

## **PART 1141--CIGARETTE PACKAGE AND ADVERTISING WARNINGS**

### Subpart A--General Provisions

#### Sec.

1141.1 Scope.

1141.3 Definitions.

### Subpart B--Cigarette Package and Advertising Warnings

1141.10 Required warnings.

1141.12 Incorporation by reference of required warnings.

1141.14 Misbranding of cigarettes.

### Subpart C--Additional Disclosure Requirements for Cigarette Packages and Advertising

1141.16 Disclosures regarding cessation.

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U.S.C. 1333; 21 U.S.C. 371, 387c, 387f.

### **Subpart A--General Provisions**

#### **Sec. 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 [regarding warning labels on cigarette packages](#) 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 license- or permit-holding tobacco 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.

### **Sec. 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 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 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 introduces into commerce any cigarette [intended for sale or distribution to consumers in the United States](#) that:

- (1) Was not manufactured inside the United States; ~~and~~
- (2) [Was manufactured inside the United States and exported for foreign distribution or sale](#)~~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--English and Spanish" and "Cigarette Required Warnings--Other Foreign Languages," which are incorporated by reference at Sec. 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 Virgin Islands, American Samoa, Wake Island, Midway Islands, Kingman Reef, and Johnston Island. The term "State" includes any political division of any State.

## **Subpart B--Cigarette Package and Advertising Warnings**

### **Sec. 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 both the front and the rear panel.

(2) The required warning shall be obtained and accurately reproduced from the electronic images contained in "Cigarette Required Warnings--English and Spanish," which is incorporated by reference at Sec. 1141.12, except that it must be adapted as necessary to meet the requirements of section 4 of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1333) and this part.

(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 publication, 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 and accurately reproduced from the electronic images contained in "Cigarette Required Warnings--English and Spanish," which is incorporated by reference at Sec. 1141.12, except that it must be adapted as necessary to meet the requirements of section 4 of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1333), including area and other formatting requirements, and this part.

(4) For foreign-language warnings, except for Spanish-language warnings, each required warning shall be the color graphic obtained and accurately reproduced from the electronic images contained in "Cigarette Required Warnings--Other Foreign Language Advertisements," which is incorporated by reference at Sec. 1141.12, and into which a true and accurate translation

of the textual warning is inserted in accordance with "Cigarette Required Warnings--Other Foreign Language Advertisements," except that the required warning must be adapted as necessary to meet the requirements of section 4 of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1333), including area and other formatting requirements, and this part.

(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.

(d) Images of cigarette packs in advertisements. Any images of cigarette packs in advertisements for cigarettes shall depict cigarette packs that have warning labels as required by this rule.

(e) Images of cigarette packs in other communications. No manufacturer, importer, distributor or retailer shall take any action to alter any images meant to depict cigarette packs as legally distributed or sold to consumers in the United States in any public communication (including but not limited to movies, websites and television programs) so that the images of those cigarette packs do not have warning labels as required by this rule.

#### **Sec. 1141.12 Incorporation by reference of required warnings.**

Certain material entitled: "Cigarette Required Warnings--English and Spanish," (edition 1.0, June 2011, Food and Drug Administration), appearing in Sec. Sec. 1141.10(a)(2), (b)(3), and 1141.16(a); and "Cigarette Required Warnings--Other Foreign Language Advertisements," (edition 1.0, June 2011, Food and Drug Administration), appearing in Sec. Sec. 1141.10(b)(4) and 1141.16(a) are incorporated by reference into this part with the approval of the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain a copy from the Food and Drug Administration, Center for Tobacco Products, Office of Compliance, 9200 Corporate Blvd., Rockville, MD 20850, 1-877-CTP-1373, and from the Web sites listed in paragraphs (a) and (b) of this section. Also, this material is available for inspection at the National Archives and Records Administration (NARA). For more information on the availability of the following material, call NARA at 202-741-6030 or go to [http://www.archives.gov/Federal\\_register/codeof\\_Federal\\_regulations/ibr\\_locations.html](http://www.archives.gov/Federal_register/codeof_Federal_regulations/ibr_locations.html):

(a) "Cigarette Required Warnings--English and Spanish," available from FDA at <http://www.fda.gov/Tobacco>, referred to at Sec. Sec. 1141.10(a)(2) and (b)(3) and Sec. 1141.16.

(b) "Cigarette Required Warnings--Other Foreign Language Advertisements," available from FDA at <http://www.fda.gov/Tobacco>, referred to at Sec. Sec. 1141.10(b)(4) and Sec. 1141.16.

#### **Sec. 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 ~~unless-if~~ its labeling does not 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 shall be deemed to be misbranded under section 903(a)(7)(A) of the Federal Food, Drug, and Cosmetic Act unless if its advertising does not 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.

(b) A cigarette advertisement or package will not 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 unless 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 if the manufacturer, packer, or distributor does not includes in all advertisements and packages 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 (15 U.S.C. 1333) and this part.

## **Subpart C--Additional Disclosure Requirements for Cigarette Packages and Advertising**

### **Sec. 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--English and Spanish" (incorporated by reference at Sec. 1141.12) or ``Cigarette Required Warnings--Other Foreign Language Advertisements" (incorporated by reference at Sec. 1141.12), whichever is applicable.

(b) The smoking cessation assistance resource required to be referenced by paragraph (a) of this section shall be operated consistent with standards and criteria established by the Centers for Disease Control and Prevention. must:

- ~~—(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 users 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;~~
- ~~—(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;~~
- ~~—(8) Other than as described in this section, not advertise or promote any particular product or service;~~
- ~~—(9) 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 or reference any drug or other medical product that FDA has not approved for tobacco cessation; and~~
- ~~—(10) Not encourage the use of any non-evidence-based smoking cessation practices.~~

~~(c) If the smoking cessation assistance resource required to be referenced by paragraph (a) of this section is a Web site, it:~~

~~—(1) Must not contain a link to any Web site unless it meets all of the criteria described in paragraph (b) of this section; and~~

~~—(2) May include references to one or more toll-free telephone numbers only if they meet the criteria described in paragraphs (b) and (d) of this section.~~

~~(d) If the smoking cessation assistance resource required to be referenced by paragraph (a) of this section is a toll-free telephone number, it must:~~

~~—(1) 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~~

~~—(2) Maintain appropriate controls to ensure the criteria described in paragraph (b) of this section are met.~~