 1988.

(t)(1) Certificates issued for D&C Orange No. 17, its lakes, and all mixtures containing this color additive are cancelled and have no effect as pertains to its use in ingested drugs and ingested cosmetics after March 31, 1983 and use of this color additive in the manufacture of ingested drugs or ingested cosmetics after this date will result in adulteration.

(2) The agency finds, on the scientific evidence before it, that no action has to be taken to remove from the market drugs and cosmetics to which the color additive was added on or before March 31, 1983.

(3) Certificates issued for D&C Orange No. 17, its lakes and all mixtures containing this color additive are cancelled and have no effect as pertains to its use in externally applied drugs and cosmetics after July 15, 1988, and use of this color in the manufacture of externally applied drugs or cosmetics after this date will result in adulteration.

(4) The agency finds, on the scientific evidence before it, that no action has to be taken to remove from the market externally applied drugs and cosmetics to which D&C Orange No. 17 was added on or before July 15, 1988.

(u)(1) Certificates issued for FD&C Red No. 3 and all mixtures containing this color additive are cancelled and have no effect as pertains to their use in cosmetics and externally applied drugs after January 29, 1990. Certificates issued for FD&C Red No. 3 lakes and all mixtures containing these lakes are cancelled and have no effect as pertains to their use in food, drugs, and cosmetics after January 29, 1990. Certificates issued for D&C Red No. 3 lakes and all mixtures containing those lakes are cancelled and have no effect as pertains to their use in drugs and cosmetics after January 29, 1990. Use of this color additve in the manufacture of cosmetics and of externally applied drugs and any use of the lakes of FD&C Red No. 3 (including the lakes of D&C Red No. 3) after this date will result in adulteration.

(2) The agency finds, on the scientific evidence before it, that no action must be taken to remove from the market food, drugs, and cosmetics to which the provisionally listed color additive or its lakes were added on or before January 29, 1990.

[42 FR 15665, Mar. 22, 1977]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 81.30, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at *www.govinfo.gov*.

§ 81.32 Limitation of certificates.

Certificates issued for the color additives listed in § 81.25 and for all mixtures containing these color additives are limited to the conditions stated in § 81.25. The use of these color additives in drugs and cosmetics in any other manner will result in adulteration. Each of these color additives shall bear a label statement of the tolerance and use limitations applicable to it.

[44 FR 48966, Aug. 21, 1979]

PART 82—LISTING OF CERTIFIED PROVISIONALLY LISTED COLORS AND SPECIFICATIONS

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82.2707a Ext. D&C Yellow No. 7.

AUTHORITY: 21 U.S.C. 371, 379e, 379e note.

SOURCE: 42 FR 15669, Mar. 22, 1977, unless otherwise noted.

Subpart A—General Provisions

§ 82.3 Definitions.

For the purposes of this part:

(a)–(f) [Reserved]

(g) The term *alumina* means a suspension in water of precipitated aluminum hydroxide.

(h) The term *blanc fixe* means a suspension in water of precipitated barium sulfate.

(i) The term *gloss white* means a suspension in water of co-precipitated aluminum hydroxide and barium sulfate.

(j) The term *mixed oxides* means the sum of the quantities of aluminum, iron, calcium, and magnesium (in whatever combination they may exist in a coal-tar color) calculated as aluminum trioxide, ferric oxide, calcium oxide, and magnesium oxide.

(k)–(m) [Reserved]

(n) The term *externally applied drugs and cosmetics* means drugs and cosmetics which are applied only to external parts of the body and not to the lips or any body surface covered by mucous membrane.

(o)–(p) [Reserved]

(q) 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 this part.

§ 82.5 General specifications for straight colors.

No batch of a straight color listed in subpart B, C, or D shall be certified under this part unless:

(a) It is free from all impurities (other than those named in paragraph (b) of this section or in the specifications set forth in such paragraph for such color) to the extent that such impurities can be avoided by good manufacturing practice.

(b) It conforms to the following specifications:

(1) In the case of a straight color listed in subpart B:

(i) Lead (as Pb), not more than 0.001 percent.

(ii) Arsenic (as As_2O_3), not more than 0.00014 percent.

(iii) Heavy metals (except Pb and As) (by precipitation as sulfides), not more than trace.

(2) In the case of a straight color listed in subpart C or D:

(i) Lead (as Pb), not more than 0.002 percent.

(ii) Arsenic (as As_2O_3), not more than 0.0002 percent.

(iii) Heavy metals (except Pb and As) (by precipitation as sulfides), not more than 0.003 percent.

(3) In the case of a straight color which contains a barium salt listed in subpart C or D—soluble barium (in dilute HCl) (as $BaCl_2$), not more than 0.05 percent.

§ 82.6 Certifiable mixtures.

(a) A batch of a mixture which contains no straight color listed in subpart C or D may be certified for use in food, drugs and cosmetics, if:

(1) Each coal-tar color used as an ingredient in mixing such batch is from a previously certified batch and such color has not changed in composition in any manner whatever since such previous certification, except by mixing into such batch of mixture;

(2) Each diluent in such batch of mixture is harmless and suitable for use therein; and

(3) No diluent (except resins, natural gum, pectin and, in the case of mixtures which are aqueous solutions or aqueous pastes, sodium benzoate in a quantity of not more than 1/10 of 1 percent) in such mixture is a nonnutritive substance, unless such mixture is for external application to shell eggs, or for use in coloring a food specified in the requests for certification of such batch submitted in accordance with § 80.21 of this chapter, and such diluent, in the usual process of manufacturing such food, is removed and does not become a component of such food.

(b) A batch of a mixture which contains no straight color listed in subpart D, or which contains a diluent not permitted by paragraph (a)(3) of this section, may be certified in accordance with the provisions of this part, for use only in drugs and cosmetics, if:

(1) Each coal-tar color used as an ingredient in mixing such batch is from a previously certified batch and such color has not changed in composition in any manner whatever since such previous certification, except by mixing into such batch of mixture.

(2) Each diluent in such batch of mixture is harmless and suitable for use therein.

(c) A batch of a mixture which contains a straight color listed in subpart D may be certified in accordance with the provisions of this part, for use only in externally applied drugs and cosmetics, if:

(1) Each coal-tar color used as an ingredient in mixing such batch is from a previously certified batch and such color has not changed in composition in any manner whatever since such previous certification, except by mixing into such batch of mixture; and

(2) Each diluent in such batch of mixture is harmless and suitable for use therein.

Subpart B—Foods, Drugs, and Cosmetics

§ 82.50 General.

A batch of a straight color listed in this subpart may be certified, in accordance with the provisions of the regulations in this part, for use in food, drugs, and cosmetics, if such batch conforms to the requirements of § 82.5 and to the specifications in this subpart set forth for such color.

§ 82.51 Lakes (FD&C).

(a)(1) *General.* Any lake made by extending on a substratum of alumina, a salt prepared from one of the certified water-soluble straight colors hereinbefore listed in this subpart by combining such color with the basic radical aluminum or calcium.

(2) *Specifications.* Prepared from previously certified colors listed in this subpart.

Soluble chlorides and sulfates (as sodium salts), not more than 2.0 percent.

Inorganic matter, insoluble HCl, not more than 0.5 percent.

(b) Each lake made as prescribed in paragraph (a) of this section shall be considered to be a straight color and to be listed therein under the name which is formed as follows:

(1) The listed name of the color from which the lake is prepared;

(2) The name of the basic radical combined in such color; and

(3) The word ''Lake''.

(For example, the name of a lake prepared by extending the aluminum salt prepared from FD&C Blue No. 1 upon

the substratum would be FD&C Blue No. 1—Aluminum Lake.)

§ 82.101 FD&C Blue No. 1.

The color additive FD&C Blue No. 1 shall conform in identity and specifications to the requirements of § 74.101(a)(1) and (b) of this chapter.

§ 82.102 FD&C Blue No. 2.

The color additive FD&C Blue No. 2 shall conform in identity and specifications to the requirements of § 74.102(a)(1) and (b) of this chapter.

[48 FR 5261, Feb. 4, 1983]

§ 82.203 FD&C Green No. 3.

The color additive FD&C Green No. 3 shall conform in identity and specifications to the requirements of § 74.203(a)(1) and (b) of this chapter.

[47 FR 52144, Nov. 19, 1982]

§ 82.304 FD&C Red No. 4.

The color additive FD&C Red No. 4 shall conform in identity and specifications to the requirements of § 74.1304(a)(1) and (b) of this chapter. FD&C Red No. 4 is restricted to use in externally applied drugs and cosmetics.

§ 82.705 FD&C Yellow No. 5.

The color additive FD&C Yellow No. 5 shall conform in identity and specifications to the requirements of § 74.705 (a)(1) and (b) of this chapter.

[51 FR 24519, July 7, 1986]

§ 82.706 FD&C Yellow No. 6.

(a) The color additive FD&C Yellow No. 6 shall conform in identity and specifications to the requirements of § 74.706 (a)(1) and (b) of this chapter.

(b) All lakes including current D&C external and D&C lakes of FD&C Yellow No. 6 shall be manufactured from previously certified batches of the straight color additive.

[52 FR 21509, June 8, 1987]

Subpart C—Drugs and Cosmetics

§ 82.1050 General.

A batch of a straight color listed in this subpart may be certified, in accordance with the provisions of this part, for use only in drugs and cosmetics, if such batch conforms to the requirements of § 82.5 and to the specifications set forth in this subpart for such color.

§ 82.1051 Lakes (D&C).

(a)(1) *General.* Any lake, other than those listed in subpart B, made by extending on a substratum of alumina, blanc fixe, gloss white, clay, titanium dioxide, zinc oxide, talc, rosin, aluminum benzoate, calcium carbonate, or any combination of two or more of these, (i) one of the straight colors (except lakes) listed in subpart B or hereinbefore listed in this subpart, which color is a salt in which is combined the basic radical sodium, potassium, aluminum, barium, calcium, strontium, or zirconium; or (ii) a salt prepared from one of the straight colors (except lakes) listed in subpart B, or hereinbefore listed in this subpart, by combining such color with the basic radical sodium, potassium, aluminum, barium, calcium, strontium, or zirconium.

(2) *Specifications.*

Ether extracts, not more than 0.5 percent.
Soluble chlorides and sulfates (as sodium salts), not more than 3.0 percent.
Intermediates, not more than 0.2 percent.

(b) Each lake made as prescribed in paragraph (a) of this section shall be considered to be a straight color and to be listed therein under the name which is formed as follows:

(1) The listed name of the color from which the lake is prepared, except that if such name contains the symbol ''FD&C'' such symbol shall be changed to ''D&C'';

(2) The name of the basic radical combined in such color; and

(3) The word ''Lake.''

(For example, the name of a lake prepared by extending the color D&C Red No. 9 upon a substratum is ''D&C Red No. 9—Barium Lake'', and a lake prepared by extending the aluminum salt prepared from FD&C Green No. 1 upon a substratum other than alumina is ''D&C Green No. 1—Aluminum Lake''.)

§ 82.1104 D&C Blue No. 4.

The color additive D&C Blue No. 4 shall conform in identity and specifications to the requirements of

§ 74.1104(a)(1) and (b) of this chapter. D&C Blue No. 4 is restricted to use in externally applied drugs and cosmetics.

§ 82.1205 D&C Green No. 5.

The color additive D&C Green No. 5 shall conform in identity and specifications to the requirements of § 74.1205(a)(1) and (b)(2) of this chapter.

[47 FR 24285, June 4, 1982]

§ 82.1206 D&C Green No. 6.

The color additive D&C Green No. 6 shall conform in identity and specifications to the requirements of § 74.1206 (a) and (b) of this chapter. D&C Green No. 6 is restricted to use in externally applied drugs and cosmetics.

[47 FR 14147, Apr. 2, 1982, as amended at 51 FR 9785, Mar. 21, 1986]

§ 82.1254 D&C Orange No. 4.

The color additive D&C Orange No. 4 shall conform in identity and specifications to the requirements of § 74.1254(a)(1) and (b) of this chapter. D&C Orange No. 4 is restricted to use in externally applied drugs and cosmetics.

[42 FR 52396, Sept. 30, 1977]

§ 82.1255 D&C Orange No. 5.

(a) The color additive D&C Orange No. 5 shall conform in identity and specifications to the requirements of § 74.1255(a)(1) and (b) of this chapter. D&C Orange No. 5 is restricted to the uses described in this section.

(b) The color additive D&C Orange No. 5. may be safely used for coloring externally applied drugs in amounts not exceeding 5 milligrams per daily dose of the drug. The color additive D&C Orange No. 5 may be safely used for coloring lipsticks and other cosmetics intended to be applied to the lips in amounts not exceeding 5.0 percent by weight of the finished cosmetic products, and for coloring mouthwashes, dentifrices, and externally applied cosmetics in amounts consistent with current good manufacturing practice.

[49 FR 13343, Apr. 4, 1984]

§ 82.1260 D&C Orange No. 10.

The color additive D&C Orange No. 10 shall conform in identity and specifications to the requirements to § 74.1260(a)(1) and (b) of this chapter. D&C Orange No. 10 is restricted to use in externally applied drugs and cosmetics.

[46 FR 18954, Mar. 27, 1981]

§ 82.1261 D&C Orange No. 11.

The color additive D&C Orange No. 11 shall conform in identity and specifications to the requirements of § 74.1261(a)(1) and (b) of this chapter. D&C Orange No. 11 is restricted to use in externally applied drugs and cosmetics.

[46 FR 18954, Mar. 27, 1981]

§ 82.1306 D&C Red No. 6.

(a) The color additive D&C Red No. 6 shall conform in identity and specifications to the requirements of § 74.1306 (a)(1) and (b) of this chapter.

(b) The color additive D&C Red No. 6 may be safely used for coloring drugs such that the combined total of D&C Red No. 6 and D&C Red No. 7 does not exceed 5 milligrams per daily dose of the drug.

[47 FR 57691, Dec. 28, 1982]

§ 82.1307 D&C Red No. 7.

(a) The color additive D&C Red No. 7 shall conform in identity and specifications to the requirements of § 74.1307 (a)(1) and (b) of this chapter.

(b) The color additive D&C Red No. 7 may be safely used for coloring drugs such that the combined total of D&C Red No. 6 and D&C Red No. 7 does not exceed 5 milligrams per daily dose of the drug.

[47 FR 57691, Dec. 28, 1982]

§ 82.1317 D&C Red No. 17.

The color additive D&C Red No. 17 shall conform in identity and specifications to the requirements of § 74.1317 (a)(1) and (b) of this chapter. D&C Red No. 17 is restricted to use in externally applied drugs and cosmetics.

§ 82.1321 D&C Red No. 21.

The color additive D&C Red No. 21 shall conform in identity and specifications to the requirements of § 74.1321 (a)(1) and (b) of this chapter.

[47 FR 53847, Nov. 30, 1982]

§ 82.1322 D&C Red No. 22.

The color additive D&C Red No. 22 shall conform in identity and specifications to the requirements of § 74.1322 (a)(1) and (b) of this chapter.

[47 FR 53847, Nov. 30, 1982]

§ 82.1327 D&C Red No. 27.

The color additive D&C Red No. 27 shall conform in identity and specifications to the requirements of § 74.1327 (a)(1) and (b) of this chapter.

[47 FR 42568, Sept. 28, 1982]

§ 82.1328 D&C Red No. 28.

The color additive D&C Red No. 28 shall conform in identity and specifications to the requirements of § 74.1328 (a)(1) and (b) of this chapter.

[47 FR 42568, Sept. 28, 1982]

§ 82.1330 D&C Red No. 30.

The color additive D&C Red No. 30 shall conform in identity and specifications to the requirements of § 74.1330 (a)(1) and (b) of this chapter.

[47 FR 22511, May 25, 1982]

§ 82.1331 D&C Red No. 31.

The color additive D&C Red No. 31 shall conform in identity and specifications to the requirements of § 74.1331(a)(1) and (b) of this chapter. D&C Red No. 31 is restricted to use in externally applied drugs and cosmetics.

§ 82.1333 D&C Red No. 33.

(a) The color additive D&C Red. No. 33 shall conform in identity and specifications to the requirements of § 74.1333(a) (1) and (b) of this chapter.

(b) All lakes of D&C Red. No. 33 shall be manufactured from previously certified batches of the straight color additive.

[53 FR 33121, Aug. 30, 1988]

§ 82.1334 D&C Red No. 34.

Calcium salt of 3-hydroxy-4-[(1-sulfo-2 -naphthalenyl)azol-2-naphthalenecarboxylic acid.

Sum of volatile matter (at 135 °C) and chlorides and sulfates (calculated as sodium salts), not more than 15 percent.

2-Amino-1-naphthalenesulfonic acid, calcium salt, not more than 0.2 percent.

3-Hydroxy-2-naphthoic acid, not more than 0.4 percent.

Subsidiary colors, not more than 4 percent.

Total color not less than 85 percent.

§ 82.1336 D&C Red No. 36.

(a) The color additive D&C Red No. 36 shall conform in identity and specifications to the requirements of § 74.1336 (a)(1) and (b) of this chapter.

(b) All lakes of D&C Red No. 36 shall be manufactured from previously certified batches of the straight color additive.

[53 FR 29031, Aug. 2, 1988]

§ 82.1602 D&C Violet No. 2.

The color additive D&C Violet No. 2 shall conform in identity and specifications to the requirements of § 74.1602(a)(1) and (b) of this chapter.

§ 82.1707 D&C Yellow No. 7.

The color additive D&C Yellow No. 7 shall conform in identity and specifications to the requirements of § 74.1707(a)(1) and (b) of this chapter. D&C Yellow No. 7 is restricted to use in externally applied drugs and cosmetics.

§ 82.1708 D&C Yellow No. 8.

The color additive D&C Yellow No. 8 shall conform in identity and specifications to the requirements of § 74.1707(a)(1) and (b) of this chapter. D&C Yellow No. 8 is restricted to use in externally applied drugs and cosmetics.

§ 82.1710 D&C Yellow No. 10.

The color additive D&C Yellow No. 10 shall conform in identity and specifications to the requirements of § 74.1710(a)(1) and (b) of this chapter.

[48 FR 39220, Aug. 30, 1983]

Subpart D—Externally Applied Drugs and Cosmetics

§ 82.2050 General.

A batch of a straight color listed in this subpart may be certified, in accordance with the provisions of this part, for use in externally applied drugs and cosmetics, if such batch conforms to the requirements of § 82.5 and to the specifications set forth in this subpart for such color.

§ 82.2051 Lakes (Ext. D&C).

(a)(1) *General.* Any lake made by extending on a substratum of alumina, blanc fixe, gloss white, clay, titanium dioxide, zinc oxide, talc, rosin, aluminum benzoate, calcium carbonate, or on any combination of two or more of these (i) one of the straight colors hereinbefore listed in this subpart, which color is a salt in which is combined the basic radical sodium, potassium, barium, or calcium; or (ii) a salt prepared from one of the straight colors hereinbefore listed in this subpart by combining such color with the basic radical sodium, potassium, aluminum, barium, calcium, strontium, or zirconium.

(2) *Specifications.*

Ether extracts, not more than 0.5 percent.
Soluble chlorides and sulfates (as sodium salts), not more than 3.0 percent.
Intermediates, not more than 0.2 percent.

(b) Each lake made as prescribed in paragraph (a) of this section shall be considered to be a straight color and to be listed therein under the name which is formed as follows:

(1) The listed name of the color from which the lake is prepared;

(2) The name of the basic radical combined in such color; and

(3) The word ''Lake.'' (For example, the name of a lake prepared by extending the color Ext. D&C Yellow No. 2 upon a substratum is ''Ext. D&C Yellow No. 2—Calcium Lake,'' and a lake prepared by extending the barium salt prepared from Ext. D&C Red No. 2 upon the substratum is ''Ext. D&C Red No. 2—Barium Lake.'')

§ 82.2707a Ext. D&C Yellow No. 7.

The color additive Ext. D&C Yellow No. 7 shall conform in identity with specifications to the requirements of § 74.1707a(a)(1) and (b) of this chapter. Ext. D&C Yellow No. 7 is restricted to use in externally applied drugs and cosmetics.

PARTS 83–98 [RESERVED]

PART 99—DISSEMINATION OF INFORMATION ON UNAPPROVED/NEW USES FOR MARKETED DRUGS, BIOLOGICS, AND DEVICES

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Subpart F—Recordkeeping and Reports

99.501 Recordkeeping and reports.

AUTHORITY: 21 U.S.C. 321, 331, 351, 352, 355, 360, 360c, 360e, 360aa–360aaa–6, 371, and 374; 42 U.S.C. 262.

SOURCE: 63 FR 64581, Nov. 20, 1998, unless otherwise noted.

Subpart A—General Information

§ 99.1 Scope.

(a) This part applies to the dissemination of information on human drugs, including biologics, and devices where the information to be disseminated:

(1) Concerns the safety, effectiveness, or benefit of a use that is not included in the approved labeling for a drug or device approved by the Food and Drug Administration for marketing or in the statement of intended use for a device cleared by the Food and Drug Administration for marketing; and

(2) Will be disseminated to a health care practitioner, pharmacy benefit manager, health insurance issuer, group health plan, or Federal or State Government agency.

(b) This part does not apply to a manufacturer's dissemination of information that responds to a health care practitioner's unsolicited request.

§ 99.3 Definitions.

(a) *Agency* or *FDA* means the Food and Drug Administration.

(b) For purposes of this part, a *clinical investigation* is an investigation in humans that tests a specific clinical hypothesis.

(c) *Group health plan* means an employee welfare benefit plan (as defined in section 3(1) of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1002(1))) to the extent that the plan provides medical care (as defined in paragraphs (c)(1) through (c)(3) of this section and including items and services paid for as medical care) to employees or their dependents (as defined under the terms of the plan) directly or through insurance, reimbursement, or otherwise. For purposes of this part, the term *medical care* means:

(1) Amounts paid for the diagnosis, cure, mitigation, treatment, or prevention of disease, or amounts paid for the purpose of affecting any structure or function of the body;

(2) Amounts paid for transportation primarily for and essential to medical care referred to in paragraph (c)(1) of this section; and

(3) Amounts paid for insurance covering medical care referred to in paragraphs (c)(1) and (c)(2) of this section.

(d) *Health care practitioner* means a physician or other individual who is a health care provider and licensed under State law to prescribe drugs or devices.

(e) *Health insurance issuer* means an insurance company, insurance service, or insurance organization (including a health maintenance organization, as defined in paragraph (e)(2) of this section) which is licensed to engage in the business of insurance in a State and which is subject to State law which regulates insurance (within the meaning of section 514(b)(2) of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1144(b)(2))).

(1) Such term does not include a group health plan.

(2) For purposes of this part, the term *health maintenance organization* means:

(i) A Federally qualified health maintenance organization (as defined in section 1301(a) of the Public Health Service Act (42 U.S.C. 300e(a)));

(ii) An organization recognized under State law as a health maintenance organization; or

(iii) A similar organization regulated under State law for solvency in the same manner and to the same extent as such a health maintenance organization.

(f) *Manufacturer* means a person who manufactures a drug or device or who is licensed by such person to distribute or market the drug or device. For purposes of this part, the term may also include the sponsor of the approved, licensed, or cleared drug or device.

(g) *New use* means a use that is not included in the approved labeling of an approved drug or device, or a use that is not included in the statement of intended use for a cleared device.

(h) *Pharmacy benefit manager* means a person or entity that has, as its principal focus, the implementation of one or more device and/or prescription drug benefit programs.

(i) A *reference publication* is a publication that:

(1) Has not been written, edited, excerpted, or published specifically for, or at the request of, a drug or device manufacturer;

(2) Has not been edited or significantly influenced by such a manufacturer;

(3) Is not solely distributed through such a manufacturer, but is generally available in bookstores or other distribution channels where medical textbooks are sold;

(4) Does not focus on any particular drug or device of a manufacturer that disseminates information under this part and does not have a primary focus on new uses of drugs or devices that are marketed or are under investigation by a manufacturer supporting the dissemination of information; and

(5) Does not present materials that are false or misleading.

(j) *Scientific or medical journal* means a scientific or medical publication:

(1) That is published by an organization that has an editorial board, that uses experts who have demonstrated expertise in the subject of an article under review by the organization and who are independent of the organization, to review and objectively select, reject, or provide comments about proposed articles, and that has a publicly stated policy, to which the organization adheres, of full disclosure of any conflict of interest or biases for all authors or contributors involved with the journal or organization;

(2) Whose articles are peer-reviewed and published in accordance with the regular peer-review procedures of the organization;

(3) That is generally recognized to be of national scope and reputation;

(4) That is indexed in the Index Medicus of the National Library of Medicine of the National Institutes of Health; and

(5) That is not in the form of a special supplement that has been funded in whole or in part by one or more manufacturers.

(k) *Supplemental application* means:

(1) For drugs, a supplement to support a new use to an approved new drug application;

(2) For biologics, a supplement to an approved license application;

(3) For devices that are the subject of a cleared 510(k) submission and devices that are exempt from the 510(k) process, a new 510(k) submission to support a new use or, for devices that are the subject of an approved premarket approval application, a supplement to support a new use to an approved premarket approval application.

Subpart B—Information To Be Disseminated

§ 99.101 Information that may be disseminated.

(a) A manufacturer may disseminate written information concerning the safety, effectiveness, or benefit of a use not described in the approved labeling for an approved drug or device or in the statement of intended use for a cleared device, provided that the manufacturer complies with all other relevant requirements under this part. Such information shall:

(1) Be about a drug or device that has been approved, licensed, or cleared for marketing by FDA;

(2) Be in the form of:

(i) An unabridged reprint or copy of an article, peer-reviewed by experts qualified by scientific training or experience to evaluate the safety or effectiveness of the drug or device involved, which was published in a scientific or medical journal. In addition, the article must be about a clinical investigation with respect to the drug or device and must be considered to be scientifically sound by the experts described in this paragraph; or

(ii) An unabridged reference publication that includes information about a clinical investigation with respect to the drug or device, which experts qualified by scientific training or experience to evaluate the safety or effectiveness of the drug or device that is the subject of the clinical investigation would consider to be scientifically sound;

(3) Not pose a significant risk to the public health;

(4) Not be false or misleading. FDA may consider information disseminated under this part to be false or misleading if, among other things, the information includes only favorable publications when unfavorable publications exist or excludes articles, reference publications, or other information required under § 99.103(a)(4) or the information presents conclusions that clearly cannot be supported by the results of the study; and

(5) Not be derived from clinical research conducted by another manufacturer unless the manufacturer disseminating the information has the permission of such other manufacturer to make the dissemination.

(b) For purposes of this part:

(1) FDA will find that all journal articles and reference publications (as those terms are defined in § 99.3) are scientifically sound except:

(i) Letters to the editor;

(ii) Abstracts of a publication;

(iii) Those regarding Phase 1 trials in healthy people;

(iv) Flagged reference publications that contain little or no substantive discussion of the relevant clinical investigation; and

(v) Those regarding observations in four or fewer people that do not reflect any systematic attempt to collect data, unless the manufacturer demonstrates to FDA that such reports could help guide a physician in his/her medical practice.

(2) A reprint or copy of an article or reference publication is ''unabridged'' only if it retains the same appearance, form, format, content, or configuration as the original article or publication. Such reprint, copy of an article, or reference publication shall not be disseminated with any information that is promotional in nature. A manufacturer may cite a particular discussion about a new use in a reference publication in the explanatory or other information attached to or otherwise accompanying the reference publication under § 99.103.

§ 99.103 Mandatory statements and information.

(a) Any information disseminated under this part shall include:

(1) A prominently displayed statement disclosing:

(i) For a drug, ''This information concerns a use that has not been approved by the Food and Drug Administration.'' For devices, the statement shall read, ''This information concerns a use that has not been approved or cleared by the Food and Drug Administration.'' If the information to be disseminated includes both an approved and unapproved use or uses or a cleared and uncleared use or uses, the manufacturer shall modify the statement to identify the unapproved or uncleared new use or uses. The manufacturer shall permanently affix the statement to the front of each reprint or copy of an article from a scientific or medical journal and to the front of each reference publication disseminated under this part;

(ii) If applicable, the information is being disseminated at the expense of the manufacturer;

(iii) If applicable, the names of any authors of the information who were employees of, or consultants to, or received compensation from the manufacturer, or who had a significant financial interest in the manufacturer during the time that the study that is the subject of the dissemination was conducted up through 1 year after the time the article/reference publication was written and published;

(iv) If applicable, a statement that there are products or treatments that have been approved or cleared for the use that is the subject of the information being disseminated; and

(v) The identification of any person that has provided funding for the conduct of a study relating to the new use of a drug or device for which such information is being disseminated; and

(2) The official labeling for the drug or device;

(3) A bibliography of other articles (that concern reports of clinical investigations both supporting and not supporting the new use) from a scientific reference publication or scientific or medical journal that have been previously published about the new use of the drug or device covered by the information that is being disseminated, unless the disseminated information already includes such a bibliography; and

(4) Any additional information required by FDA under § 99.301(a)(2). Such information shall be attached to the front of the disseminated information or, if attached to the back of the disseminated information, its presence shall be made known to the reader by a sticker or notation on the front of the disseminated information and may consist of:

(i) Objective and scientifically sound information pertaining to the safety or effectiveness of the new use of the drug or device and which FDA determines is

necessary to provide objectivity and balance. This may include information that the manufacturer has submitted to FDA or, where appropriate, a summary of such information and any other information that can be made publicly available; and

(ii) An objective statement prepared by FDA, based on data or other scientifically sound information, bearing on the safety or effectiveness of the new use of the drug or device.

(b) Except as provided in paragraphs (a)(1)(i) and (a)(4) of this section, the statements, bibliography, and other information required by this section shall be attached to such disseminated information.

(c) For purposes of this section, factors to be considered in determining whether a statement is ''prominently displayed'' may include, but are not limited to, type size, font, layout, contrast, graphic design, headlines, spacing, and any other technique to achieve emphasis or notice. The required statements shall be outlined, boxed, highlighted, or otherwise graphically designed and presented in a manner that achieves emphasis or notice and is distinct from the other information being disseminated.

§ 99.105 Recipients of information.

A manufacturer disseminating information on a new use under this part may only disseminate that information to a health care practitioner, a pharmacy benefit manager, a health insurance issuer, a group health plan, or a Federal or State Government agency.

Subpart C—Manufacturer's Submissions, Requests, and Applications

§ 99.201 Manufacturer's submission to the agency.

(a) Sixty days before disseminating any written information concerning the safety, effectiveness, or benefit of a new use for a drug or device, a manufacturer shall submit to the agency:

(1) An identical copy of the information to be disseminated, including any information (e.g., the bibliography) and statements required under § 99.103;

(2) Any other clinical trial information which the manufacturer has relating to the effectiveness of the new use, any other clinical trial information that the manufacturer has relating to the safety of the new use, any reports of clinical experience pertinent to the safety of the new use, and a summary of such information. For purposes of this part, clinical trial information includes, but is not limited to, published papers and abstracts, even if not intended for dissemination, and unpublished manuscripts, abstracts, and data analyses from completed or ongoing investigations. The reports of clinical experience required under this paragraph shall include case studies, retrospective reviews, epidemiological studies, adverse event reports, and any other material concerning adverse effects or risks reported for or associated with the new use. If the manufacturer has no knowledge of clinical trial information relating to the safety or effectiveness of the new use or reports of clinical experience pertaining to the safety of the new use, the manufacturer shall provide a statement to that effect;

(3) An explanation of the manufacturer's method of selecting the articles for the bibliography (e.g., the databases or sources and criteria (i.e., subject headings/keywords) used to generate the bibliography and the time period covered by the bibliography); and

(4) If the manufacturer has not submitted a supplemental application for the new use, one of the following:

(i) If the manufacturer has completed studies needed for the submission of a supplemental application for the new use:

(A) A copy of the protocol for each completed study or, if such protocol was submitted to an investigational new drug application or an investigational device exemption, the number(s) for the investigational new drug application or investigational device exemption covering the new use, the date of submission of the protocol(s), the protocol number(s), and the date of any amendments to the protocol(s); and

(B) A certification stating that, ''On behalf of [insert manufacturer's name], I certify that [insert manufacturer's name] has completed the studies needed for the submission of a supplemental application for [insert new use] and will submit a supplemental application

for such new use to the Food and Drug Administration no later than [insert date no later than 6 months from date that dissemination of information under this part can begin]''; or

(ii) If the manufacturer has planned studies that will be needed for the submission of a supplemental application for the new use:

(A) The proposed protocols and schedule for conducting the studies needed for the submission of a supplemental application for the new use. The protocols shall comply with all applicable requirements in parts 312 of this chapter (investigational new drug applications) and 812 of this chapter (investigational device exemptions). The schedule shall include the projected dates on which the manufacturer expects the principal study events to occur (e.g., initiation and completion of patient enrollment, completion of data collection, completion of data analysis, and submission of the supplemental application); and

(B) A certification stating that, ''On behalf of [insert manufacturer's name], I certify that [insert manufacturer's name] will exercise due diligence to complete the clinical studies necessary to submit a supplemental application for [insert new use] and will submit a supplemental application for such new use to the Food and Drug Administration no later than [insert date no later than 36 months from date that dissemination of information under this part can begin or no later than such time period as FDA may specify pursuant to an extension granted under § 99.303(a)];'' or

(iii) An application for exemption from the requirement of a supplemental application; or

(5) If the manufacturer has submitted a supplemental application for the new use, a cross-reference to that supplemental application.

(b) The manufacturer's attorney, agent, or other authorized official shall sign the submission and certification statement or application for exemption. If the manufacturer does not have a place of business in the United States, the submission and certification statement or application for exemption shall contain the signature, name, and address of the manufacturer's attorney, agent, or other authorized official who resides or maintains a place of business in the United States.

(c) The manufacturer shall send three copies of the submission and certification statement or application for exemption to FDA. The outside of the shipping container shall be marked as ''Submission for the Dissemination of Information on an Unapproved/New Use.'' The manufacturer shall send the submission and certification statement or application for exemption to the appropriate FDA component listed in paragraphs (c)(1) through (c)(3) of this section.

(1) For biological products and devices regulated by the Food and Drug Administration, Center for Biologics Evaluation and Research, Document Control Center, 10903 New Hampshire Ave., Bldg. 71, Rm. G112, Silver Spring, MD 20993–0002;

(2) For human drug products, biological products, and devices regulated by the Center for Drug Evaluation and Research, the Division of Drug Marketing, Advertising, and Communications (HFD–42), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857; or

(3) For medical devices, the Promotion and Advertising Policy Staff (HFZ–302), Office of Compliance, Center for Devices and Radiological Health, Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850.

(d) The 60-day period shall begin when FDA receives a manufacturer's submission, including, where applicable, a certification statement or an application for an exemption.

[63 FR 64581, Nov. 20, 1998, as amended at 70 FR 14980, Mar. 24, 2005; 80 FR 18090, Apr. 3, 2015]

§ 99.203 Request to extend the time for completing planned studies.

(a) A manufacturer may request, prior to or at the time of making a submission to FDA under § 99.201, that FDA extend the 36-month time period for completing the studies and submitting a supplemental application for the new use that is the subject of the information to be disseminated. Such request must set forth the reasons that such studies cannot be completed and

submitted in a supplemental application within 36 months.

(b) A manufacturer who has certified that it will complete the studies necessary to submit a supplemental application for a new use within a specified period of time from the date that dissemination of information under this part can begin under § 99.201(a)(4)(ii), but later finds that it will be unable to complete such studies and submit a supplemental application within that time period may request an extension of time from FDA. The manufacturer, in its request for extension, shall identify the product, the new use, and shall:

(1) Describe the study or studies that cannot be completed on time and explain why the study or studies cannot be completed on time;

(2) Describe the current status of the incomplete study or studies and summarize the work conducted, including the dates on which principal events concerning the study or studies occurred; and

(3) Estimate the additional time needed to complete the studies and submit a supplemental application. The requested extension shall not exceed an additional 24 months.

(c) The manufacturer shall send three copies of the request for extension to the same FDA office that received the manufacturer's initial submission and certification statement. The outside of the envelope shall be marked as ''Request for Time Extension—Dissemination of Information on an Unapproved Use.''

§ 99.205 Application for exemption from the requirement to file a supplemental application.

(a) In certain circumstances, described in paragraph (b) of this section, a manufacturer may submit an application for an exemption from the requirement to submit a supplemental application for a new use for purposes of disseminating information on that use.

(b) The manufacturer's application for an exemption shall identify the basis for the proposed exemption and shall include materials demonstrating that it would be economically prohibitive or that it would be unethical to conduct the studies necessary to submit a supplemental application for the new use.

(1) If the basis for the manufacturer's application for exemption is that it would be economically prohibitive to incur the costs necessary to submit a supplemental application for a new use, the manufacturer shall, at a minimum, provide:

(i) Evidence explaining why existing data characterizing the safety and effectiveness of the drug or device, including data from the study described in the information to be disseminated, are not adequate to support the submission of a supplemental application for the new use. Such evidence shall include an analysis of all data relevant to the safety and effectiveness of the use, a summary of those data, and any documentation resulting from prior discussions with the agency concerning the adequacy of the existing data; and

(ii) Evidence demonstrating that the cost of the study or studies for the new use reasonably exceeds the expected revenue from the new use minus the costs of goods sold and marketing and administrative expenses attributable to the new use of the product. Such evidence shall include:

(A) A description of the additional studies that the manufacturer believes are necessary to support the submission of a supplemental application for the new use, including documentation from prior discussions, if any, with the agency concerning the studies that would be needed, and an estimate of the projected costs for such studies;

(B) The expected patient population for the new use;

(C) The expected revenue for the new use, including an explanation of the price at which the drug or device will be sold;

(D) Any exclusivity for the drug or device for the new use; and

(E) Any other information that the manufacturer has showing that conducting the studies on the new use would be economically prohibitive; and

(iii) An attestation by a responsible individual of the manufacturer or an individual acting on the manufacturer's behalf verifying that the estimates included with the submission are accurate and were prepared in accordance with generally accepted accounting

procedures. The data underlying and supporting the estimates shall be made available to FDA upon request. Alternatively, a manufacturer may submit a report of an independent certified public accountant in accordance with the Statement of Standards for Attestation established by the American Institute of Certified Public Accountants and agreed upon procedures performed with respect to the estimates submitted under this section.

(2) If the basis for the manufacturer's application for exemption is that it would be unethical to conduct the studies necessary for the supplemental application for a new use, the manufacturer shall provide evidence:

(i) Explaining why existing data characterizing the safety and effectiveness of the drug or device, including data from the study described in the information to be disseminated, are not adequate to support the submission of a supplemental application for the new use. Such evidence shall include an analysis of all data relevant to the safety and effectiveness of the new use, a summary of those data, and any documentation resulting from prior discussions with the agency concerning the adequacy of the existing data; and

(ii) Explaining why it would be unethical to conduct the further studies that would be necessary for the approval of the new use. Such evidence shall establish that, notwithstanding the insufficiency of available data to support the submission of a supplemental application for the new use, the data are persuasive to the extent that withholding the drug or device in a controlled study (e.g., by providing no therapy, a placebo, an alternative therapy, or an alternative dose) would pose an unreasonable risk of harm to human subjects. In assessing the appropriateness of conducting studies to support the new use, the manufacturer may provide evidence showing that the new use is broadly accepted as current standard medical treatment or therapy. The manufacturer shall also address the possibility of conducting studies in different populations or of modified design (e.g., adding the new therapy to existing treatments or using an alternative dose if monotherapy studies could not be conducted).

Subpart D—FDA Action on Submissions, Requests, and Applications

§ 99.301 Agency action on a submission.

(a) *Submissions.* Within 60 days after receiving a submission under this part, FDA may:

(1) Determine that the manufacturer does not comply with the requirements under this part and that, as a result, the manufacturer shall not disseminate any information under this part;

(2) After providing the manufacturer notice and an opportunity for a meeting, determine that the information submitted regarding a new use fails to provide data, analyses, or other written matter that is objective and balanced and:

(i) Require the manufacturer to disseminate additional information, including information that the manufacturer has submitted to FDA or, where appropriate, a summary of such information or any other information that can be made publicly available, which, in the agency's opinion:

(A) Is objective and scientifically sound;

(B) Pertains to the safety or effectiveness of the new use; and

(C) Is necessary to provide objectivity and balance; and

(ii) Require the manufacturer to disseminate an objective statement prepared by FDA that is based on data or other scientifically sound information available to the agency and bears on the safety or effectiveness of the drug or device for the new use; and

(3) Require the manufacturer to maintain records that will identify individual recipients of the information that is to be disseminated when such individual records are warranted due to special safety considerations associated with the new use.

(b) *Protocols/Studies.* Within 60 days after receiving a submission under this part, FDA shall:

(1) If the manufacturer has planned studies that will be needed for the submission of a supplemental application

for the new use, review the manufacturer's proposed protocols and schedule for completing such studies and determine whether the proposed protocols are adequate and whether the proposed schedule for completing the studies is reasonable. FDA shall notify the manufacturer of its determination; or

(2) If the manufacturer has completed studies that the manufacturer believes would be an adequate basis for the submission of a supplemental application for the new use, conduct a review of the protocols submitted for such studies to determine whether they are adequate. FDA shall notify the manufacturer of its determination.

§ 99.303 Extension of time for completing planned studies.

(a) Upon review of a drug or device manufacturer's proposed protocols and schedules for conducting studies needed for the submission of a supplemental application for a new use, FDA may, with or without a request for an extension from the manufacturer, determine that such studies cannot be completed and submitted within 36 months. The agency may exercise its discretion in extending the time period for completing the studies and submitting a supplemental application. Extensions under this paragraph are not subject to any time limit, but shall be made before the manufacturer begins the studies needed for the submission of a supplemental application for the new use.

(b) The manufacturer may, after beginning the studies needed for the submission of a supplemental application for a new use, request in writing that FDA extend the time period for conducting studies needed for the submission of a supplemental application for a new use and submitting a supplemental application to FDA. FDA may grant or deny the request or, after consulting the manufacturer, grant an extension different from that requested by the manufacturer. FDA may grant a manufacturer's request for an extension if FDA determines that the manufacturer has acted with due diligence to conduct the studies needed for the submission of a supplemental application for a new use and to submit such a supplemental application to FDA in a timely manner and that, despite such actions, the manufacturer needs additional time to complete the studies and submit the supplemental application. Extensions under this paragraph shall not exceed 24 months.

(c) If FDA extends the time period for completing the studies and submitting a supplemental application under paragraph (a) of this section after the manufacturer has submitted a certification under § 99.201(a)(4)(ii)(B), or if FDA grants a manufacturer's request for an extension under paragraph (b) of this section, the manufacturer shall submit a new certification under § 99.201(a)(4)(ii)(B) that sets forth the timeframe within which clinical studies will be completed and a supplemental application will be submitted to FDA.

§ 99.305 Exemption from the requirement to file a supplemental application.

(a) Within 60 days after receipt of an application for an exemption from the requirement of a supplemental application, FDA shall approve or deny the application.

(1) If FDA does not act on the application for an exemption within the 60-day period, the application for an exemption shall be deemed to be approved.

(2) If an application for an exemption is deemed to be approved, FDA may, at any time, terminate such approval if it determines that the requirements for granting an exemption have not been met. FDA shall notify the manufacturer if the approval is terminated.

(b) In reviewing an application for an exemption, FDA shall consider the materials submitted by the manufacturer and may consider any other appropriate information, including, but not limited to, any pending or previously approved applications for exemption submitted by the manufacturer.

(c) FDA may grant an application for an exemption if FDA determines that:

(1) It would be economically prohibitive for the manufacturer to incur the costs necessary to submit a supplemental application for a new use, which at a minimum requires:

(i) That existing data characterizing the safety and effectiveness of the drug or device, including data from the

study described in the information to be disseminated are not adequate to support the submission of a supplemental application for the new use; and

(ii) That the cost of the study or studies for the new use reasonably exceeds the expected revenue from the new use minus the cost of goods sold and marketing and administrative expenses attributable to the new use of the product, and there are not less expensive ways to obtain the needed information; or

(2) It would be unethical to conduct clinical studies needed to support the submission of a supplemental application for the new use because:

(i) Existing data characterizing the safety and effectiveness of the drug or device, including data from the study described in the information to be disseminated are not adequate to support the submission of a supplemental application for the new use; and

(ii) Although available evidence would not support the submission of a supplemental application for the new use, the data are persuasive to the extent that withholding the drug or device in a controlled study would pose an unreasonable risk of harm to human subjects and no studies in different populations or of modified design can be utilized. In determining whether it would be unethical to conduct clinical studies, the agency shall consider, in addition to the persuasiveness of available evidence of effectiveness, whether the new use of the drug or device is broadly accepted as current standard medical treatment or therapy.

Subpart E—Corrective Actions and Cessation of Dissemination

§ 99.401 Corrective actions and cessation of dissemination of information.

(a) *FDA actions based on post dissemination data.* If FDA receives data after a manufacturer has begun disseminating information on a new use and, based on that data, determines that the new use that is the subject of information disseminated under this part may not be effective or may present a significant risk to public health, FDA shall consult the manufacturer and, after such consultation, take appropriate action to protect the public health. Such action may include ordering the manufacturer to cease disseminating information on the new use and to take appropriate corrective action.

(b) *FDA actions based on information disseminated by a manufacturer.* If FDA determines that a manufacturer is disseminating information that does not comply with the requirements under this part, FDA may:

(1) Provide to the manufacturer an opportunity to bring itself into compliance with the requirements under this part if the manufacturer's noncompliance constitutes a minor violation of these requirements; or

(2) Order the manufacturer to cease dissemination of information and to take corrective action. FDA shall issue such an order only after it has:

(i) Provided notice to the manufacturer regarding FDA's intent to issue an order to cease dissemination; and

(ii) Provided to the manufacturer an opportunity for a meeting. FDA need not provide an opportunity for a meeting if the manufacturer certified that it will submit a supplemental application for the new use within 6 months of the date that dissemination can begin and the noncompliance involves a failure to submit such supplemental application.

(c) *FDA actions based on a manufacturer's supplemental application.* FDA may order a manufacturer to cease disseminating information under this part and to take corrective action if:

(1) In the case of a manufacturer that has submitted a supplemental application for the new use, FDA determines that the supplemental application does not contain adequate information for approval of the new use;

(2) In the case of a manufacturer that has certified that it will submit a supplemental application for the new use within 6 months, the manufacturer has not, within the 6-month period, submitted a supplemental application for the new use;

(3) In the case of a manufacturer that has certified that it will submit a supplemental application for the new use within 36 months or within such time

as FDA has determined to be appropriate under § 99.303(a) or (b), such manufacturer has not submitted the supplemental application within the certified time, or FDA, after an informal hearing, has determined that the manufacturer is not acting with due diligence to initiate or complete the studies necessary to support a supplemental application for the new use; or

(4) In the case of a manufacturer that has certified that it will submit a supplemental application for the new use within 36 months or within such time as FDA has determined to be appropriate under § 99.303(a) or (b), the manufacturer has discontinued or terminated the clinical studies that would be necessary to support a supplemental application for a new use.

(d) *Effective date of orders to cease dissemination.* An order to cease dissemination of information shall be effective upon date of receipt by the manufacturer, unless otherwise stated in such order.

(e) *Cessation of dissemination by a noncomplying manufacturer.* A manufacturer that begins to disseminate information in compliance with this part, but subsequently fails to comply with this part, shall immediately cease disseminating information under this part. A manufacturer that discontinues, terminates, or fails to conduct with due diligence clinical studies that it certified it would complete under § 99.201(a)(4)(ii) shall be deemed not in compliance with this part. A manufacturer shall notify FDA immediately if it ceases dissemination under this paragraph.

§ 99.403 Termination of approvals of applications for exemption.

(a) FDA may, at any time, terminate the approval of an application for an exemption from the requirement to file a supplemental application if:

(1) The application for an exemption had been deemed to be approved because the agency had not acted on the application within 60 days after its receipt by FDA;

(2) The manufacturer is disseminating written information on the new use; and

(3) FDA determines that it would be economically and ethically possible for the manufacturer to conduct the clinical studies needed to submit a supplemental application for the new use.

(b) If FDA terminates a deemed approval of an application for an exemption under paragraph (a) of this section, FDA also may:

(1) Order the manufacturer to cease disseminating information; and

(2) Order the manufacturer to take action to correct the information that has been disseminated if FDA determines that the new use described in the disseminated information would pose a significant risk to public health.

(c) FDA shall notify the manufacturer if it terminates the deemed approval of an application for an exemption under paragraph (a) of this section. If FDA also issues an order to cease dissemination of information, the manufacturer shall comply with the order no later than 60 days after its receipt.

(d) FDA may, at any time, terminate the approval of an application for an exemption from the requirement to file a supplemental application for a new use if, after consulting with the manufacturer that was granted such exemption, FDA determines that the manufacturer no longer meets the requirements for an exemption on the basis that it is economically prohibitive or unethical to conduct the studies needed to submit a supplemental application for the new use.

(e) If FDA terminates an approval of an application for an exemption under paragraph (d) of this section, the manufacturer must, within 60 days of being notified by FDA that its exemption approval has been terminated, file a supplemental application for the new use that is the subject of the information being disseminated under the exemption, certify, under § 99.201(a)(4)(i) or (a)(4)(ii) that it will file a supplemental application for the new use, or cease disseminating the information on the new use. FDA may require a manufacturer that ceases dissemination of information on the new use to undertake corrective action.

§ 99.405 Applicability of labeling, adulteration, and misbranding authority.

The dissemination of information relating to a new use for a drug or device may constitute labeling, evidence of a new intended use, adulteration, or misbranding of the drug or device if such dissemination fails to comply with section 551 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360aaa) and the requirements of this part. A manufacturer's failure to exercise due diligence in submitting the clinical studies that are necessary for the approval of a new use that is the subject of information disseminated under this part or in beginning or completing such clinical studies shall be deemed a failure to comply with section 551 of the act and the requirements of this part.

Subpart F—Recordkeeping and Reports

§ 99.501 Recordkeeping and reports.

(a) A manufacturer disseminating information under this part shall:

(1) Maintain records sufficient to allow the manufacturer to take corrective action as required by FDA. The manufacturer shall make such records available to FDA, upon request, for inspection and copying. Such records shall either:

(i) Identify, by name, those persons receiving the disseminated information; or

(ii) Identify, by category, the recipients of the disseminated information, unless FDA requires the manufacturer to retain records identifying individual recipients of the disseminated information. Manufacturers whose records identify recipients by category only shall:

(A) Identify subcategories of recipients where appropriate (e.g., oncologists, pediatricians, obstetricians, etc.); and

(B) Ensure that any corrective action to be taken will be sufficiently conspicuous to individuals within that category of recipients;

(2) Maintain an identical copy of the information disseminated under this part; and

(3) Upon the submission of a supplemental application to FDA, notify the appropriate office identified in § 99.201(c) of this part.

(b) A manufacturer disseminating information on a new use for a drug or device shall, on a semiannual basis, submit to the FDA office identified in § 99.201(c) of this part:

(1) A list containing the titles of articles and reference publications relating to the new use of drugs or devices that the manufacturer disseminated to a health care practitioner, pharmacy benefit manager, health insurance issuer, group health plan, or Federal or State Government agency. The list shall cover articles and reference publications disseminated in the 6-month period preceding the date on which the manufacturer provides the list to FDA;

(2) A list identifying the categories of health care practitioners, pharmacy benefit managers, health insurance issuers, group health plans, or Federal or State Government agencies that received the articles and reference publications in the 6-month period described in paragraph (b)(1) of this section. The list shall also identify which category of recipients received a particular article or reference publication;

(3) A notice and summary of any additional clinical research or other data relating to the safety or effectiveness of the new use, and, if the manufacturer possesses such clinical research or other data, a copy of the research or data. Such other data may include, but is not limited to, new articles published in scientific or medical journals, reference publications, and summaries of adverse effects that are or may be associated with the new use;

(4) If the manufacturer is conducting studies necessary for the submission of a supplemental application, the manufacturer shall submit periodic progress reports on these studies to FDA. Such reports shall describe the studies' current status (i.e., progress on patient enrollment, any significant problems that could affect the manufacturer's ability to complete the studies, and expected completion dates). If the manufacturer discontinues or terminates a study before completing it, the manufacturer shall, as part of the next periodic progress report, state the reasons

for such discontinuation or termination; and

(5) If the manufacturer was granted an exemption from the requirements to submit a supplemental application for the new use, any new or additional information that relates to whether the manufacturer continues to meet the requirements for such exemption. This information may include, but is not limited to, new or additional information regarding revenues from the product that is the subject of the dissemination and new or additional information regarding the persuasiveness of the data on the new use, including information regarding whether the new use is broadly accepted as current standard medical treatment or therapy.

(c) A manufacturer shall maintain a copy of all information, lists, records, and reports required or disseminated under this part for 3 years after it has ceased dissemination of such information and make such documents available to FDA for inspection and copying.