

Guidance for Industry

Required Warnings for Cigarette Packages and Advertisements

Small Entity Compliance Guide

Written comments and suggestions may be submitted at any time for Agency consideration to Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Alternatively, electronic comments may be submitted to <http://www.regulations.gov>. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*. For questions regarding this draft document contact the Center for Tobacco Products (CTP) at 1-877-CTP-1373.

**U.S. Department of Health and Human Services
Food and Drug Administration
Center for Tobacco Products**

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This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call 1-877-CTP-1373 listed on the title page of this guidance.

I. Introduction

This guidance is intended to help small businesses understand and comply with FDA's regulations regarding the required warnings on cigarette packages and in cigarette advertisements. The rule requires a combined textual statement and graphic image (known as a "required warning") to appear on all cigarette packages and in cigarette advertisements. Parties must be in compliance with this final rule beginning on September 22, 2012. The Food and Drug Administration has prepared this Small Entity Compliance Guide in accordance with section 212 of the Small Business Regulatory Enforcement Fairness Act (P.L. 104-121).

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidance documents describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidance documents means that something is suggested or recommended, but not required.

II. Summary of the Regulation and this Guidance

In the *Federal Register* of November 12, 2010 (75 FR 69524), FDA published a proposed rule seeking to modify the health warnings that appear on cigarette packages and in advertisements to include color graphic images depicting the negative health consequences of smoking. These images were proposed to accompany the nine new textual warning statements in

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the Federal Cigarette Labeling and Advertising Act (FCLAA), as amended by the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act). In the *Federal Register* of June 22, 2011 (76 FR 36628), FDA published the final rule, codified at 21 C.F.R. part 1141.

The final rule changed both the content and appearance of the health warnings on cigarette packages and in advertisements. The new required warning will consist of a textual warning statement and an accompanying graphic image. The required warning must occupy the top 50 percent of the front and back panels of cigarette packages. 21 C.F.R. § 1141.10(a)(4). It also must occupy 20 percent of the area of cigarette advertisements and appear at the top of the advertisement. 21 C.F.R. § 1141.10(b)(5). You will need to refer directly to the documents incorporated by reference for the electronic files containing the required warnings.

III. Questions and Answers

A. Where can I find the Cigarette Graphic Health Warning regulation, the actual files to be used, and any explanation?

The final regulation can be found in chapter 21 of the Code of Federal Regulations (C.F.R.) at Part 1141. The citation is 21 C.F.R. Part 1141. In addition, the full preamble to the rule, which gives additional information about FDA's thoughts on the issues and other analysis, can be found in the *Federal Register* issued on June 22, 2011. 76 FR 36628, <http://www.regulations.gov/#!documentDetail;D=FDA-2010-N-0568-0251>. The files to be used for the actual required warnings are contained in the "Cigarette Required Warnings" Edition 1.0, also referred to as the "Incorporated by Reference" or "IBR document," discussed in section G below.

B. What does FDA's cigarette graphic warning rule now require for cigarette packages and advertisements?

This rule mandates the use of a "required warning," consisting of one of the nine new textual warning statements, a corresponding color graphic depicting the negative health consequences of smoking, and a toll free smoking cessation assistance resource phone number on cigarette packages and advertisements.

C. What items are covered by this rule?

This rule covers cigarette packages and cigarette advertisements only. For the purposes of this rule:

- A cigarette is defined at 21 C.F.R. § 1141.3 as:

“(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,

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is likely to be offered to, or purchased by, consumers as a cigarette described in paragraph (1) of this definition.”

Please note that roll-your-own tobacco and cigarette tobacco are not covered by this regulation. These products, however, must comply with all applicable provisions of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 301 et seq.), as amended by the Tobacco Control Act, and applicable regulations, including 21 C.F.R. Part 1140, and all other applicable state and federal statutes and regulations.

- All cigarette packages must display the required warnings. A cigarette “package” is defined as “a pack, box, carton, or container of any kind in which cigarettes are offered for sale, sold, or otherwise distributed to consumers.” 21 C.F.R. § 1141.3.
 - For example, if cigarettes are sent to a retailer in a shipping box used solely for transportation, and the cigarettes are not offered for sale, sold, or otherwise distributed to consumers in that shipping box, then the shipping box does not need to display the required warnings. However, if the cigarettes are offered for sale, sold, or otherwise distributed to consumers in that shipping box, then the shipping box must display the required warnings. Please note that shipping boxes must still comply with all applicable requirements established by the FD&C Act and other relevant laws and regulations.
- All advertisements, regardless of form, must display the required warnings. Advertisements could include materials such as magazine and newspaper advertisements, pamphlets, leaflets, brochures, coupons, catalogues, retail or point-of-sale displays (including functional items such as clocks), posters, billboards, direct mailers, and Internet advertising (*e.g.*, Web pages, banner ads).

D. Who is responsible and subject to enforcement?

1. Who must comply with this final rule?

For cigarette packages, this final rule applies to any person who manufactures, packages, distributes, imports, sells, offers to sell, or imports for sale or distribution cigarettes within the United States. For advertisements, this final rule applies to any manufacturer, importer, distributor, or retailer of cigarettes who advertises or causes to be advertised cigarettes within the United States.

For the purposes of this rule:

- A “**manufacturer**” is “any person, including any repacker or relabeler, who manufactures, fabricates, assembles, processes, or labels a finished cigarette product.” 21 C.F.R. § 1141.3.
 - For example, if you make cigarettes, you are a manufacturer under these regulations. Similarly, if you take finished cigarettes from Company A, remove the cigarettes from Company A’s cartons, and place them in packages with your company’s name (or any

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other name) on the package, you are a manufacturer because you repacked and relabeled the cigarettes, even though you did not make the finished cigarettes themselves.

- A “**distributor**” is “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,” but excludes common carriers. 21 C.F.R. § 1141.3.
 - For example, if you own a trucking firm and are contracted solely to transport cigarettes from a warehouse to a retailer, you are a “common carrier” and are, therefore, not a “distributor” for the purpose of this rule.
- An “**importer**” is “any person who imports any cigarette that is intended for sale or distribution to consumers in the United States.” 21 C.F.R. § 1141.3.
- A “**retailer**” is “any person who sells cigarettes to individuals for personal consumption, or who operates a facility where vending machines or self-service displays are permitted.” 21 C.F.R. § 1141.3.

2. Will this rule apply equally to small businesses that meet the definition of manufacturer, distributor, importer, or retailer?

The required warnings are required to be on all cigarette packages and in all cigarette advertisements regardless of who manufactures, distributes, imports, sells, or offers to sell the product.

FDA’s Center for Tobacco Products (CTP) has established an Office of Small Business Assistance in an effort to help small businesses access up-to-date information and comply with the requirements of the Tobacco Control Act. CTP’s Office of Small Business Assistance can be reached at SmallBiz.Tobacco@fda.hhs.gov or at 1-877-CTP-1373 (1-877-287-1373) Monday–Friday, 9:00 a.m. – 4:00 p.m. EDT.

3. What are the consequences if a company is found to be out of compliance?

In general, cigarette packages and advertisements that do not comply with the final rule violate FCLAA. In addition, cigarettes are misbranded under the FD&C Act if, for example, their packages or advertisements do not include one of the required warnings. Violations of FCLAA and the misbranding of cigarettes under the FD&C Act, could lead to, among other things, warning letters, criminal penalties, civil money penalties, injunction, seizure, and no-tobacco-sale orders.

4. Are retailers subject to enforcement actions? – 21 C.F.R. § 1141.1(c), (d)

Yes, retailers who violate the rule will be subject to enforcement penalties. However, a retailer is not in violation of the rule with respect to cigarette packages as long as the package:

- contains a health warning,

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- is supplied by a license- or permit-holding tobacco product manufacturer, importer, or distributor, and
- is not altered by the retailer in a way that is material to the requirements of section 4(a) of FCLAA or 21 C.F.R. Part 1141 (*e.g.*, obscuring the warning, reducing the warning's size, severing the warning in any way).

Similarly, a retailer will not be considered in violation of the rule if it displays an advertisement in a location open to the public that does not comply with all the requirements of the rule so long as the advertisement:

- contains a health warning,
- is not created by or on behalf of the retailer (and the retailer is not otherwise responsible for including the required warning), and
- is not altered by the retailer in a way that is material to the requirements of section 4(b) or 4(c) of FCLAA or 21 C.F.R. Part 1141 (*e.g.*, see above).

5. *In cases where the retailer exceptions are applicable, can FDA still take enforcement actions against other entities or violative products?*

Yes. Even when a retailer is not in violation of the rule because it falls within the retailer exceptions, if the cigarette package and/or advertisement violates the rule, FDA can take action against the responsible party (*i.e.*, manufacturer, importer, or distributor) and, potentially, the product (*e.g.*, by seizing it and asking a court to condemn it).

E. What is the timeframe for implementing this rule?

1. *When does the new rule become effective?*

The rule becomes effective on September 22, 2012, which is the date 15 months from the date the rule was issued.

2. *When are the new graphic health warnings required to be included on cigarette packages and in advertisements?*

After the effective date (September 22, 2012), no person may manufacture for sale or distribution within the United States any cigarette package without the new graphic health warnings. In addition, no manufacturer, importer, distributor, or retailer may advertise cigarettes within the United States if the advertisement does not comply with the rule.

3. *After the effective date, can manufacturers sell-off their remaining stock of cigarette packages that do not comply with the rule?*

For cigarette packages manufactured before September 22, 2012, manufacturers may continue to sell and distribute the packages for an additional 30 days after the rule goes into effect.

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4. After the effective date, can importers, distributors, and retailers sell-off their remaining stock of cigarette packages that do not comply with the rule?

Importers, distributors, and retailers may continue to sell and distribute the cigarette packages after the effective date if they were manufactured **before** September 22, 2012. They may not sell or distribute the non-compliant cigarette packages if they were manufactured **after** September 22, 2012. However, please note the retailer exception addressed above in question D.4 and below in the table of effective dates for cigarette packaging.

Effective Dates for Covered Entities

Entity	Packaged Cigarettes Manufactured before September 22, 2012 without the graphic health warnings	Packaged Cigarettes Manufactured after September 22, 2012 without the graphic health warnings
Manufacturer	May continue to introduce these products into U.S. commerce until October 22, 2012.	May not introduce these products into U.S. commerce.
Importer	May continue to introduce these products into U.S. commerce.	May not introduce these products into U.S. commerce.
Distributor	May continue to introduce these products into U.S. commerce.	May not introduce these products into U.S. commerce.
Retailer	May continue to sell or offer to sell these products to consumers.	May not sell or offer to sell these products to consumers unless the retailer demonstrates that it meets the requirements for the retailer exception.

F. How must the required warnings appear on cigarette packages and cigarette advertisements?

1. How many textual warning statements are required by the Tobacco Control Act?

The Tobacco Control Act requires one of the following nine textual warning statements to appear on cigarette packages and in cigarette advertisements:

- WARNING: Cigarettes are addictive.
- WARNING: Tobacco smoke can harm your children.
- WARNING: Cigarettes cause fatal lung disease.
- WARNING: Cigarettes cause cancer.
- WARNING: Cigarettes cause strokes and heart disease.
- WARNING: Smoking during pregnancy can harm your baby.

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- WARNING: Smoking can kill you.
- WARNING: Tobacco smoke causes fatal lung disease in nonsmokers.
- WARNING: Quitting smoking now greatly reduces serious risks to your health.

2. *How must the required warnings appear on packages? – 21 C.F.R. § 1141.10*

- **Size and location** – Required warnings must occupy the top 50% of the front and rear panels of the individual cigarette package (*i.e.*, the two largest sides or surfaces of the package). For cartons, the required warnings must occupy at least the left 50% of the front and rear panels (*i.e.*, the two largest sides or surfaces of the carton). They must be clearly visible and must not be obscured. Any outer wrappings must be clear (*i.e.*, transparent), and any material placed on the outside of the package, such as price information or promotional materials (*e.g.*, onserts), must not be placed over or otherwise obscure the required warning.
- **Orientation** – Required warnings and the other information on the panels must be oriented in the same direction. For example, if the brand name appears in a left to right orientation, the required warning and its accompanying textual statement must also be placed in a left to right orientation.
- **Equal Display and Random Distribution** – In each 12-month period, all nine required warnings must be randomly displayed in an equal number of times as is possible on each brand of the product and must be randomly distributed in all areas of the United States in which the product is marketed, in accordance with an FDA-approved warning plan. Guidance for warning plans will be addressed separately.
- **Irremovable or permanent warnings** – Required warnings must be indelibly printed on or permanently affixed to cigarette packages (*i.e.*, non-removable). For example, a removable required warning on a cigarette package or a required warning printed or affixed on an outer wrapper that is meant to be removed is not sufficient to comply with these regulations.

3. *How must the required warnings appear in cigarette advertisements? – 21 C.F.R. § 1141.10*

- **Size and location** - Required warnings must appear in the upper portion of each cigarette advertisement and occupy at least 20 percent of the area of the advertisement. *See also* 15 U.S.C. § 1333(b) (establishing additional requirements for cigarette advertisements). Please refer to the IBR document for additional information.
- **Rotation** - The nine required warnings must be rotated quarterly in cigarette advertisements for each brand of cigarettes, in accordance with an FDA-approved warning plan. Guidance for warning plans will be addressed separately.
- **Irremovable or permanent warnings** – Required warnings must be indelibly printed on or permanently affixed to a cigarette advertisement (*i.e.*, non-removable).

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G. How do I obtain and utilize the electronic files for the required warnings?

1. How do I obtain a copy of “Cigarette Required Warnings” Edition 1.0 (June 2011) containing the electronic files of the required warnings and instructions for use?

“Cigarette Required Warnings” (also referred to as the “IBR document”) includes the files of the electronic images of the required warnings and the “Instructions for: Cigarette Required Warnings,” and is available from a variety of sources. You can access the material:

- directly via Internet at <http://www.fda.gov/cigarettewarningfiles> (note: this involves the transfer of large electronic files which may require increased computer capacity),
- by submitting a request to FDA at the following email address cigarettewarningfiles@fda.hhs.gov, or
- 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, or by calling 1-877-CTP-1373.

The electronic files included in the IBR document are built as .eps files, with separate layers for text and images. The required warnings must be accurately reproduced from the electronic images and must not be distorted. 21 C.F.R. § 1141.10(a)(2), (b)(3), (b)(4).

The “Instructions for: Cigarette Required Warnings” provides directions for using the accompanying electronic files of the required warnings that must be displayed on cigarette packages and cigarette advertisements. Any modifications to files must be done in accordance with these instructions and must result in an accurate reproduction.

The .eps files for the required warnings, which are contained in Cigarette Required Warnings, may not be used, reproduced, displayed, modified, or distributed for any purpose other than for the purpose of displaying them on cigarette packages (including cartons) and in cigarette advertising as required by 21 C.F.R. § 1141 without the express written permission of FDA or as permitted under the Copyright Act.

2. In what language must the required warnings appear on packages and advertisements?

The textual statement of the required warnings must be in the English language on all cigarette packages. The textual statement also must be in English in all cigarette advertisements except in the following cases:

- (1) If an advertisement appears in a foreign language publication (*e.g.*, newspaper, magazine, periodical, etc.), the textual warning statement must be in the predominant language of the publication, even if the advertisement is presented in a different language. The predominant language is the primary language used in the content in the publication (*e.g.*, stories or articles featured in newspapers, magazines, periodicals, etc.).
 - For example, if the majority of the content in the publication is in Spanish but the cigarette advertisement is wholly or partially in English, then Spanish is the

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predominant language used in the content of the publication, and the required warning would have to appear in the Spanish language.

(2) If an advertisement appears in an English language publication, but the advertisement is not presented in English, the textual portion of the required warning would need to be presented in the foreign language principally used in the advertisement.

- For example, if a cigarette advertisement presented in French appears in an English-language entertainment magazine, then the text of the required warning would have to appear in the French language, as it is the foreign language principally used in the advertisement.

21 C.F.R. § 1141.10(b)(2); FCLAA § 4(b)(2) (15 U.S.C. 1333(b)(2)).

3. Can I obtain electronic files of the required warnings with textual statements in foreign languages?

The IBR document offers Spanish-language versions of the required warnings.

For foreign languages other than Spanish, companies must use the downloadable electronic files of the color graphics and turn off the English text layer that accompanies each color graphic. Regulated entities are responsible for inserting a true and accurate translation of the textual warning language required by FCLAA. Regulated entities may contact CTP's Office of Small Business Assistance at SmallBiz.Tobacco@fda.hhs.gov or at 1-877-CTP-1373 (1-877-287-1373) for assistance in generating a true and accurate translation of the textual warning statement for the advertisement.

4. Do I need to adjust the font sizes in the electronic files for the required warnings?

For English and Spanish language warnings, the font size and font style are built into the electronic files provided in the IBR document. For advertisements in foreign languages other than Spanish, companies must comply with the font size requirements in section 4(b)(2) of FCLAA (15 U.S.C. 1333(b)(2)) and any format requirements included in the IBR document.

In all situations, it is the advertiser's responsibility to ensure that the textual statements appear in conspicuous and legible type and that the required warning complies with the applicable format specifications in section 4 of FCLAA (15 U.S.C. 1333) and 21 C.F.R. 1141, including the IBR document.

H. How will I appropriately size the warnings for my cigarette packages and advertisements?

1. Will I be able to adapt the graphic warnings to fit cigarette packages of varying sizes and shapes?

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To help prevent distortion of the image and text and to minimize the need for adaptation, we are providing electronic files in different formats designed to fit packaging of various sizes and shapes. Companies must select the appropriate format.

The IBR document provides instructions as to when each of the formats must be used and how to adapt the files in certain instances (*i.e.*, hinged lid packs or soft packs) when necessary.

2. Will I be able to incorporate the required warnings in advertisements of varying sizes and shapes?

The electronic files provided in the IBR document include required warnings designed with a variety of different aspect ratios. Specifically, the files are designed with aspect ratios of 1:1, 1.5:1, 1:2, 2:1, and 2.5:1. Companies must choose an aspect ratio that, once it is sized (*i.e.*, expanded or compressed) to occupy the required area of the advertisement, provides for the greatest clarity and integrity of the required warning. These files will permit companies to incorporate the required warnings into their advertisements without significant distortion or loss of clarity.

3. How do I combine and display the graphic warning image developed for small advertisements (i.e., less than 12 square inches) with the required textual warnings?

In advertisements with a small surface area of less than 12 square inches, the advertiser must use the image of the exclamation point enclosed within a red equilateral triangle, included in the IBR document. This image must be used in combination with one of the nine textual statements. It is the advertiser's responsibility to ensure that the textual warning statement appears in conspicuous and legible type and that the combined warning complies with FCLAA and these regulations.

I. Must I reference a smoking cessation assistance resource in all of my required warnings?

Yes. All nine required warnings must refer to the smoking cessation assistance resource "1-800-QUIT-NOW." 21 C.F.R. § 1141.16(a). No other cessation resource may be used. The electronic files provided in the IBR document include this cessation resource in each graphic warning image.

For small advertisements (*i.e.*, less than 12 square inches), reference to a smoking cessation assistance resource is not required.