

Food and Drug Administration, HHS

§ 1141.3

1141.12 Incorporation by reference of required warnings.

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Subpart C—Additional Disclosure Requirements for Cigarette Packages and Advertising

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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.

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 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 re-

tailer 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.

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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. 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 Warn-

ings,” 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 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 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,