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person purchasing cigarettes or smokeless tobacco in consideration of the purchase thereof, or to any person in consideration of furnishing evidence, such as credits, proofs-of-purchase, or coupons, of such a purchase.

(c) No manufacturer, distributor, or retailer may sponsor or cause to be sponsored any athletic, musical, artistic, or other social or cultural event, or any entry or team in any event, in the brand name (alone or in conjunction with any other word), logo, symbol, motto, selling message, recognizable color or pattern of colors, or any other indicia of product identification identical or similar to, or identifiable with, those used for any brand of cigarettes or smokeless tobacco. Nothing in this paragraph prevents a manufacturer, distributor, or retailer from sponsoring or causing to be sponsored any athletic, musical, artistic, or other social or cultural event, or team or entry, in the name of the corporation which manufactures the tobacco product, provided that both the corporate name and the corporation were registered and in use in the United States prior to January 1, 1995, and that the corporate name does not include any brand name (alone or in conjunction with any other word), logo, symbol, motto, selling message, recognizable color or pattern of colors, or any other indicia of product identification identical or similar to, or identifiable with, those used for any brand of cigarettes or smokeless tobacco.

**PART 1141—CIGARETTE PACKAGE AND ADVERTISING WARNINGS
(eff. until 11-6-23)****Subpart A—General Provisions**

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AUTHORITY: 15 U.S.C. 1333; 21 U.S.C. 371, 387c, 387f; Secs. 201 and 202, Pub. L. 111-31, 123 Stat. 1776.

SOURCE: 76 FR 36753, June 22, 2011, unless otherwise noted.

EFFECTIVE DATE NOTE: At 85 FR 15708, Mar. 8, 2020, part 1141 was revised, effective June 18, 2021. At 85 FR 32296, May 29, 2020, the effective date was delayed to delayed until Oct. 16, 2021. At 86 FR 3793, Jan. 14, 2021, this amended was further delayed until Jan. 14, 2022. At 86 FR 36509, July 12, 2021, this amendment was further delayed until July 13, 2022. At 86 FR 50855, Sept. 13, 2021, this amendment was further delayed until Oct. 11, 2022. At 86 FR 70052, Dec. 9, 2021, this amendment was further delayed until Jan. 9, 2023. At 87 FR 11295, Mar. 1, 2022, this amendment further delayed until Apr. 9, 2023. At 87 FR 32990, June 1, 2022, this amendment further delayed until July 8, 2023. At 87 FR 50765, Aug. 18, 2022, this amendment further delayed until Oct. 9, 2023. At 87 FR 72387, Nov. 25, 2022, this amendment further delayed until Nov. 6, 2023. For the convenience of the user, the new part 1141 follows the text of this part.

Subpart A—General Provisions**§ 1141.1 Scope.**

(a) This part sets forth the requirements for the display of health warnings on cigarette packages and in advertisements for cigarettes. FDA may require additional statements to be displayed on packages and in advertisements under the Federal Food, Drug, and Cosmetic Act or other authorities.

(b) The requirements of this part do not apply to manufacturers or distributors of cigarettes that do not manufacture, package, or import cigarettes for sale or distribution within the United States.

(c) A cigarette retailer shall not be considered in violation of this part as it applies to the display of health warnings on a cigarette package if the package:

(1) Contains a health warning;

(2) Is supplied to the retailer by a licensee- or permit-holding tobacco

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product manufacturer, importer, or distributor; and

(3) Is not altered by the retailer in a way that is material to the requirements of section 4(a) of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1333(a)) or this part, including by obscuring the warning, by reducing its size, by severing it in whole or in part, or by otherwise changing it in a material way.

(d) A cigarette retailer shall not be considered in violation of this part as it applies to the display of health warnings in an advertisement for cigarettes if the advertisement is not created by or on behalf of the retailer and the retailer is not otherwise responsible for the inclusion of the required warnings. This paragraph shall not relieve a retailer of liability if the retailer displays, in a location open to the public, an advertisement that does not contain a health warning or that contains a warning that has been altered by the retailer in a way that is material to the requirements of section 4(b) of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1333(b)), this part, or section 4(c) of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1333(c)), including by obscuring the warning, by reducing its size, by severing it in whole or in part, or by otherwise changing it in a material way.

§ 1141.3 Definitions.

For the purposes of this part,

Cigarette means:

(1) Any roll of tobacco wrapped in paper or in any substance not containing tobacco; and

(2) Any roll of tobacco wrapped in any substance containing tobacco which, because of its appearance, the type of tobacco used in the filler, or its packaging and labeling, is likely to be offered to, or purchased by, consumers as a cigarette described in paragraph (1) of this definition.

Commerce means:

(1) Commerce between any State, the District of Columbia, the Commonwealth of Puerto Rico, Guam, the U.S. Virgin Islands, American Samoa, Wake Island, Midway Islands, Kingman Reef, or Johnston Island and any place outside thereof;

(2) Commerce between points in any State, the District of Columbia, the Commonwealth of Puerto Rico, Guam, the U.S. Virgin Islands, American Samoa, Wake Island, Midway Islands, Kingman Reef, or Johnston Island, but through any place outside thereof; or

(3) Commerce wholly within the District of Columbia, Guam, the U.S. Virgin Islands, American Samoa, Wake Island, Midway Island, Kingman Reef, or Johnston Island.

Distributor means any person who furthers the distribution of cigarettes at any point from the original place of manufacture to the person who sells or distributes the product to individuals for personal consumption. Common carriers are not considered distributors for the purposes of this part.

Front panel and *rear panel* mean the two largest sides or surfaces of the package.

Importer means any person who imports any cigarette that is intended for sale or distribution to consumers in the United States.

Manufacturer means any person, including any repacker or relabeler, who manufactures, fabricates, assembles, processes, or labels a finished cigarette product.

Package means a pack, box, carton, or container of any kind in which cigarettes are offered for sale, sold, or otherwise distributed to consumers.

Person means an individual, partnership, corporation, or any other business or legal entity.

Required warning means the combination of one of the textual warning statements and its accompanying color graphic, which are set forth in "Cigarette Required Warnings," which is incorporated by reference at § 1141.12.

Retailer means any person who sells cigarettes to individuals for personal consumption, or who operates a facility where vending machines or self-service displays of cigarettes are permitted.

United States, when used in a geographical sense, includes the several States, the District of Columbia, the Commonwealth of Puerto Rico, Guam, the U.S. Virgin Islands, American Samoa, Wake Island, Midway Islands, Kingman Reef, and Johnston Island.

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The term "State" includes any political division of any State.

Subpart B—Cigarette Package and Advertising Warnings

§ 1141.10 Required warnings.

(a) *Packages.* (1) It shall be unlawful for any person to manufacture, package, sell, offer to sell, distribute, or import for sale or distribution within the United States any cigarettes the package of which fails to bear, in accordance with section 4 of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1333) and this part, one of the required warnings on the front and the rear panels.

(2) The required warning shall be obtained from the electronic images contained in "Cigarette Required Warnings," which is incorporated by reference at § 1141.12, and accurately reproduced as specified in "Cigarette Required Warnings."

(3) The required warning shall appear directly on the package and shall be clearly visible underneath the cellophane or other clear wrapping.

(4) The required warning shall be located in the upper portion of the front and rear panels of the package and shall comprise at least the top 50 percent of these panels; *Provided, however,* that on cigarette cartons, the required warning shall be located on the left side of the front and rear panels of the carton and shall comprise at least the left 50 percent of these panels.

(5) The required warning shall be positioned such that the text of the required warning and the other information on that panel of the package have the same orientation.

(b) *Advertisements.* (1) It shall be unlawful for any manufacturer, importer, distributor, or retailer of cigarettes to advertise or cause to be advertised within the United States any cigarette unless its advertising bears, in accordance with section 4 of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1333) and this part, one of the required warnings.

(2) The text in each required warning shall be in the English language, except that:

(i) In the case of an advertisement that appears in a non-English publica-

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tion, the text in the required warning shall appear in the predominant language of the publication whether or not the advertisement is in English; and

(ii) In the case of an advertisement that appears in an English language publication but that is not in English, the text in the required warning shall appear in the same language as that principally used in the advertisement.

(3) For English-language and Spanish-language warnings, each required warning shall be obtained from the electronic images contained in "Cigarette Required Warnings," which is incorporated by reference at § 1141.12, and accurately reproduced as specified in "Cigarette Required Warnings."

(4) For foreign-language warnings, except for Spanish-language warnings, each required warning shall be obtained from the electronic images contained in "Cigarette Required Warnings," which is incorporated by reference at § 1141.12, and accurately reproduced as specified in "Cigarette Required Warnings," including the insertion of a true and accurate translation of the textual warning. The inserted textual warning must comply with the requirements of section 4(b)(2) of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1333(b)(2)).

(5) The required warning shall occupy at least 20 percent of the area of each advertisement, and shall be placed in accordance with the requirements in the Federal Cigarette Labeling and Advertising Act.

(c) *Irremovable or permanent warnings.* The required warnings shall be indelibly printed on or permanently affixed to the package or advertisement. Such warnings, for example, must not be printed or placed on a label affixed to a clear outer wrapper that is likely to be removed to access the product within the package.

§ 1141.12 Incorporation by reference of required warnings.

"Cigarette Required Warnings" Edition 1.0 (June 2011), consisting of electronic files, U.S. Food and Drug Administration, referred to at § 1141.3, § 1141.10(a) and (b), and § 1141.16(a), is incorporated by reference into this section with the approval of the Director

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of the Federal Register under 5 U.S.C. 552(a) and 1 CFR part 51. To enforce any edition other than that specified in this section, FDA must publish notice of change in the FEDERAL REGISTER and the material must be available to the public. All approved material is available for inspection 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. Also, you may obtain a copy of the material by contacting the Center for Tobacco Products, Food and Drug Administration, Office of Health Communication and Education, ATTN: Cigarette Warning File Requests, 9200 Corporate Blvd., Rockville, MD 20850, 1-877-CTP-1373, or cigarettewarningfiles@fda.hhs.gov. You may also obtain the material at <http://www.fda.gov/cigarettewarningfiles>.

§ 1141.14 Misbranding of cigarettes.

(a) A cigarette shall be deemed to be misbranded under section 903(a)(1) of the Federal Food, Drug, and Cosmetic Act if its package does not bear one of the required warnings in accordance with section 4 of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1333) and this part. A cigarette shall be deemed to be misbranded under section 903(a)(7)(A) of the Federal Food, Drug, and Cosmetic Act if its advertising does not bear one of the required warnings in accordance with section 4 of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1333) and this part.

(b) A cigarette advertisement or package will be deemed to include a brief statement of relevant warnings for the purposes of section 903(a)(8) of the Federal Food, Drug, and Cosmetic Act if it bears one of the required warnings in accordance with section 4 of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1333) and this part. A cigarette distributed or offered for sale in any State shall be deemed to be misbranded under section 903(a)(8) of the Federal Food, Drug, and Cosmetic Act unless the manufacturer, packer, or distributor includes in all advertisements and packages issued or caused to be issued by the manufac-

turer, packer, or distributor with respect to the cigarette one of the required warnings in accordance with section 4 of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1333) and this part.

Subpart C—Additional Disclosure Requirements for Cigarette Packages and Advertising**§ 1141.16 Disclosures regarding cessation.**

(a) The required warning shall include a reference to a smoking cessation assistance resource in accordance with, and as specified in, “Cigarette Required Warnings” (incorporated by reference at § 1141.12).

(b) In meeting the smoking cessation needs of an individual caller, the smoking cessation assistance resource required to be referenced by paragraph (a) of this section must, as appropriate:

(1) Provide factual information about the harms to health associated with cigarette smoking and the health benefits of quitting smoking;

(2) Provide factual information about what smokers can expect when trying to quit;

(3) Provide practical advice (problem solving/skills training) about how to deal with common issues faced by smokers trying to quit;

(4) Provide evidence-based advice about how to formulate a plan to quit smoking;

(5) Provide evidence-based information about effective relapse prevention strategies;

(6) Provide factual information on smoking cessation treatments, including FDA-approved cessation medications; and

(7) Provide information, advice, and support that is evidence-based, unbiased (including with respect to products, services, persons, and other entities), and relevant to tobacco cessation.

(c) The smoking cessation resource must:

(1) Other than as described in this section, not advertise or promote any particular product or service;

(2) Except to meet the particularized needs of an individual caller as determined in the context of individual

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counseling, not selectively present information about a subset of FDA-approved cessation products or product categories while failing to mention other FDA-approved cessation products or product categories;

(3) Not provide or otherwise encourage the use of any drug or other medical product that FDA has not approved for tobacco cessation;

(4) Not encourage the use of any non-evidence-based smoking cessation practices;

(5) Ensure that staff providing smoking cessation information, advice, and support are trained specifically to help smokers quit by delivering unbiased and evidence-based information, advice, and support; and

(6) Maintain appropriate controls to ensure the criteria described in paragraphs (b) and (c) of this section are met.

(d) If the Secretary of the Department of Health and Human Services (Secretary) determines that a part of the smoking cessation assistance resource referenced by paragraph (a) of this section does not meet the criteria described in paragraphs (b) and (c) of this section, the Secretary shall take appropriate steps to address the non-compliance.

EFFECTIVE DATE NOTE: At 85 FR 15708, Mar. 8, 2020, part 1141 was revised, effective June 18, 2021. At 85 FR 32296, May 29, 2020, the effective date was delayed to delayed until Oct. 16, 2021. At 86 FR 3793, Jan. 14, 2021, this amended was further delayed until Jan. 14, 2022. At 86 FR 36509, July 12, 2021, this amendment was further delayed until July 13, 2022. At 86 FR 50855, Sept. 13, 2021, this amendment was further delayed until Oct. 11, 2022. At 86 FR 70052, Dec. 9, 2021, this amendment was further delayed until Jan. 9, 2023. At 87 FR 11295, Mar. 1, 2022, this amendment further delayed until Apr. 9, 2023. At 87 FR 32990, June 1, 2022, this amendment further delayed until July 8, 2023. At 87 FR 50765, Aug. 18, 2022, this amendment further delayed until Oct. 9, 2023. At 87 FR 72387, Nov. 25, 2022, this amendment further delayed until Nov. 6, 2023. For the convenience of the user, the new part 1141 is set forth as follows:

21 CFR Ch. I (4-1-23 Edition)**PART 1141—REQUIRED WARNINGS FOR CIGARETTE PACKAGES AND ADVERTISEMENTS (eff. 11-6-23)****Subpart A—General Provisions**

Sec.

1141.1 Scope.

1141.3 Definitions.

1141.5 Incorporation by reference.

Subpart B—Required Warnings for Cigarette Packages and Advertisements

1141.10 Required warnings.

1141.12 Misbranding of cigarettes.

AUTHORITY: 15 U.S.C. 1333; 21 U.S.C. 371, 374, 387c, 387e, 387i; Secs. 201 and 202, Pub. L. 111-31, 123 Stat. 1776.

Subpart A—General Provisions**§ 1141.1 Scope.**

(a) This part sets forth the requirements for the display of required warnings on cigarette packages and in advertisements for cigarettes.

(b) The requirements of this part do not apply to manufacturers or distributors of cigarettes that do not manufacture, package, or import cigarettes for sale or distribution within the United States.

(c) A cigarette retailer will not be in violation of § 1141.10 for packaging that:

(1) Contains a warning;

(2) Is supplied to the retailer by a license-or permit-holding tobacco product manufacturer, or distributor; and

(3) Is not altered by the retailer in a way that is material to the requirements of section 4 of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1333) or this part.

(d) Section 1141.10(d) applies to a cigarette retailer only if that retailer is responsible for or directs the warnings required under § 1141.10 for advertising. However, this paragraph (d) does not relieve a retailer of liability if the retailer displays, in a location open to the public, an advertisement that does not contain a warning or has been altered by the retailer in a way that is material to the requirements of section 4 of the Federal Cigarette Labeling and Advertising Act or this part.

§ 1141.3 Definitions.

For purposes of this part:

Cigarette means—

(1) Any roll of tobacco wrapped in paper or in any substance not containing tobacco; and

(2) Any roll of tobacco wrapped in any substance containing tobacco which, because of its appearance, the type of tobacco used in the filler, or its packaging and labeling, is likely to be offered to, or purchased by, consumers as a cigarette described in paragraph (1) of this definition.

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Commerce means:

(1) Commerce between any State, the District of Columbia, the Commonwealth of Puerto Rico, Guam, the Virgin Islands, American Samoa, Wake Island, Midway Islands, Kingman Reef, or Johnston Island and any place outside thereof;

(2) Commerce between points in any State, the District of Columbia, the Commonwealth of Puerto Rico, Guam, the Virgin Islands, American Samoa, Wake Island, Midway Islands, Kingman Reef, or Johnston Island, but through any place outside thereof; or

(3) Commerce wholly within the District of Columbia, Guam, the Virgin Islands, American Samoa, Wake Island, Midway Island, Kingman Reef, or Johnston Island.

Distributor means any person who furthers the distribution of cigarettes, whether domestic or imported, at any point from the original place of manufacture to the person who sells or distributes the product to individuals for personal consumption. Common carriers are not considered distributors for the purposes of this part.

Front panel and *rear panel* mean the two largest sides or surfaces of the package.

Manufacturer means any person, including any repacker or relabeler, who manufactures, fabricates, assembles, processes, or labels a finished cigarette product; or imports any cigarette that is intended for sale or distribution to consumers in the United States.

Package or *packaging* means a pack, box, carton, or container of any kind in which cigarettes are offered for sale, sold, or otherwise distributed to consumers.

Person means an individual, partnership, corporation, or any other business or legal entity.

Retailer means any person who sells cigarettes to individuals for personal consumption, or who operates a facility where vending machines or self-service displays of cigarettes are permitted.

United States, when used in a geographical sense, includes the several States, the District of Columbia, the Commonwealth of Puerto Rico, Guam, the Virgin Islands, American Samoa, Wake Island, Midway Islands, Kingman Reef, and Johnston Island. The term "State" includes any political division of any State.

§ 1141.5 Incorporation by reference.

(a) Certain material is incorporated by reference into this part with the approval of the Director of the Federal Register under 5 U.S.C. 552(a) and 1 CFR part 51. All approved material is available for inspection at U.S. Food and Drug Administration, Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, and is available from the source listed in paragraph (b) of this section. It is also available for inspection at the National Archives and Records Administration (NARA). For information on

the availability of this material at NARA, email fedreg.legal@nara.gov or go to www.archives.gov/federal-register/cfr/ibr-locations.html.

(b) Center for Tobacco Products, U.S. Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993; 1-888-463-6332. You may also obtain the material at <https://www.fda.gov/cigarette-warning-files>.

(1) "Required Cigarette Health Warnings, 2020", IBR approved for § 1141.10.

(2) [Reserved]

Subpart B—Required Warnings for Cigarette Packages and Advertisements

§ 1141.10 Required warnings.

(a) *Required warnings.* A required warning must include the following:

(1) One of the following textual warning label statements:

(i) WARNING: Tobacco smoke can harm your children.

(ii) WARNING: Tobacco smoke causes fatal lung disease in nonsmokers.

(iii) WARNING: Smoking causes type 2 diabetes, which raises blood sugar.

(iv) WARNING: Smoking reduces blood flow to the limbs, which can require amputation.

(v) WARNING: Smoking causes cataracts, which can lead to blindness.

(vi) WARNING: Smoking causes bladder cancer, which can lead to bloody urine.

(vii) WARNING: Smoking reduces blood flow, which can cause erectile dysfunction.

(viii) WARNING: Smoking causes head and neck cancer.

(ix) WARNING: Smoking can cause heart disease and strokes by clogging arteries.

(x) WARNING: Smoking during pregnancy stunts fetal growth.

(xi) WARNING: Smoking causes COPD, a lung disease that can be fatal.

(2) A color graphic to accompany the textual warning label statement.

(b) *Accurately reproduced.* Each required warning, comprising a combination of a textual warning label statement and its accompanying color graphic, must be accurately reproduced as shown in the materials contained in "Required Cigarette Health Warnings, 2020," which is incorporated by reference at § 1141.5.

(c) *Packages.* It is unlawful for any person to manufacture, package, sell, offer to sell, distribute, or import for sale or distribution within the United States any cigarettes unless the package of which bears a required warning in accordance with section 4 of the Federal Cigarette Labeling and Advertising Act and this part.

(1) The required warning must appear directly on the package and must be clearly visible underneath any cellophane or other clear wrapping.

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(2) The required warning must comprise at least the top 50 percent of the front and rear panels; provided, however, that on cigarette cartons, the required warning must be located on the left side of the front and rear panels of the carton and must comprise at least the left 50 percent of these panels.

(3) The required warning must be positioned such that the text of the required warning and the other information on that panel of the package have the same orientation.

(d) *Advertisements*. It is unlawful for any manufacturer, distributor, or retailer of cigarettes to advertise or cause to be advertised within the United States any cigarette unless each advertisement bears a required warning in accordance with section 4 of the Federal Cigarette Labeling and Advertising Act and this part.

(1) For print advertisements and other advertisements with a visual component (including, for example, advertisements on signs, retail displays, internet web pages, digital platforms, mobile applications, and email correspondence), the required warning must appear directly on the advertisement.

(2) The required warning must comprise at least 20 percent of the area of the advertisement in a conspicuous and prominent format and location at the top of each advertisement within the trim area, if any.

(3) The text in each required warning must be in the English language, except as follows:

(i) In the case of an advertisement that appears in a non-English medium, the text in the required warning must appear in the predominant language of the medium whether or not the advertisement is in English; and

(ii) In the case of an advertisement that appears in an English language medium but that is not in English, the text in the required warning must appear in the same language as that principally used in the advertisement.

(4) For English-language and Spanish-language warnings, each required warning must be accurately reproduced as shown in the materials contained in "Required Cigarette Health Warnings, 2020," which is incorporated by reference at §1141.5.

(5) For non-English-language warnings, other than Spanish-language warnings, each required warning must be accurately reproduced as shown in the materials contained in "Required Cigarette Health Warnings, 2020," which is incorporated by reference at §1141.5, including the substitution and insertion of a true and accurate translation of the textual warning label statement in place of the English language version. The inserted textual warning label statement must comply with the requirements of section 4 of the Federal Cigarette Labeling and Advertising Act, including area and other formatting requirements, and this part.

(e) *Irremovable or permanent warnings*. The required warnings must be indelibly printed on or permanently affixed to the package or advertisement. These warnings, for example, must not be printed or placed on a label affixed to a clear outer wrapper that is likely to be removed to access the product within the package.

(f) *Sale or distribution*. No person may manufacture, package, sell, offer for sale, distribute, or import for sale or distribution within the United States cigarettes whose packages or advertisements are not in compliance with section 4 of the Federal Cigarette Labeling and Advertising Act and this part, except as provided by §1141.1(c) and (d).

(g) *Marketing requirements*—(1) *Random display*. The required warnings for packages specified in paragraph (a) of this section must be randomly displayed in each 12-month period, in as equal a number of times as is possible on each brand of the product and be randomly distributed in all areas of the United States in which the product is marketed in accordance with a plan submitted by the tobacco product manufacturer, distributor, or retailer to, and approved by, the Food and Drug Administration.

(2) *Rotation*. The required warnings for advertisements specified in paragraph (a) of this section must be rotated quarterly in alternating sequence in advertisements for each brand of cigarettes in accordance with a plan submitted by the tobacco product manufacturer, distributor, retailer to, and approved by, the Food and Drug Administration.

(3) *Review*. The Food and Drug Administration will review each plan submitted under this section and approve it if the plan:

(i) Will provide for the equal distribution and display on packaging and the rotation required in advertising under this subsection; and

(ii) Assures that all of the labels required under this section will be displayed by the tobacco product manufacturer, distributor, or retailer at the same time.

(4) *Record retention*. Each tobacco product manufacturer required to randomly and equally display and distribute warnings on packaging or rotate warnings in advertisements in accordance with an FDA-approved plan under section 4 of the Federal Cigarette Labeling and Advertising Act and this part must maintain a copy of such FDA-approved plan and make it available for inspection and copying by officers or employees duly designated by the Secretary of Health and Human Services. The FDA-approved plan must be retained while in effect and for a period of not less than 4 years from the date it was last in effect.

§1141.12 Misbranding of cigarettes.

(a) A cigarette will be deemed to be misbranded under section 903(a)(1) of the Federal

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Food, Drug, and Cosmetic Act if its package does not bear one of the required warnings in accordance with section 4 of the Federal Cigarette Labeling and Advertising Act and this part. A cigarette will be deemed to be misbranded under section 903(a)(7)(A) of the Federal Food, Drug, and Cosmetic Act if its advertising does not bear one of the required warnings in accordance with section 4 of the Federal Cigarette Labeling and Advertising Act and this part.

(b) A cigarette advertisement and other descriptive printed matter issued or caused to be issued by the manufacturer, packer, or distributor will be deemed to include a brief statement of relevant warnings for the purposes of section 903(a)(8) of the Federal Food, Drug, and Cosmetic Act if it bears one of the required warnings in accordance with section 4 of the Federal Cigarette Labeling and Advertising Act and this part. A cigarette distributed or offered for sale in any State shall be deemed to be misbranded under section 903(a)(8) of the Federal Food, Drug, and Cosmetic Act unless the manufacturer, packer, or distributor includes in all advertisements and other descriptive printed matter issued or caused to be issued by the manufacturer, packer, or distributor with respect to the cigarette one of the required warnings in accordance with section 4 of the Federal Cigarette Labeling and Advertising Act and this part.

PART 1143—MINIMUM REQUIRED WARNING STATEMENTS

Sec.

1143.1 Definitions.

1143.3 Required warning statement regarding addictiveness of nicotine.

1143.5 Required warning statements for cigars.

1143.7 Language requirements for required warning statements.

1143.9 Irremovable or permanent required warning statements.

1143.11 Does not apply to foreign distribution.

1143.13 Effective date.

AUTHORITY: 21 U.S.C. 387a(b), 387f(d), Pub. L. 117-103, 136 Stat. 49.

SOURCE: 81 FR 29103, May 10, 2016, unless otherwise noted.

§ 1143.1 Definitions.

For purposes of this part:

Accessory means any product that is intended or reasonably expected to be used with or for the human consumption of a tobacco product; does not contain tobacco and is not made or derived

from tobacco; and meets either of the following:

(1) Is not intended or reasonably expected to affect or alter the performance, composition, constituents, or characteristics of a tobacco product; or

(2) Is intended or reasonably expected to affect or maintain the performance, composition, constituents, or characteristics of a tobacco product but

(i) Solely controls moisture and/or temperature of a stored tobacco product; or

(ii) Solely provides an external heat source to initiate but not maintain combustion of a tobacco product

Cigar means a tobacco product that:

(1) Is not a cigarette and

(2) Is a roll of tobacco wrapped in leaf tobacco or any substance containing tobacco.

Cigarette tobacco means any product that consists of loose tobacco that is intended for use by consumers in a cigarette. Unless otherwise stated, the requirements applicable to cigarettes under this chapter also apply to cigarette tobacco.

Component or *part* means any software or assembly of materials intended or reasonably expected:

(1) To alter or affect the tobacco product's performance, composition, constituents, or characteristics; or

(2) to be used with or for the human consumption of a tobacco product. Component or part excludes anything that is an accessory of a tobacco product.

Covered tobacco product means any tobacco product deemed to be subject to the Federal Food, Drug, and Cosmetic Act pursuant to § 1100.2 of this chapter, but excludes any component or part that is not made or derived from tobacco.

Package or *packaging* means a pack, box, carton, or container of any kind or, if no other container, any wrapping (including cellophane), in which a tobacco product is offered for sale, sold, or otherwise distributed to consumers.

Point of sale means any location at which a consumer can purchase or otherwise obtain tobacco products for personal consumption.

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Principal display panels means the panels of a package that are most likely to be displayed, presented, shown, or examined by the consumer.

Required warning statement means a textual warning statement required to be on packaging and in advertisements for cigarette tobacco, roll-your-own tobacco, cigars, and other covered tobacco products.

Retailer means any person who sells tobacco products to individuals for personal consumption, or who operates a facility where vending machines or self-service displays are permitted under this part.

Roll-your-own tobacco means any tobacco product that, because of its appearance, type, packaging, or labeling, is suitable for use and likely to be offered to, or purchased by, consumers as tobacco for making cigarettes.

Tobacco product, as stated in section 201(rr) of the Federal Food, Drug, and Cosmetic Act in relevant part:

(1) Means any product made or derived from tobacco, or containing nicotine from any source, that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product); and

(2) Does not mean an article that is a drug under section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act; a device under section 201(h) of the Federal Food, Drug, and Cosmetic Act; a combination product described in section 503(g) of the Federal Food, Drug, and Cosmetic Act; or a food under 201(f) of the Federal Food, Drug, and Cosmetic Act if such article contains no nicotine or no more than trace amounts of naturally occurring nicotine.

[81 FR 29103, May 10, 2016, as amended at 88 FR 16553, Mar. 20, 2023]

§ 1143.3 Required warning statement regarding addictiveness of nicotine.

(a) *Packages.* (1) For cigarette tobacco, roll-your-own tobacco, and covered tobacco products other than cigars, it is unlawful for any person to manufacture, package, sell, offer to sell, distribute, or import for sale or distribution within the United States

such product unless the tobacco product package bears the following required warning statement on the package label: "WARNING: This product contains nicotine. Nicotine is an addictive chemical."

(2) The required warning statement must appear directly on the package and must be clearly visible underneath any cellophane or other clear wrapping as follows:

(i) Be located in a conspicuous and prominent place on the two principal display panels of the package and the warning area must comprise at least 30 percent of each of the principal display panels;

(ii) Be printed in at least 12-point font size and ensures that the required warning statement occupies the greatest possible proportion of the warning area set aside for the required text;

(iii) Be printed in conspicuous and legible Helvetica bold or Arial bold type (or other sans serif fonts) and in black text on a white background or white text on a black background in a manner that contrasts by typography, layout, or color, with all other printed material on the package;

(iv) Be capitalized and punctuated as indicated in paragraph (a)(1) of this section; and

(v) Be centered in the warning area in which the text is required to be printed and positioned such that the text of the required warning statement and the other information on the principal display panel have the same orientation.

(3) A retailer of any tobacco product covered by paragraphs (a)(1) and (2) of this section will not be in violation of this section for packaging that:

(i) Contains a health warning;

(ii) Is supplied to the retailer by the tobacco product manufacturer, importer, or distributor, who has the required state, local, or Alcohol and Tobacco Tax and Trade Bureau (TTB)-issued license or permit, if applicable, and

(iii) Is not altered by the retailer in a way that is material to the requirements of this section.

(b) *Advertisements.* (1) For cigarette tobacco, roll-your-own tobacco, and

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covered tobacco products other than cigars, it is unlawful for any such tobacco product manufacturer, packager, importer, distributor, or retailer of the tobacco product to advertise or cause to be advertised within the United States any tobacco product unless each advertisement bears the required warning statement specified in paragraph (a)(1) of this section.

(2) For print advertisements and other advertisements with a visual component (including, for example, advertisements on signs, shelf-talkers, Internet Web pages, and electronic mail correspondence), the required warning statement must appear in the upper portion of the area of the advertisement within the trim area as follows:

(i) Occupy at least 20 percent of the area of the advertisement;

(ii) Appear in at least 12-point font size and ensures that the required warning statement occupies the greatest possible proportion of the warning area set aside for the required text;

(iii) Appear in conspicuous and legible Helvetica bold or Arial bold type (or other similar sans serif fonts) and in black text on a white background or white text on a black background in a manner that contrasts by typography, layout, or color, with all other material on the advertisement;

(iv) Be capitalized and punctuated as indicated in paragraph (a)(1) of this section;

(v) Be centered in the warning area in which the text is required to appear and positioned such that the text of the required warning statement and the other textual information in the advertisement have the same orientation; and

(vi) Be surrounded by a rectangular border that is the same color as the text of the required warning statement and that is not less than 3 millimeters (mm) or more than 4 mm.

(3) This paragraph (b) applies to a retailer only if that retailer is responsible for or directs the health warning required under the paragraph. However, this paragraph does not relieve a retailer of liability if the retailer displays, in a location open to the public, an advertisement that does not contain a health warning or contains a health

warning that has been altered by the retailer in a way that is material to the requirements of this section.

(c) *Self-certification.* A tobacco product that would otherwise be required to bear the warning in paragraph (a)(1) of this section but does not contain nicotine is not required to bear the warning in paragraph (a)(1) of this section on packages or advertisements if the tobacco product manufacturer has submitted to FDA a confirmation statement certifying to be true and accurate that the product does not contain nicotine and that the tobacco product manufacturer has data to support that assertion. Any product not required to bear the warning in paragraph (a)(1) of this section must include the statement "This product is made from tobacco." on all packages and advertisements in accordance with the requirements of this part.

(d) *Small packages.* A tobacco product that would otherwise be required to bear the warning in paragraph (a)(1) of this section but is too small or otherwise unable to accommodate a label with sufficient space to bear such information is exempt from compliance with the requirement *provided* that the information and specifications required under paragraphs (a)(1) and (2) of this section appear on the carton or other outer container or wrapper if the carton, outer container, or wrapper has sufficient space to bear the information, or appear on a tag otherwise firmly and permanently affixed to the tobacco product package. In such cases, the carton, outer container, wrapper, or tag will serve as the location of the principal display panels.

§ 1143.5 Required warning statements for cigars.

(a) *Packages.* (1) It is unlawful for any person to manufacture, package, sell, offer to sell, distribute, or import for sale or distribution within the United States any cigar product unless the product package bears one of the following required warning statements on the package label:

(i) WARNING: Cigar smoking can cause cancers of the mouth and throat, even if you do not inhale.

(ii) WARNING: Cigar smoking can cause lung cancer and heart disease.

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(iii) WARNING: Cigars are not a safe alternative to cigarettes.

(iv) WARNING: Tobacco smoke increases the risk of lung cancer and heart disease, even in nonsmokers.

(v)(A) WARNING: Cigar use while pregnant can harm you and your baby.; or

(B) SURGEON GENERAL WARNING: Tobacco Use Increases the Risk of Infertility, Stillbirth and Low Birth Weight.

(vi) WARNING: This product contains nicotine. Nicotine is an addictive chemical.

(2) Each required warning statement must appear directly on the package and must be clearly visible underneath any cellophane or other clear wrapping as follows:

(i) Be located in a conspicuous and prominent place on the two principal display panels of the package and the warning area must comprise at least 30 percent of each of the principal display panels;

(ii) Appear in at least 12-point font size and ensure that the required warning statement occupies the greatest possible proportion of the warning area set aside for the required text;

(iii) Be printed in conspicuous and legible Helvetica bold or Arial bold type (or other similar sans serif fonts) and in black text on a white background or white text on a black background in a manner that contrasts by typography, layout, or color, with all other printed material on the package;

(iv) Be capitalized and punctuated as indicated in paragraph (a)(1) of this section; and

(v) Be centered in the warning area in which the text is required to be printed and positioned such that the text of the required warning statement and the other information on that principal display panel have the same orientation.

(3) No person may manufacture, package, sell, offer to sell, distribute, or import for sale or distribution within the United States any cigar without a required warning statement, except for cigars that are sold individually and not in a product package. For cigars that are sold individually and not in a product package, the required warning statements must be posted at

the retailer's point-of-sale in accordance with the following:

(i) All of the warnings in paragraph (a) of this section must be placed on a sign that is a minimum of 8.5 x 11 inches, posted on or within 3 inches of each cash register where payment may be made so that the sign(s) are unobstructed in their entirety and can be read easily by each consumer making a purchase;

(ii) The sign must be clear, legible, and conspicuous and be printed in black Helvetica bold or Arial bold type (or other similar sans serif fonts) against a solid white background in at least 17 point type with appropriate space between the warning statements;

(iii) Be printed in a manner that contrasts by typography, layout, or color, with all other printed material; and

(iv) Be capitalized and punctuated as indicated in paragraph (a)(1) of this section.

(4) A retailer of any cigar covered by paragraphs (a)(1) and (2) of this section will not be in violation of this section for packaging that:

(i) Contains a health warning;

(ii) Is supplied to the retailer by the tobacco product manufacturer, importer, or distributor who has the required state, local, or Alcohol and Tobacco Tax and Trade Bureau (TTB)-issued license or permit, if applicable, and

(iii) Is not altered by the retailer in a way that is material to the requirements of this section.

(b) *Advertisements.* (1) It is unlawful for any tobacco product manufacturer, packager, importer, distributor, or retailer of cigars to advertise or cause to be advertised within the United States any cigar unless each advertisement bears one of the required warning statements specified in paragraph (a)(1) of this section.

(2) For print advertisements and other advertisements with a visual component (including, for example, advertisements on signs, shelf-talkers, Internet Web pages, and electronic mail correspondence), each required warning statement must appear in the upper portion of the area of the advertisement within the trim area as follows:

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- (i) Occupy at least 20 percent of the area of the advertisement;
 - (ii) Appear in at least 12-point font size that ensures that the required warning statement occupies the greatest possible proportion of the warning area set aside for the text required;
 - (iii) Appear in conspicuous and legible Helvetica bold or Arial bold type (or other similar sans serif fonts) and in black text on a white background or white text on a black background in a manner that contrasts by typography, layout, or color, with all other material on the advertisement;
 - (iv) Be capitalized and punctuated as indicated in paragraph (a)(1) of this section;
 - (v) Be centered in the warning area in which the text is required to appear and positioned such that the text of the required warning statement and the other textual information in the advertisement have the same orientation; and
 - (vi) Be surrounded by a rectangular border that is the same color as the text of the required warning statement and that is not less than 3 mm or more than 4 mm.
- (3) This paragraph (b) applies to a retailer only if that retailer is responsible for or directs the warning statements required under the paragraph. However, this paragraph does not relieve a retailer of liability if the retailer displays, in a location open to the public, an advertisement that does not contain a health warning or contains a health warning that has been altered by the retailer in a way that is material to the requirements of this section.

(c) *Marketing requirements.* (1) Except for cigars sold individually and not in a product package, the warning statements required for packages in paragraph (a)(1) of this section must be randomly displayed in each 12-month period, in as equal a number of times as is possible on each brand of cigar sold in product packaging and be randomly distributed in all areas of the United States in which the product is marketed in accordance with a plan submitted by the cigar manufacturer, importer, distributor, or retailer to, and approved by, the Food and Drug Administration.

(2) The warning statements required for advertisements in paragraph (a)(1) of this section must be rotated quarterly in alternating sequence in each advertisement for each brand of cigar in accordance with a plan submitted by the cigar manufacturer, importer, distributor, or retailer to, and approved by, the Food and Drug Administration.

(3) Each person required to randomly display and distribute or rotate warnings in accordance with an FDA-approved plan under this part shall submit a proposed warning plan to FDA no later than either 12 months after May 10, 2016, or 12 months before advertising or commercially marketing a product that is subject to such requirement, whichever is later.

§ 1143.7 Language requirements for required warning statements.

The text in each warning statement required in §1143.3 or §1143.5 must be in the English language, except as follows:

(a) In the case of an advertisement that appears in a non-English medium, the text in the required warning statement must appear in the predominant language of the medium whether or not the advertisement is in English, and;

(b) In the case of an advertisement that appears in an English language medium but that is not in English, the text in the required warning statement must appear in the same language as that principally used in the advertisement.

§ 1143.9 Irremovable or permanent required warning statements.

The warning statements required by this section must be indelibly printed on or permanently affixed to the package or advertisement. These warnings, for example, must not be printed or placed on a product label affixed to a clear outer wrapper that is likely to be removed to access the product within the package.

§ 1143.11 Does not apply to foreign distribution.

The provisions of this part do not apply to a manufacturer or distributor of tobacco products that does not manufacture, package, or import tobacco

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products for sale or distribution within the United States.

§ 1143.13 Effective date.

(a) Except as stated in paragraph (b) of this section, this part will take effect 24 months after May 10, 2016. The effective date will be with respect to the date of manufacture, provided that, in any case, beginning 30 days after the effective date, a manufacturer may not introduce into the domestic commerce of the United States any product, irrespective of the date of manufacture, that is not in conformance with this part.

(b) The requirement to submit a warning plan to FDA under § 1143.5(c)(3) will take effect 12 months after May 10, 2016.

PART 1150—USER FEES

Sec.

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AUTHORITY: 21 U.S.C. 371, 387a, 387b, 387i, 387s, 21 CFR 1100.1.

SOURCE: 79 FR 39310, July 10, 2014, unless otherwise noted.

§ 1150.1 Scope.

This part establishes requirements related to tobacco product user fees under section 919 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 387s). The total amount of user fees may not exceed the amount specified for that fiscal year in section 919(b) of the Federal Food, Drug, and Cosmetic Act. All domestic manufacturers and importers of tobacco products are required to pay to FDA their percentage share of the total assessment for a fiscal year.

§ 1150.3 Definitions.

The following definitions are applicable to this part:

Class of tobacco products means each of the following types of tobacco prod-

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ucts as defined in 26 U.S.C. 5702 and for which taxes are required to be paid for the removal of such into domestic commerce: Cigarettes, cigars, snuff, chewing tobacco, pipe tobacco, and roll-your-own tobacco.

Domestic manufacturer means a person who is required to obtain a permit from the Alcohol and Tobacco Tax and Trade Bureau of the Department of the Treasury with respect to the production of tobacco products under title 27 of the Code of Federal Regulations.

Fiscal year quarter means a quarter in a fiscal year (the fiscal year is October 1 through September 30). The fiscal year quarters are October 1–December 31, January 1–March 31, April 1–June 30, and July 1–September 30.

Importer means a person who is required to obtain a permit from the Alcohol and Tobacco Tax and Trade Bureau of the Department of the Treasury with respect to the importation of tobacco products under title 27 of the Code of Federal Regulations.

Total assessment means the total amount of user fees (in dollars) authorized to be assessed and collected for a specific fiscal year under section 919 of the Federal Food, Drug, and Cosmetic Act.

Units of product means:

(1) The number of sticks for cigarettes, or

(2) The weight (measured in pounds) for snuff, chewing tobacco, and roll-your-own tobacco.

Units of product means:

(1) The number of sticks for cigarettes and cigars, or

(2) The weight (measured in pounds) for snuff, chewing tobacco, pipe tobacco, and roll-your-own tobacco.

Yearly class allocation means the amount of user fees (in dollars) assessed for a class of tobacco products for a particular fiscal year.

[79 FR 39310, July 10, 2014, as amended at 81 FR 28715, May 10, 2016]

§ 1150.5 Required information.

(a) *General.* Each domestic manufacturer and importer of tobacco products that are part of a class of tobacco products must submit the information described in this section for such products each month, and the information must be received by FDA no later than

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the 20th day of each month. The information must be submitted using the form that FDA provides. The information must be submitted even if the domestic manufacturer or importer had no removals subject to tax during the prior month. FDA will use the information submitted under this section and any other available information, as FDA determines appropriate, to make tobacco product user fee assessments.

(b) *Contents.* Each domestic manufacturer and importer must submit the following:

(1) *Identification information.* (i) Its name and the mailing address of its principal place of business;

(ii) The name and a telephone number including area code of an office or individual that FDA may contact for further information;

(iii) The email address and postal address at which it wishes to receive notifications FDA sends under this part;

(iv) The Alcohol and Tobacco Tax and Trade Bureau (TTB) Permit Number(s); and

(v) The Employer Identification Number(s) (EIN).

(2) *Removal information.* The units of product, by class, removed and not tax exempt for the prior month and the Federal excise tax it paid, by class, for such removal.

(i) This information must be reported for each TTB tobacco permit.

(ii) If the domestic manufacturer or importer did not remove any amount of tobacco product, it must report that no tobacco product was removed into domestic commerce.

(3) *Certified copies.* Certified copies of the returns and forms that relate to:

(i) The removal of tobacco products into domestic commerce (as defined by section 5702 of the Internal Revenue Code of 1986); and

(ii) The payment of the Federal excise taxes imposed under chapter 52 of the Internal Revenue Code of 1986.

(c) *First report for cigars.* Domestic manufacturers and importers of cigars must submit the information described in this section beginning no later than the 20th day of August, 2016. Domestic manufacturers and importers of cigars must submit the information described in this section for each of the prior months of fiscal year 2016 as their first

monthly submission. The previous sentence only applies for the first report in fiscal year 2016.

(d) *First report for pipe tobacco.* Domestic manufacturers and importers of pipe tobacco must submit the information described in this section beginning no later than the 20th day of August, 2016.

[79 FR 39310, July 10, 2014, as amended at 81 FR 28715, May 10, 2016]

§ 1150.7 Yearly class allocation.

For each fiscal year, FDA will allocate the total assessment among the classes of tobacco products.

(a) *Calculation.* FDA will calculate the percentage shares for each class as follows:

(1) Except for cigars, FDA will multiply the units of product removed and not tax exempt for the most recent full calendar year by the 2003 maximum Federal excise tax rate for that class (class dollar figure).

(2) For cigars, FDA will:

(i) Multiply the units of small cigars removed and not tax exempt for the most recent full calendar year by the 2003 maximum Federal excise tax rate for small cigars (small cigar subclass dollar figure).

(ii) Multiply the units of large cigars removed and not tax exempt for the most recent full calendar year by the 2003 maximum Federal excise tax rate for large cigars (large cigar subclass dollar figure).

(iii) Add the small cigar subclass dollar figure and the large cigar subclass dollar figure (cigar class dollar figure).

(3) FDA will total the class dollar figures for all tobacco classes for the most recent full calendar year (total dollar figure).

(4) FDA will divide the class dollar figure by the total dollar figure to determine the percentage share for each class.

(5) FDA will calculate the allocation for each class of tobacco products by multiplying the percentage share for each class by the total assessment.

(b) *Reallocation.* For any class of tobacco products that is not deemed by FDA to be subject to regulation under chapter IX of the Federal Food, Drug, and Cosmetic Act, the amount of user fees that would otherwise be assessed

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to such class of tobacco products will be reallocated to the classes of tobacco products that are subject to chapter IX of the Federal Food, Drug, and Cosmetic Act in the same manner and based on the same relative percentages otherwise determined under paragraph (a) of this section.

[79 FR 39310, July 10, 2014, as amended at 81 FR 28716, May 10, 2016]

§ 1150.9 Domestic manufacturer or importer assessment.

Each quarter, FDA will calculate the assessment owed by each domestic manufacturer or importer for that quarter.

(a) *Calculation.* (1) For each class of tobacco products except cigars, FDA will calculate the percentage share for each domestic manufacturer and importer by dividing the Federal excise taxes that it paid for the class for the prior quarter by the total excise taxes that all domestic manufacturers and importers paid for the class for that same quarter.

(2) For the cigar class, FDA will calculate the percentage share for each domestic manufacturer and importer by dividing the Federal excise taxes that it paid for the class for the prior fiscal year by the total excise taxes that all domestic manufacturers and importers paid for the class for the prior fiscal year.

(3) If the percentage share calculated for a domestic manufacturer or importer in this section, as applicable, is less than 0.0001 percent, the share is excluded from the assessment for that class of tobacco products.

(4) Within each class of tobacco products, the assessment owed by a domestic manufacturer or importer for the quarter is the yearly class allocation, determined as described in §1150.7, divided by four, multiplied by the domestic manufacturer's or importer's percentage share, truncated to the fourth decimal place, for that class of tobacco products.

(b) *Adjustments.* Annually, FDA will make any necessary adjustments to individual domestic manufacturer or importer assessments if needed to account for any corrections (for example, to include domestic manufacturers or

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importers that were not included in a relevant assessment calculation).

[79 FR 39310, July 10, 2014, as amended at 81 FR 28716, May 10, 2016]

§ 1150.11 Notification of assessments.

(a) *Notification.* No later than 30 calendar days before the end of each fiscal year quarter, FDA will notify each domestic manufacturer and importer of the amount of the quarterly assessment imposed on the domestic manufacturer or importer.

(b) *Content of notification.* The notification under paragraph (a) of this section will include the following:

(1) The amount of the quarterly assessment imposed on the domestic manufacturer or importer and the date that payment of the assessment must be received by FDA;

(2) Class assessment information, including each class' initial percentage share, the reallocation amount (if any) and each class' percentage share after any such reallocation, and the quarterly assessment for each class;

(3) Domestic manufacturer or importer assessment information, including the domestic manufacturer's or importer's percentage share of each relevant class of tobacco products and invoice amount;

(4) Any adjustments FDA has made under § 1150.9(b);

(5) The manner in which assessments are to be remitted to FDA;

(6) Information about the accrual of interest if a payment is late; and

(7) Information regarding where to send a dispute and when it needs to be sent.

§ 1150.13 Payment of assessments.

(a) Payment of an assessment must be received by FDA no later than the last day of each fiscal year quarter.

(b) Payments must be submitted to FDA in U.S. dollars and in the manner specified in the notification.

(c) Except as provided in paragraph (d) of this section, if an assessment is not received by the last day of the fiscal year quarter, FDA will begin assessing interest on the unpaid amount in accordance with 31 U.S.C. 3717.

(d) If FDA does not send the notification described in § 1150.11(a) 30 calendar

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days before the end of a quarter, no interest will be assessed by FDA under paragraph (c) of this section until 30 calendar days have elapsed from the date FDA sent notification of the amount owed.

(e) If a domestic manufacturer or importer disputes the amount of an assessment, it must still pay the assessment in accordance with paragraphs (a) and (b) of this section.

§ 1150.15 Disputes.

(a) A domestic tobacco manufacturer or importer may dispute an FDA assessment. The dispute must include the basis for the dispute, and the dispute must be:

- (1) Submitted in writing;
- (2) Received by FDA no later than 45 days after the date on the assessment notification;
- (3) Legible and in English; and
- (4) Sent to the address found on our Web site (<http://www.fda.gov/tobaccoproducts>).

(b) If FDA determines that there was an error related to the assessment and the assessment was too high, FDA will refund the amount assessed in error to the domestic manufacturer or importer.

(c) FDA will provide a dated, written response, and its response will provide information about how to submit a request for further Agency review.

(d) A request for further Agency review under § 10.75 of this chapter may be submitted. Such a request must be

submitted in writing by the domestic manufacturer or importer and received by FDA within 30 days from the date on FDA's response. The request for further Agency review must be legible, in English, and submitted to the address found on our Web site (<http://www.fda.gov/tobaccoproducts>).

§ 1150.17 Penalties.

(a) Under section 902(4) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 387b), a tobacco product is deemed adulterated if the domestic manufacturer or importer of the tobacco product fails to pay a user fee assessed to such manufacturer or importer by the later of the date the assessment is due, 30 days from the date FDA sent notification of the amount owed, or 30 days after final Agency action on a resolution of any dispute as to the amount of the fee.

(b) Under section 902(4) of the Federal Food, Drug, and Cosmetic Act, a tobacco product is deemed adulterated if the domestic manufacturer or importer of the tobacco product fails to report the information required by § 1150.5 to calculate assessments under this part.

(c) The failure to report the information required by § 1150.5 to calculate assessments under this part is a prohibited act under section 301(e) of the Federal Food, Drug, and Cosmetic Act.

(d) Information submitted under § 1150.5 is subject to 18 U.S.C. 1001 and other appropriate civil and criminal statutes.