

Required Warnings for Cigarette Packages and Advertisements

Small Entity Compliance Guide (Revised)*

Guidance for Industry

Comments may be submitted at any time for Agency consideration. Electronic comments may be submitted to <https://www.regulations.gov>. Alternatively, submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852. 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 guidance, contact the Center for Tobacco Products at (Tel) 1-877-CTP-1373 (1-877-287-1373) Monday-Friday, 9 a.m. – 4 p.m. ET.

Additional copies are available online at <http://www.fda.gov/TobaccoProducts/Labeling/RulesRegulationsGuidance/default.htm>. You may send an e-mail request to SmallBiz.Tobacco@fda.hhs.gov to receive an electronic copy of this guidance. You may send a request for hard copies to U.S. Food and Drug Administration, Center for Tobacco Products, Attn: Office of Small Business Assistance, Document Control Center, Bldg. 71, Rm. G335, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002.

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

February 2021

*This is a revision to the second edition of this final guidance, which issued in May 2020. A summary of the revisions is at the end of the guidance.

Contains Nonbinding Recommendations

Table of Contents

I. INTRODUCTION.....1

II. BACKGROUND.....2

A. Definitions.....3

III. QUESTIONS AND ANSWERS.....4

IV. DOCUMENT HISTORY.....15

Required Warnings for Cigarette Packages and Advertisements

Small Entity Compliance Guide (Revised)

Guidance for Industry¹

This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance as listed on the title page.

I. INTRODUCTION

FDA (Agency, we) is issuing this guidance to help small businesses understand and comply with FDA's final rule², "Required Warnings for Cigarette Packages and Advertisements," which establishes new required cigarette health warnings for cigarette packages and advertisements. The final rule implements a provision of the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (Public Law 111-31) that requires FDA to issue regulations requiring color graphics depicting the negative health consequences of smoking to accompany new textual warning statements. The Tobacco Control Act amends the Federal Cigarette Labeling and Advertising Act (FCLAA) (15 U.S.C. 1333) to require each cigarette package and advertisement to bear one of the new required warnings. FDA has prepared this Small Entity Compliance Guide in accordance with section 212 of the Small Business Regulatory Enforcement Fairness Act (Public Law 104-121).

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe FDA'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 FDA's guidances means that something is suggested or recommended, but not required.

¹ This guidance was prepared by the Office of Compliance and Enforcement, Office of Science, and Office of Regulations in the Center for Tobacco Products at FDA.

² For the purposes of this guidance, we refer to "rule" or "final rule" to refer to the final rule published in the *Federal Register* of March 18, 2020, codified at 21 CFR 1141.

Contains Nonbinding Recommendations

II. BACKGROUND

The Tobacco Control Act was enacted on June 22, 2009, and granted FDA important new authority to regulate the manufacture, marketing, and distribution of tobacco products. The Tobacco Control Act also amended section 4 of the FCLAA to direct FDA to issue new cigarette health warnings that would include a color graphic component depicting the negative health consequences of smoking to accompany the new textual warnings (section 201 of the Tobacco Control Act). In enacting this legislation, Congress also provided that FDA may adjust the required warnings if FDA found that such a change would promote greater public understanding of the risks associated with the use of tobacco products (section 202 of the Tobacco Control Act). Additionally, as required under the FCLAA, the rule establishes marketing requirements that include the random and equal display and distribution of the required warnings on cigarette packages and quarterly rotations of the required warnings in cigarette advertisements.

Section 201(a) of the Tobacco Control Act requires manufacturers, distributors, and retailers of cigarettes to submit plans for the random and equal display and distribution of required warnings on cigarette packages and the quarterly rotation of required warnings on cigarette advertisements, and to obtain FDA approval of their plans before products required to bear such warnings enter the market. The Tobacco Control Act also modified the FCLAA's requirements regarding the submission of plans for cigarette packages and advertisements and requires that such plans be submitted to FDA (as delegated by the Secretary of Health and Human Services) for review and approval, rather than to the Federal Trade Commission.

In the *Federal Register* of March 18, 2020, FDA published a final rule, codified at 21 CFR 1141, that establishes new required warnings for cigarette packages and advertisements.³ Section 201(b) of the Tobacco Control Act provides that the required warnings are to become effective 15 months after the date the final rule publishes in the *Federal Register*. On April 3, 2020, the final rule was challenged in the U.S. District Court for the Eastern District of Texas.⁴ On May 8, 2020, the Court granted a joint motion to govern proceedings in that case and postpone the effective date of the final rule by 120 days.⁵ On December 2, 2020, the same Court granted a motion by the plaintiffs in the same case to postpone the effective date of the final rule by an additional 90 days.⁶ The new effective date of the final rule is January 14, 2022. Pursuant to the court order, any obligation to comply with a deadline tied to the effective date of the rule is similarly postponed, and those obligations and deadlines are now tied to the postponed effective

³ In the *Federal Register* of August 16, 2019 (84 FR 42754), FDA issued a notice of proposed rulemaking (NPRM) to amend 21 CFR 1141.

⁴ *R.J. Reynolds Tobacco Co. et al., v. United States Food and Drug Administration et al.*, No. 6:20-cv-00176 (E.D. Tex. filed April 3, 2020).

⁵ *R.J. Reynolds Tobacco Co. et al., v. United States Food and Drug Administration et al.*, No. 6:20-cv-00176 (E.D. Tex. May 8, 2020) (order granting joint motion and establishing schedule), Doc. No. 33.

⁶ *R.J. Reynolds Tobacco Co. et al., v. United States Food and Drug Administration et al.*, No. 6:20-cv-00176 (E.D. Tex. December 2, 2020) (order granting Plaintiffs' motion and postponing effective date), Doc. No. 80 (hereafter, the "December 2, 2020, court order").

Contains Nonbinding Recommendations

date. As such, FDA strongly encourages entities to submit cigarette plans⁷ to FDA as soon as possible after publication of the final rule, and in any event by March 16, 2021 to ensure timely FDA review prior to the effective date of the required warnings.

Definitions

This guidance uses the following terms and definitions from the final rule published in the *Federal Register* of March 18, 2020:

Cigarette. As defined in section 3(1) of the FCLAA, the term “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 subparagraph (1) of this definition. (21 CFR 1141.3).

Commerce. As defined in section 3(2) of the FCLAA, “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. (21 CFR 1141.3).

Distributor. 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 proposed part. (21 CFR 1141.3)

Front panel and rear panel mean the two largest sides or surfaces of the package. (21 CFR 1141.3).

Manufacturer. 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. (21 CFR 1141.3).

⁷ For the purposes of this guidance, we refer to “cigarette plan” or “cigarette plans” to refer to the plan that provides for the random and equal display and distribution of the required warnings on cigarette packaging and the quarterly rotation of the required warnings in cigarette advertising, as described under section 4 of the FCLAA and 21 CFR 1141.

Contains Nonbinding Recommendations

Package or packaging. As defined in section 3(4) of the FCLAA, “package” means a pack, box, carton, or container of any kind in which cigarettes are offered for sale, sold, or otherwise distributed to consumers. (21 CFR 1141.3).

Person. As defined in section 3(5) of the FCLAA, “person” means an individual, partnership, corporation, or any other business or legal entity. (21 CFR 1141.3).

Required warning means the combination of a textual warning label statement and its accompanying color graphic required to be on cigarette packaging and in cigarette advertising pursuant to section 4 of the FCLAA. (21 CFR 1141.10).

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. This definition would include any person who sells cigarettes online (e.g., through a Web site or mobile phone application). (21 CFR 1141.3).

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. (21 CFR 1141.3).

III. QUESTIONS AND ANSWERS

A. What is the purpose of this rule?

This rule establishes new required cigarette health warnings for cigarette packages and advertisements. Section 201 of the Tobacco Control Act amends the FCLAA to require that each cigarette package and advertisement bear one of the new required warnings. These new cigarette health warnings consist of textual warning statements accompanied by concordant color graphics, in the form of photorealistic images, depicting the negative health consequences of cigarette smoking.

This rule also establishes marketing requirements that include the random display and equal distribution of the required warnings on cigarette packages and quarterly rotations of the required warnings in cigarette advertisements. Section 4(c) of the FCLAA and 21 CFR 1141.10(g). The marketing requirements also require submission of a cigarette plan to FDA that provides for the random and equal display and distribution of the required warnings on cigarette packaging and quarterly rotation of the required warnings in cigarette advertising, as described under section 4 of the FCLAA.

B. What items are covered by this rule?

This rule covers cigarette packages and cigarette advertisements for any cigarette that is manufactured, packaged, or imported for sale or distribution within the United States. All cigarette packages and advertisements, regardless of type, must display the required warnings, in accordance with an FDA approved cigarette plan. For print advertisements and other

Contains Nonbinding Recommendations

advertisements with a visual component (including, for example, advertisements on signs, retail displays, Internet Web pages, social media Web sites, digital platforms, mobile applications, and email correspondence), the required warning must appear directly on the top area of the advertisement. 21 CFR 1141.10(d)(1).

C. Who is responsible and subject to enforcement?

1. *Who must comply with this final rule?*

This rule applies to any person who manufactures, packages, sells, offers to sell, distributes, or imports for sale or distribution within the United States any cigarette, including small businesses. Section 4 of the FCLAA and 21 CFR 1141.10(c).

2. *Will FDA provide assistance for small businesses seeking additional information about cigarette plans?*

Yes. 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 out of compliance?*

A cigarette will be deemed misbranded under section 903(a)(1) of the FD&C Act if its package does not bear one of the required warnings in accordance with section 4 of the FCLAA and 21 CFR 1141. 21 CFR 1141.12(a). In addition, 21 CFR 1141.12(a) provides that a cigarette will be deemed misbranded under section 903(a)(7)(A) of the FD&C Act if its advertising does not bear one of the required warnings in accordance with section 4 of the FCLAA and 21 CFR 1141.

Under 21 CFR 1141.12(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 FD&C Act if it bears one of the required warnings in accordance with section 4 of the FCLAA and 21 CFR 1141. A cigarette distributed or offered for sale in any State shall be deemed to be misbranded under section 903(a)(8) of the FD&C 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 FCLAA and 21 CFR 1141.

Therefore, if a person is not in compliance with the final rule, it may be subject to actions and/or penalties under the FD&C Act, such as warning letters, criminal and civil money penalties, injunction, seizure, and no-tobacco-sale orders. Any adulterated and misbranded tobacco products offered for import into the United States may be subject to detention and refusal of admission.

Contains Nonbinding Recommendations

4. *Are retailers subject to enforcement actions?*

Yes, retailers that violate the rule could be subject to enforcement actions. However, a retailer would not be in violation of the requirements of section 4 of the FCLAA and 21 CFR 1141.10 as long as the cigarette package:

- contains a warning;
- is supplied to the retailer by a license- or permit-holding tobacco product manufacturer or distributor; and
- is not altered by the retailer in a way that is material to the requirements of section 4 of the FCLAA or 21 CFR 1141.⁸ 21 CFR 1141.1(c).

The requirements under 21 CFR 1141.10 only apply to a cigarette retailer if that retailer is responsible for or directs the warnings for advertising. 21 CFR 1141.1(d). However, this 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 FCLAA or 21 CFR 1141. 21 CFR 1141.1(d).

5. *In cases where a retailer would not be held liable for a violation, can FDA still take enforcement actions against other entities for violations under 21 CFR 1141?*

Yes. If a cigarette package and/or advertisement is not in compliance with the rule, and the retailer is not in violation of the rule because of the retailer exception in 21 CFR 1141.1(c), FDA may take enforcement action against the responsible party (e.g., the manufacturer, packer, or distributor).

D. What is the timeframe for implementing this rule?

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

Consistent with the language of section 201(b) of the Tobacco Control Act and the December 2, 2020, court order described above, the effective date of the final rule is January 14, 2022. Section 201(a) of the Tobacco Control Act requires manufacturers, distributors, and retailers of cigarettes to submit plans for the random and equal display and distribution of required warnings on cigarette packages and the quarterly rotation of required warnings on cigarette advertisements, and to obtain FDA approval of their plans before products required to bear such warnings enter the market.

Therefore, FDA strongly encourages entities to submit their cigarette plans as soon as possible after publication of the final rule, and in any event by March 16, 2021 to ensure timely FDA review before the effective date of the required warnings.

⁸ For example, this would require that a retailer ensure that all cigarette packages it displays or sells contain a warning that is unobscured by stickers, sleeves, or other materials on the packages.

Contains Nonbinding Recommendations

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

Pursuant to section 201(b) of the Tobacco Control Act and the December 2, 2020, court order described above, cigarette packages and advertisements must bear the required warnings beginning January 14, 2022. Cigarette packages that do not comply with the requirements of the final rule must not be manufactured for sale or distribution in the United States as of January 14, 2022. In addition, beginning 30 days after the effective date, a manufacturer must not introduce into domestic commerce of the United States any product, irrespective of the date of manufacture, that does not conform with the final rule.

In addition, as of the effective date, January 14, 2022, no manufacturer, distributor, or retailer of cigarettes may advertise or cause to be advertised within the United States any cigarette product unless the advertising complies with the final rule. Section 201(b) of the Tobacco Control Act; December 2, 2020, court order.

3. *After the effective date for the required warnings, can manufacturers continue to sell and distribute their remaining stock of cigarettes if the packaging does not comply with the final rule?*

In the final rule, if a cigarette product was manufactured prior to the effective date of the final rule and its package does not contain the required warning, the product may be introduced into commerce in the United States within 30 days from the effective date of the final rule. After the 30-day period, manufacturers would not be permitted to introduce into domestic commerce any cigarette packages, irrespective of the date of manufacture, that does not conform with the requirements under 21 CFR 1141. While the limitation applies to only manufacturers, FDA believes that under the final rule, keeping products without the required warnings on the market for an extended period would not be in the interest of the public health.

4. *After the effective date of the final rule, may distributors and/or retailers sell-off their remaining stock of cigarette products if the packaging does not comply with the final rule?*

Yes. Distributors and retailers may continue to sell and distribute the cigarette product after the effective date of the final rule, but only if the product was manufactured before the effective date, and introduced into domestic commerce by the manufacturer within 30 days from the effective date of the rule.

Contains Nonbinding Recommendations

E. What are the new textual warning label statements?

Under 21 CFR 1141.10(a), a required warning must include (1) a textual warning label statement; and (2) a color graphic to accompany the textual warning label statement.

The textual warning label statements are as follows:

- WARNING: Tobacco smoke can harm your children.
- WARNING: Tobacco smoke causes fatal lung disease in nonsmokers.
- WARNING: Smoking causes type 2 diabetes, which raises blood sugar.
- WARNING: Smoking reduces blood flow to the limbs, which can require amputation.
- WARNING: Smoking causes cataracts, which can lead to blindness.
- WARNING: Smoking causes bladder cancer, which can lead to bloody urine.
- WARNING: Smoking reduces blood flow, which can cause erectile dysfunction.
- WARNING: Smoking causes head and neck cancer.
- WARNING: Smoking can cause heart disease and strokes by clogging arteries.
- WARNING: Smoking during pregnancy stunts fetal growth.
- WARNING: Smoking causes COPD, a lung disease that can be fatal.

21 CFR 1141.10(a)(1).

Under 21 CFR 1141.10(b), 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 21 CFR 1141.5.

F. How do I obtain the electronic files for the required warnings?

The rule identifies the material that FDA incorporates by reference, entitled “Required Cigarette Health Warnings, 2020.” 21 CFR 1141.5. You may obtain a free copy of the material from FDA's web site, located at <https://www.fda.gov/cigarette-warning-files>; the Docket at <https://www.regulations.gov>; or from the Food and Drug Administration, Center for Tobacco Products, Document Control Center, Bldg. 71, Rm. G335, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, email: cigarettewarningfiles@fda.hhs.gov.

The material incorporated by reference, entitled “Required Cigarette Health Warnings, 2020,” includes the required warnings (comprising a textual warning label statement, as specified in 21 CFR 1141.10(a), and its accompanying color graphic) in different layouts based on the size and aspect ratio of the display area where the required warning must appear (i.e., on cigarette packages, in cigarette advertisements). The rule includes an electronic portable document format (.pdf) file containing all the required warnings as a reference in the docket for the final rule (Ref. Required Cigarette Warnings, 2020). FDA is also making this material available on its web site at <https://www.fda.gov/cigarette-warning-files>.

As discussed in the final rule, FDA recognizes that adaptations to the required warnings may be needed to avoid technical implementation issues due to the varying features, formats, and

Contains Nonbinding Recommendations

sizes of cigarette packages and advertisements. FDA has created electronic, layered design files, built as Encapsulated PostScript (.eps) files,⁹ in different formats and aspect ratios designed to fit packaging and advertising of various shapes and sizes. The final rule does not require the use of these .eps files, but we are providing the files as a resource to assist regulated entities implement 21 CFR part 1141 and section 4 of the FCLAA, 15 U.S.C. 1333.

G. How must the required warnings appear on cigarette packages?

- **Size and location** – The required warning must comprise at least the top 50 percent of the front and rear panels of the cigarette package (i.e., the two largest sides or surfaces of the package). 21 CFR 1141.10(c)(2). For cigarette cartons, the required warnings 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. 21 CFR 1141.10(c)(2). The required warning must appear directly on the package and must be clearly visible underneath any cellophane or other clear wrapping. 21 CFR 1141.10(c)(1).
- **Orientation** – The required warning must be positioned so that the text of the required warning and the other information on that panel of the package have the same orientation. 21 CFR 1141.10(c)(3). For example, if the front panel of a cigarette package contains information, such as the brand name of the cigarette, in a left to right orientation, the required warning, including the textual warning statement, must also appear in a left to right orientation.
- **Random and equal display and distribution** – All 11 required warnings for packages 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 must be randomly distributed in all areas of the United States in which the product is marketed, in accordance with an FDA-approved cigarette plan. Section 4(c) of the FCLAA and 21 CFR 1141.10(g)(1).
- **Irremovable or permanent warnings** – Required warnings must be indelibly printed on or permanently affixed to the cigarette package. 21 CFR 1141.10(e). For example, these required warnings 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. 21 CFR 1141.10(e).

H. How must the required warnings appear in cigarette advertisements?

- **Size and location** – For print advertisements and other advertisements with a visual component (including, for example, advertisements on signs, retail displays, Internet Web pages, social media Web pages, digital platforms, mobile applications, and email correspondence), the required warning must appear directly on the advertisement. 21 CFR 1141.10(d)(1). Additionally, required warnings must comprise at least 20 percent of

⁹ The United States government owns all rights in the required warnings, which may not be used, reproduced, displayed, modified or distributed except for purposes of displaying them on cigarette packages (including cartons) and in cigarette advertising as required by 21 CFR part 1141, or with the express written permission of FDA, or as permitted under the Copyright Act.

Contains Nonbinding Recommendations

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. Section 4(b) of the FCLAA and 21 CFR 1141.10(d)(2).

- **Rotation** – The 11 required warnings must be rotated quarterly, in alternating sequence, in advertisements for each brand of cigarettes, in accordance with an FDA-approved cigarette plan. Section 4(c) of the FCLAA and 21 CFR 1141.10(g)(2).
- **Irremovable or permanent warnings** – Required warnings must be indelibly printed on or permanently affixed to a cigarette advertisement. 21 CFR 1141.10(e).

I. How do I implement the required warnings on different sized and shaped cigarette packages and advertisements?

FDA recognizes that adaptations to the required warnings may be needed to avoid technical implementation issues due to the varying features, formats, and sizes of cigarette packages and advertisements. FDA has created electronic, layered design files, built as Encapsulated PostScript (.eps) files, in different formats and aspect ratios designed to fit packaging and advertising of various shapes and sizes. The final rule does not require the use of these .eps files, but we are providing the files as a resource to assist regulated entities implement 21 CFR 1141. In addition to the material incorporated by reference and the .eps files, FDA is making available technical specifications (i.e., instructions) document that includes information on how to access, select, use, and adapt the .eps files based on the size and aspect ratio of the display area where the required warning must appear. These .eps files and technical specifications are also available on FDA's web site at <https://www.fda.gov/cigarette-warning-files>.

J. How do I incorporate the required warnings on packs with hinged lids?

To ensure that the required warning is clear and legible on a hinged lid package, FDA is allowing for minor variations in how the required warnings appear. Manufacturers can separate two lines of text within the textual warning statement such that the line at the location where the lid is to open cuts across the background space between two lines rather than through a line of text. This will help ensure that the textual warning statement is not severed when the package is opened and is clear, conspicuous, and legible in accordance with section 4 of the FCLAA.

K. How do I incorporate the required warnings on “soft pack” style packaging?

As described in the final rule, to incorporate the required warnings without obstructing any of the elements of the warning (i.e., the image and the textual warning statement), a company may adapt the warnings on "soft pack" style packaging by moving the warning below the closure. Because of the importance of maintaining the integrity of the required warning (e.g., not distorting the image or text), an adaptation of 0.375 inches may be acceptable only when it is not technologically feasible to incorporate the required warnings on "soft pack" style packaging without the need to adapt the required warning and when the required warning after the adaptation is still accurately reproduced (e.g., the required warning is not distorted). Anything in

Contains Nonbinding Recommendations

excess of 0.375 inches may begin to distort the required warning and likely would not be in compliance with the requirements of section 4 of the FCLAA and 21 CFR 1141. FDA strongly encourages manufacturers to reach out to us to discuss these issues and any related questions.

As illustrated in the preamble of the final rule, companies using "soft pack" style packaging could move only the upper boundary of the display area of the warning so that it runs along a line that is parallel to and not more than 0.375 inches from the top edge of the package. The companies may compress the vertical size of the required warning and then shift it down (so that it stays within the top 50 percent of the package), but companies who do this must ensure that, to the extent the required warning is adapted to fit the dimensions of the warning area below the closure, the proportions of the required warning are maintained. In addition, the closure and the portion of the packaging that appears between the top edge of the package and the upper boundary of the display area of the required warning must be either solid black or solid white. This will allow companies to continue to produce "soft pack" style packaging with closures at the top center of the pack without obstructing the required warning. However, if FDA determines that it would be technologically feasible to incorporate the required warnings on "soft pack" style packaging without the need to adapt the warning in this way, we plan to notify the regulated companies and the public of this conclusion and give regulated companies a reasonable amount of time to modify their packaging before any regulatory action is taken under this rule.

L. How do I determine if I should use the required warnings with the white background or the black background?

As required by section 4 of the FCLAA, the text of the cigarette health warnings on packages must be black on a white background, or white on a black background, in a manner that contrasts, by typography, layout, or color, with all other printed material on the package. Therefore, companies must determine which text and background color option contrasts with the other printed materials. In addition, the required warnings will be provided in the final rule, and companies must select the appropriate warnings and must ensure the required warnings are accurately reproduced across various sizes and shapes of cigarette packages and cigarette advertisements.

M. How do I ensure that the required warnings are “indelibly printed on” or “permanently affixed to” digital advertisements?

To ensure that the required warnings are indelibly printed on or permanently affixed to digital advertisements, the required warning must remain on the advertisement at all times and be clear, conspicuous, and legible as required in section 4 of the FCLAA. FDA invites manufacturers to raise any specific implementation issue they have as part of the submission of the cigarette plans under 21 CFR 1141.10(g) to facilitate a solution that reflects the requirements and is also technically feasible for the manufacturer or other responsible entity.

N. How do I implement the required warnings in “small” advertisements?

It is the advertiser’s responsibility to ensure that the required warning is clear, conspicuous, and legible as required by section 4 of the FCLAA. FDA invites manufacturers to

Contains Nonbinding Recommendations

raise the specific implementation issue they have as part of the submission of the plan under 21 CFR 1141.10(g) to facilitate a solution that reflects the requirements and is also technically feasible for the manufacturer or other responsible entity.

O. In what language must the required warnings appear on cigarette packages and in cigarette advertisements?

The rule requires that the text of the required warning be in English, except in the following cases:

- (1) If an advertisement appears in a medium (e.g., newspaper, social media Web site, Internet Web pages) where the predominant language is not English, the text in the required warning must appear in the predominant language of the medium, whether or not the advertisement is in English. The predominant language is the primary language used in the non-sponsored content in the publication (e.g., stories or articles featured in or on newspapers, social media Web sites, Internet Web pages).
 - For example, if the predominant language of the medium is French, but the advertisement is in English, the text of the required warning would be required to be in French.
- (2) If the advertisement appears in a medium (e.g., newspaper, social media Web site, Internet Web page) where the predominant language is English but the advertisement itself is not in English, then the text of the required warning should not appear in English. In this case, the text in the required warning must appear in the predominant language used in the advertisement.
 - For example, if the predominant language of the medium is English, but the advertisement is in Spanish, the text in the required warning would have to appear in Spanish, which is the language predominantly used in the advertisement.

21 CFR 1141.10(d)(3).

P. Can I obtain the required warnings with textual statements in languages other than English?

English-language and Spanish-language warnings are contained in “Required Cigarette Health Warnings, 2020,” which is incorporated by reference at 21 CFR 1141.5. FDA is also making available electronic, layered design files, built as .eps files for all the required warnings contained in “Required Cigarette Health Warnings, 2020,” including the Spanish-language textual warning label statements for advertisements. The technical specifications document includes instructions for selecting either the English-language or Spanish-language text layer within the .eps files. See the response to question I, above, for more information on the .eps files and accompanying technical specifications document.

Contains Nonbinding Recommendations

For non-English 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 21 CFR 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 FCLAA, including area and other formatting requirements. 21 CFR 1141.10(d)(5). The manufacturer, distributor, or retailer is required to accurately and appropriately translate the textual warning label statement into the appropriate non-English language, or the advertisement is in violation of the FCLAA and 21 CFR 1141. The translated required warning also needs to meet the area, format, and other requirements of section 4 of the FCLAA and 21 CFR 1141.

Q. What if my advertisement only contains text without images? Do I still have to use the textual warning label statement and a color graphic, or can I only use the textual warning label statement?

The advertisement must bear a required warning, which includes the combination of a textual warning label statement and its accompanying color graphic. 21 CFR 1141.10.

R. Who can I contact for technical assistance if I need help accessing, selecting, using, or adapting the electronic files for the required warnings?

For assistance accessing and using the electronic, layered design files (i.e., .eps files) for the required warnings, contact CTP at cigarettewarningfiles@fda.hhs.gov. For questions regarding the technical specifications document, contact CTP at ASKCTPRegulations@fda.hhs.gov.

S. How can I obtain Printer’s Proofs of the required warnings?

FDA intends to provide Printer's Proofs upon request. Regulated entities can request a set of SWOP or GRACoL Printer's Proofs for the required cigarette health warnings (each set will contain a total of 22 proofs: the 11 warnings with black text on white backgrounds and the 11 warnings with white text on black backgrounds). Requests can be submitted by email (cigarettewarningfiles@fda.hhs.gov), phone (1-877-CTP-1373) or regular mail (Food and Drug Administration, Center for Tobacco Products, Document Control Center, Building 71, Room G335, ATTN: Office of Health Communication and Education, 10903 New Hampshire Avenue, Silver Spring, MD 20993-0002).

T. When do I have to submit a cigarette plan for cigarette packages and advertisements?

Section 201(a) of the Tobacco Control Act requires manufacturers, distributors, and retailers of cigarettes to submit plans for the random and equal display and distribution of required warnings on cigarettes packages and the quarterly rotation of required warnings on cigarette advertisements, and to obtain FDA approval of their plans before products required to bear such warnings enter the market. To ensure timely FDA review prior to the effective date of the required warnings, FDA strongly encourages entities to submit their cigarette plans as soon as possible after publication of the final rule, and in any event by March 16, 2021). Doing so will benefit regulated industry, as firms may need to work with printers to implement the required

Contains Nonbinding Recommendations

warnings as outlined in their approved plans. Early submission will facilitate timely FDA review prior to the effective date of the required warnings, encourage dialogue with entities regarding any implementation concerns, and provide the Agency with the ability to consider proposals by entities in a timely manner.

Given the initial high volume of original submissions FDA may receive and based on our experience with review of plans for required warnings on other tobacco products, our best estimate is that it will take up to 6 months for the Agency to review those original submissions. FDA will ensure that its review of cigarette plans will be completed no later than 6 months after receipt of an adequate plan from persons who work in good faith with FDA to complete its review (e.g., persons should work diligently with FDA and be responsive by submitting any requested information in a timely manner). If there is a higher volume of submissions received than currently expected, for those entities who submit an adequate plan within 5 months and 120 days of publication of this final rule and who work in good faith with FDA to complete its review, FDA intends to ensure that entities are not delayed or prevented from distributing cigarette packages or advertising their products due to the Agency's not having approved their plans by the effective date of the final rule (January 14, 2022).

In reviewing the cigarette plans, FDA will apply the criteria specified in section 4(c)(3) of the FCLAA and in 21 CFR 1141.10(g). For FDA to approve a cigarette plan for cigarette packaging, the plan must provide for the required random and equal display and distribution of required warnings on cigarette packaging and must assure that all of the required warnings will be displayed by the manufacturer, distributor, or retailer at the same time. Section 4(c)(3) of the FCLAA and 21 CFR 1141.10(g)(3). For FDA to approve a cigarette plan for cigarette advertising, the plan must provide that all of the required warnings are rotated quarterly, in alternating sequence, in advertisements for each brand of cigarettes. Section 4(c)(2) of the FCLAA and 21 CFR 1141.10(g)(3). Although we acknowledge that there may be some challenges as industry moves to implement these requirements, FDA intends to assist manufacturers, distributors, and retailers, as applicable, with specific questions and concerns regarding these requirements. Manufacturers with concerns about complying with this requirement for their products should reach out to FDA to discuss their approach and proposal for reasonably achieving the random and equal display and distribution of the required warnings, in as equal a number of times as is possible, and any other specific concerns or circumstances regarding compliance with the final rule.

In general, we recommend that for efficiency of review and to the extent possible, each manufacturer, distributor, or retailer submit a single cigarette plan under proposed 21 CFR 1141.10(g) that covers both packaging and advertising, rather than submitting each plan separately, when applicable.

U. Where can I find information on the submission of cigarette plans for cigarette packages and advertisements?

FDA intends to issue a final guidance document with additional information and recommendations that may be helpful in preparing these plans, which, when issued, may be found at <https://www.fda.gov/tobacco-products/rules-regulations-and-guidance/guidance>.

Contains Nonbinding Recommendations

IV. DOCUMENT HISTORY

March 2020 – First edition of guidance issued.

May 2020 – Guidance is revised to reflect the court order granting a joint motion in the case of *R.J. Reynolds Tobacco Co. et al. v. United States Food and Drug Administration et al.*, No. 6:20-cv-00176 (E.D. Tex. May 8, 2020), to govern proceedings in that case and postpone the effective date of FDA’s final rule on required warnings for cigarette packages and advertisements by 120 days (until October 16, 2021), in light of the COVID-19 pandemic. Specific revisions include the following:

- Section II – Added reference to order postponing the effective date of the final rule by 120 days.
- Section II (and throughout) – Changed effective date of the final rule to October 16, 2021.
- Section II (and throughout) – Changed language stating that FDA strongly encourages entities to submit cigarette plans to FDA as soon as possible after publication of the final rule, and in any event within “5 months after the publication of the final rule” (i.e., August 18, 2020) to “5 months and 120 days after the publication of the final rule” (i.e., December 16, 2020).

December 2020 – Guidance is revised to reflect the court order that granted a motion by the plaintiffs in the case of *R.J. Reynolds Tobacco Co. et al. v. United States Food and Drug Administration et al.*, No. 6:20-cv-00176 (E.D. Tex. December 2, 2020), to further postpone the effective date of the final rule on required warnings for cigarette packages and advertisements (until January 14, 2022). Specific revisions include the following:

- Section II – Added reference to order postponing the effective date of the final rule to January 14, 2022.
- Section II (and throughout) – Changed effective date of the final rule from October 16, 2021, to January 14, 2022.
- Section II (and throughout) – Changed language stating that FDA strongly encourages entities to submit cigarette plans to FDA as soon as possible after publication of the final rule, and in any event “within 5 months and 120 days after the publication of the final rule (i.e., December 16, 2020)” to “by March 16, 2021.”