Draft Guidance for Industry

Submission of Warning Plans for Cigarettes and Smokeless Tobacco Products

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Written comments and suggestions may be submitted within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 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For questions regarding this draft guidance, contact the Center for Tobacco Products at (Tel) 1-877-CTP-1373 (1-877-287-1373) Monday-Friday, 9:00 a.m. – 4:00 p.m. EDT.

Additional copies are available online at http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/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, Building 71, Room G335, 10903 New Hampshire Avenue, Silver Spring, MD 20993-0002.

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

September 2011

Table of Contents

Draft Guidance for Industry[1]

Submission of Warning Plans for Cigarettes and Smokeless Tobacco Products

This draft guidance, when finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic.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 the appropriate telephone number listed on the title page of this guidance.

I. Introduction

This guidance document is intended to assist persons submitting warning plans for cigarettes, as required by section 4 of the Federal Cigarette Labeling and Advertising Act (FCLAA), and warning plans for smokeless tobacco products, as required by Section 3 of the Comprehensive Smokeless Tobacco Health Education Act of 1986 (Smokeless Tobacco Act). This guidance document discusses, among other things:

- The statutory requirements to submit warning plans
- Definitions
- Who submits a warning plan
- The scope of a warning plan
- When to submit a warning plan
- What information should be submitted in a warning plan
- Where to submit a warning plan
- What approval of a warning plan means

[1] This guidance has been prepared by the Office of Compliance and Enforcement and the Office of Regulations in the Center for Tobacco Products at the U.S. Food and Drug Administration.

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

II. Background

On June 22, 2009, the President signed the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (Public Law 111-31) into law. The Tobacco Control Act granted FDA important new authority to regulate the manufacture, marketing, and distribution of tobacco products to protect the public health and to reduce tobacco use by minors.

Section 201 of the Tobacco Control Act amended section 4 of FCLAA, 15 U.S.C. 1333, to prescribe nine health warning statements that must appear on cigarette packages and advertisements. It also modified FCLAA's requirements regarding the submission of warning plans for cigarette packages and advertisements and requires that such warning 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 (FTC). However, these requirements are currently not in effect, which means that the FTC will continue to review warning plans for current cigarette warnings that will be in effect until 15 months after FDA issues regulations as directed by Section 201(b). Section 4(d) of FCLAA requires FDA to issue regulations that require color graphics depicting the negative health consequences of smoking to accompany those warning statements. 15 U.S.C. 1333(d). Section 201(b) of the Tobacco Control Act states that the requirements take effect 15 months after FDA issues these regulations. Under the provision, however, if a cigarette product was manufactured prior to the effective date of the final rule but its package does not contain a required warning, the product may be introduced into commerce in the United States within thirty days from such effective date. After the 30-day period, manufacturers must not introduce into domestic commerce any cigarette the package of which does not contain a required warning, irrespective of the date of manufacture. FDA issued a proposed rule regarding these requirements on November 12, 2010. 75 FR 69524. FDA issued final regulations on June 22, 2011. 76 FR 36628. Accordingly, the requirements for the warnings for cigarettes will become effective on September 22, 2012.

Similarly, section 204 of the Tobacco Control Act amended section 3 of the Smokeless Tobacco Act, 15 U.S.C. 4402, to prescribe requirements for four warning statements that must appear on smokeless tobacco product packages and advertisements, and to require the submission of warning plans for smokeless tobacco product packages and advertisements to FDA for review and approval, rather than to the FTC. These requirements are currently in effect.

A. Cigarettes

Under 15 U.S.C. 1333, each cigarette package and advertisement must bear one of nine textual warning statements.

Packages. Once the required warnings take effect, it will be unlawful for any person to manufacture, package, sell, offer to sell, distribute, or import for sale or distribution within the United States any cigarette unless the product package bears one of the required warnings (i.e., one of the nine textual warning statements and its accompanying color graphic) in accordance with the requirements set forth in 15 U.S.C. 1333 and applicable regulations. In certain situations described in 15 U.S.C. 1333(a)(4), retailers of cigarettes are exempt from this requirement. To fall within this exemption, the retailer must ensure that cigarette packaging: 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 15 U.S.C. 1333(a). However, a retailer is still responsible for complying with other applicable requirements relating to cigarettes, including those contained in 21 CFR Part 1140.

Advertisements. Once the required warnings take effect, it will be unlawful for any tobacco product manufacturer, importer, distributor, or retailer of cigarettes to advertise or cause to be advertised within the United States any cigarette unless its advertising bears one of the required warnings in accordance with the requirements set forth in 15 U.S.C. 1333 and applicable regulations. As with packaging, retailers may be exempt from this requirement under certain circumstances, which are described in 15 U.S.C. 1333(c)(4).

Warning Plans. The requirement for submission of warning plans for cigarettes, and the specific requirements relating to the random display of required warnings on cigarette packaging and quarterly rotation of required warnings in cigarette advertising, appear at 15 U.S.C. 1333(c).

In particular, warning plans for cigarette packaging must provide that all of the required warnings:

- Are randomly displayed in each 12-month period on each brand of the product,
- Are randomly displayed in as equal a number of times as is possible on each brand of the product, and
- Are randomly distributed in all areas of the United States in which the product is marketed.

15 U.S.C. 1333(c)(1). For FDA to approve it, a warning plan must provide for the required equal distribution and display of required warnings on packaging and must assure that all of the required warnings will be displayed by the manufacturer, importer, distributor, or retailer at the same time. 15 U.S.C. 1333(c)(3).

For FDA to approve it, a warning plan for cigarette advertising must provide that all of the required warnings are rotated quarterly in alternating sequence in advertisements for each brand of cigarettes. 15 U.S.C. 1333(c)(2) and (3).

B. Smokeless Tobacco Products

Under 15 U.S.C. 4402, each smokeless tobacco product package and advertisement must bear one of four textual warning statements.

Packages. It is unlawful for any person to manufacture, package, sell, offer to sell, distribute, or import for sale or distribution within the United States any smokeless tobacco product unless the product package bears one of the following required warning statements:

- WARNING: This product can cause mouth cancer.
- WARNING: This product can cause gum disease and tooth loss.
- WARNING: This product is not a safe alternative to cigarettes.
- WARNING: Smokeless tobacco is addictive.

15 U.S.C. 4402(a)(1).

In certain situations described in 15 U.S.C. 4402(a)(5), retailers of smokeless tobacco products are exempt from this requirement. To fall within this exemption, the retailer must ensure that smokeless tobacco packaging: 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 15 U.S.C. 4402(a). 15 U.S.C. 4402(a)(5). However, a retailer is still responsible for complying with other applicable requirements relating to smokeless tobacco products, including those contained in 21 CFR Part 1140.

Advertisements. It is also unlawful for any smokeless tobacco product manufacturer, packager, importer, distributor, or retailer to advertise or cause to be advertised within the United States any smokeless tobacco product unless the advertising bears one of the required warning statements. 15 U.S.C. 4402(b)(1). As with packaging, retailers may be exempt from this requirement under certain circumstances, which are described in 42 U.S.C. 4402(b)(3)(D).

In an important change from prior law, outdoor billboard advertising for smokeless tobacco products must now include the required warning statements. Prior to its amendment by the Tobacco Control Act, the Smokeless Tobacco Act exempted outdoor billboard advertising from the requirement that smokeless tobacco product advertisements bear required warning statements,[2] but the Tobacco Control Act amendments eliminated this exemption. 15 U.S.C. 4402(b). Thus, it is unlawful for any smokeless tobacco product manufacturer, packager, importer, distributor, or retailer to advertise or cause to be advertised a smokeless tobacco product on an outdoor billboard unless the advertisement bears one of the required warning statements.

[2] This exemption had been codified at 15 U.S.C. 4402(a)(2).

Warning Plans. The requirement for submission of warning plans for smokeless tobacco products and the specific requirements relating to random display of required warning statements on smokeless tobacco product packaging and quarterly rotation of required warning statements in smokeless tobacco product advertising appear at 15 U.S.C. 4402(b)(3).

In particular, warning plans for smokeless tobacco product packaging must provide that all of the required warning statements:

- Are randomly displayed in each 12-month period on each brand of the product,
- Are randomly displayed in as equal a number of times as is possible on each brand of the product, and
- Are randomly distributed in all areas of the United States in which the product is marketed.

15 U.S.C. 4402(b)(3)(A). For FDA to approve it, a warning plan must provide for the required equal distribution and display of required warning statements on packaging and must assure that all of the required warning statements will be displayed by the manufacturer, importer, distributor, or retailer at the same time. 15 U.S.C. 4402(b)(3)(C)(ii).

Warning plans for smokeless tobacco product advertising must provide that all of the required warning statements are rotated quarterly in alternating sequence in advertisements for each brand of smokeless tobacco product. 15 U.S.C. 4402(b)(3)(B).

Because section 9(1) of the Smokeless Tobacco Act, 15 U.S.C. 4408(1) (as amended by Section 101(c) of the Tobacco Control Act), defines "smokeless tobacco," by reference to section 900(18) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 387(18)), as "any tobacco product that consists of cut, ground, powdered, or leaf tobacco and that is intended to be placed in the oral or nasal cavity," smokeless tobacco products intended to be placed in the nasal cavity must now comply with the warning requirements in section 3 of the Smokeless Tobacco Act. At this time, as an exercise of enforcement discretion, FDA does not intend to commence or recommend enforcement of the requirement that smokeless tobacco products marketed solely for use in the nasal cavity bear either the "WARNING: This product can cause mouth cancer." or the "WARNING: This product can cause gum disease and tooth loss." so long as a warning plan providing that packages and advertising for such products will bear the other two warnings has been submitted to FDA and implemented. FDA will give further consideration to the warnings smokeless tobacco products marketed solely for use in the nasal cavity should bear. FDA intends to provide further public notice prior to revising or rescinding this enforcement policy.

III. Discussion

A. Definitions

For purposes of this guidance, FDA intends to use the definitions in section 4 of FCLAA, in Section 3 of the Smokeless Tobacco Act, and in any implementing regulations, as well as the following definitions:

"Required warning" means the combination of a textual warning statement and its accompanying color graphic required pursuant to section 4 of FCLAA to be on packaging and in advertising for cigarettes.

"Required warning statement" means a textual warning statement required pursuant to section 3 of the Smokeless Tobacco Act to be on packaging and in advertising for smokeless tobacco products.

"Warnings" refers to the required warnings (for cigarettes) and the required warning statements (for smokeless tobacco products).

"Original submission." FDA considers the submission of a warning plan to be an original submission if it is the first time the submitter has provided to FDA a warning plan for cigarettes or smokeless tobacco products.

"Amendment." FDA considers a submission to be an amendment if the submitter is submitting additional information to a warning plan that is currently under review at FDA.

"Supplement." FDA considers a submission to be a supplement if the submitter is seeking approval of a change to an FDA-approved warning plan.

B. Who submits a warning plan?

This section describes what FDA believes are the relevant considerations in determining whether the manufacturer, importer, distributor, or retailer is best suited to submit a warning plan. These considerations will help ensure the applicable requirements are complied with as well as avoid situations where multiple persons unnecessarily submit a warning plan applicable to the same distribution chain.

Packages

As explained above, when the warning requirements are in effect, it is unlawful for any person to manufacture, package, sell, offer to sell, distribute, or import for sale or distribution within the United States any cigarette or smokeless tobacco product unless the product package bears one of the warnings required by 15 U.S.C. 1333 and 4402, respectively. In addition, warnings on packages must be randomly displayed on each brand and randomly distributed in all areas of the United States in accordance with a warning plan submitted to, and approved by, FDA. 15 U.S.C. 1333(c) (cigarettes) and 15 U.S.C. 4402(b)(3) (smokeless tobacco products). For a particular brand, this warning plan may be submitted by the tobacco product manufacturer, importer, distributor, or retailer. While the warning plan may be submitted by someone other than you, before you "manufacture, package, sell, offer to sell, distribute, or import for sale or distribution within the United States" a brand of cigarettes or smokeless tobacco product, it is

important that you make sure a warning plan has been approved covering your actions and you comply with this plan.

Based on the FTC's experience reviewing warning plans, we believe it is likely that for domestic products only one plan will be submitted for each brand and that the brand's manufacturer will submit this plan. Moreover, in most circumstances, the brand's manufacturer is the entity that is most able to ensure a warning plan would be sufficient for approval by FDA – that it would provide for equal distribution and display on packaging and assure that all of the warnings that are required will be displayed at the same time. This is because the brand's manufacturer is usually the entity responsible, either directly or through a contractor or other agent, for placing or directing the placement of the warnings on the brand's packages and for directing distribution of the packages. Placing the warning on the packages and directing distribution of the packages are the key elements of a warning plan. If a product is manufactured under contract, such as for a private label brand, it is likely that the contracting entity, typically the private label brand's distributor, specifies or otherwise directs the placement of the warnings on the product package. In such situations, FDA believes the private label brand distributor would be best suited to submit the warning plan. If a retailer is responsible for or directs the placement of warnings on packaging, the retailer would be best suited to submit the warning plan.

For finished cigarettes and smokeless tobacco products that are imported, distribution is usually handled by the product's importer or importers. Because importers typically either direct the foreign manufacturer's placement of the warnings on the product package or direct the packaging and placement of the warnings in the United States, we recommend that the importer or importers of a brand of cigarettes or smokeless tobacco product submit the plan. Compared with the manufacturer or other entities, importers are in a position to create a warning plan that best meets the legal requirements, particularly the requirement that the warnings will be randomly distributed in all areas of the United States in which the product is marketed.

Advertisements.

When the required warnings are in effect, it is unlawful for any tobacco product manufacturer, importer, distributor, or retailer to advertise or cause to be advertised within the United State any cigarette or smokeless tobacco product unless its advertising bears one of the required warnings in accordance with the requirements of 15 U.S.C. 1333 and 4402, respectively. One requirement is that the warnings in advertisements be rotated quarterly for each brand in accordance with a warning plan submitted to, and approved by, FDA. 15 U.S.C. 1333(c) (cigarettes) and 15 U.S.C. 4402(b)(3) (smokeless tobacco products). For a particular brand, this warning plan may be submitted by the tobacco product manufacturer, importer, distributor, or retailer. While the warning plan may be submitted by someone other than you, before you advertise a brand of cigarettes or smokeless tobacco product, it is important that you make sure a warning plan has been approved covering your actions, and your actions in rotating warnings in advertising comply with this plan.

In most circumstances, the person who creates advertising, causes advertising to be created, or is otherwise responsible for inclusion of the warning on advertising for a brand of cigarettes or smokeless tobacco products is most able to ensure a warning plan would be sufficient for approval by FDA – that it would provide for quarterly rotation of warnings in advertising for the brand. FDA recommends that each manufacturer, importer, distributor, and retailer who creates advertising, causes advertising to be created, or is otherwise responsible for inclusion of the warning on advertising for a brand of cigarettes or smokeless tobacco products submit a warning plan that covers all of the brands it advertises. A retailer typically would not submit a warning plan for advertising supplied by the manufacturer of a tobacco product if the advertising is already covered by a plan submitted by the manufacturer. The retailer would need to comply with the plan, such as by following the manufacturer's instructions for displaying advertising.

C. What is the scope of a warning plan?

If you are submitting warning plans for both cigarettes and smokeless tobacco products, you must submit one warning plan for cigarettes and one warning plan for smokeless tobacco products - because the requirements for submission of these warning plans rest on separate, albeit similar, statutory authority and the text and number of the applicable warnings is different for cigarettes and smokeless tobacco products - but you may submit these plans as a single document or together in the same envelope. For the efficiency of review, FDA asks that each warning plan cover both packaging and advertising to the extent applicable.

D. When should a warning plan be submitted?

Warnings must be equally distributed and displayed on packages, and rotated quarterly in advertisements, for cigarettes and smokeless tobacco products *in accordance with an approved warning plan*. 15 U.S.C. 1333(c)(1), (2) and 15 U.S.C. 4402(b)(3)(A), (B) (emphasis added). As discussed in the Background section, the required warnings for cigarettes will become effective on September 22, 2012. In order to afford FDA sufficient time to review and approve proposed warning plans for cigarettes before the effective date, FDA strongly recommends that the warning plans for cigarettes be submitted to the agency as soon as possible. Given the volume of submissions FDA currently believes it will receive and that all of these will be initial submissions under the requirements, our best estimate is that it will take at least six months for the agency to review a submission. If the volume is greater than anticipated, or the quality of the submissions is poor, then it will likely take FDA longer to review them. You should keep these factors in mind in deciding when to submit your warning plan.

Under section 204 of the Tobacco Control Act, the requirement for an FDA approved warning plan for smokeless tobacco products became effective June 22, 2010. On June 8, 2010, FDA announced by guidance its intent not to enforce the requirement that a brand of smokeless tobacco product must have an FDA-approved warning plan so long as

a warning plan for the brand was submitted to FDA by July 22, 2010, and implemented. (See 75 FR 32481). FDA expects to begin enforcing the requirement under section 204 that there be an approved warning plan 6 months after the publication of the notice of availability of a final guidance on the "Submission of Warning Plans for Cigarettes and Smokeless Tobacco Products" or 6 months after the publication of a final regulation regarding the submission of warning plans, whichever comes first.

Because warnings must be equally distributed and displayed on packages, and rotated quarterly in advertisements, for cigarettes and smokeless tobacco products in accordance with an approved warning plan, a new warning plan or supplement to an approved warning plan must be submitted and approved before making changes to the distribution or display of warnings on packages or rotation of warnings in advertisements. Likewise, a new plan or a supplement to an approved warning plan must be submitted and approved before distributing or displaying packages and advertisements for a new brand. In order to afford FDA sufficient time to review a supplement to an approved warning plan, FDA strongly recommends that you allow at least three months for FDA to review and approve a supplement. The amount of time it will take FDA to review a supplement, however, will depend upon the volume and quality of the submissions.

FDA may request an amendment to a warning plan or to a supplement to a warning plan if FDA needs clarification of information in the warning plan or minor additional information to determine whether it can approve the warning plan or supplement. Any such amendments will likely increase the overall review time.

E. What information should be submitted as part of a warning plan?

The following information should be submitted to FDA. Appendix A provides an example of what FDA considers to be an acceptable warning plan for cigarettes. Appendix B provides an example of what FDA considers to be an acceptable warning plan for smokeless tobacco products.

1. Cover letter

In order to facilitate FDA's review of warning plans, FDA requests that your warning plan be accompanied by a cover letter that includes:

- Date of the submission;
- One of the following subject lines:
  - "RE: WARNING PLAN FOR CIGARETTES ("Original," "Amendment," or "Supplement"), or
  - "RE: WARNING PLAN FOR SMOKELESS TOBACCO PRODUCTS ('Original,' 'Amendment,' or 'Supplement');
- A statement as to whether the warning plan covers packages, advertising, or both packages and advertising;
- The name, address, and phone number of the person making the submission, the name of the most responsible individual if the submitter is a company,

identification of the person as the manufacturer, distributor, retailer, or importer of the tobacco products covered by the warning plan; and the Data Universal Numbering System (D-U-N-S®) Number of the person making the submission;

- The name, address, phone number, fax number, and email address of the person authorized to act as the FDA contact point for the warning plan;
- A list of any submissions made to FDA relating to the warning plan, identified by CTP-assigned reference number and the date of submission;
- A list of all cigarettes or smokeless tobacco products covered by the plan, preferably identified using the unique name and identifying number (e.g., SKU, catalog number, UPC) that was provided when the product was listed under section 905 of the Federal Food, Drug, and Cosmetic Act; and
- A certification by an authorized official of the company making the submission that all information submitted has been reviewed prior to filing.

2. Information to include in the warning plan for packaging

For each cigarette or smokeless tobacco product brand, your plan should state the specific applicable statutory or regulatory warning plan requirements and provide a detailed description of how:

- Each of the warnings will be randomly displayed during each 12-month period on each brand;
- Each of the warnings will be displayed in as equal a number of times as possible on each brand of the product;
- Product packages will be randomly distributed in all areas of the United States in which the product is marketed; and
- Each of the warnings will be displayed at the same time.

The plan for packaging should include a discussion of how the requirements are to be implemented based on the specific manufacturing processes and distribution procedures. FTC previously defined as "equal number of times as possible" as permitting deviations of 4 percent or less in a 12-month period and FDA considers that to be a good rule-of-thumb (see 16 CFR 307.11, which as part of 16 CFR Part 307 was rescinded by FTC on September 28, 2010 (75 FR 59609) because of the transfer of jurisdiction to FDA).

For the reasons discussed in section II above, warning plans for smokeless tobacco products marketed solely for use in the nasal cavity should provide for the equal distribution and display of two warnings: "WARNING: This product is not a safe alternative to cigarettes." and "WARNING: Smokeless tobacco is addictive."

FDA expects that a plan for equal distribution and display of warnings on packages will ordinarily be based on the date of manufacture or shipment of the product. FDA does not consider a plan that merely re-states the statutory requirements for equal distribution and display of warnings on packages to be sufficiently detailed to enable FDA to determine whether it can approve a warning plan.

Appendices A and B provide an example of a warning plan for cigarettes and an example of a warning plan for smokeless tobacco products, respectively, that FDA believes would meet the applicable requirements for approval.

3. Information to include in the warning plan for advertising

Your plan should state the specific applicable warning plan requirements. Then, for each cigarette or smokeless tobacco brand, your plan must provide a sufficiently detailed description of how the warnings will be rotated quarterly in advertisements, including outdoor billboard advertisements.

For the reasons discussed in section II above, warning plans for smokeless tobacco products marketed solely for use in the nasal cavity should provide for the quarterly rotation of two warnings: "WARNING: This product is not a safe alternative to cigarettes." and "WARNING: Smokeless tobacco is addictive."

Among other things, your plan should specify the date on which quarterly rotation is based and, if the date varies for different types/forms of advertising, specify both the dates and their associated types/forms of advertising, and describe the schedule for rotating warnings for each brand. A warning plan may take into account practical constraints on the production and distribution of advertising. FDA does not consider a warning plan that merely re-states the statutory requirement for quarterly rotation of warnings on advertising to be sufficiently detailed to enable FDA to determine whether it can approve a warning plan.

4. Representative packaging and advertising

FDA requests that your warning plan include representative samples of packages and advertisements with each of the warnings. Such samples will place the warning plan in context and, therefore, facilitate FDA's review. By representative samples, we mean different types of cigarette or smokeless tobacco product packaging and a range of package sizes for each type of product. Samples of advertising could include actual examples of different types of advertising materials for various brands, prototypes of actual advertising materials, the warning as it would appear in different sizes of advertisements, or acetates or other facsimiles for the warning as it would appear in different sizes of advertisements.

G. Where should a warning plan be submitted?

Written warning plans, including the cover letter addressed to the Office of Compliance and Enforcement, should be directed to:

Food and Drug Administration
Center for Tobacco Products
Office of Compliance and Enforcement
Document Control Center
Building 71, Room G335
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

H. What does it mean to get FDA approval of a warning plan?

FDA's review of a warning plan is only for the purpose of determining compliance with the statutory criteria for approval of a warning plan, as set forth in 15 U.S.C. 1333(c)(3) and 4402(b)(3)(C). Approval of a warning plan does ***not*** represent a determination by FDA that any specific package or advertisement complies with any of the other requirements set forth in FCLAA or the Smokeless Tobacco Act, including the requirements set forth in 15 U.S.C. 1333(a)(2), and (b)(2), 4402(a)(2) and (b)(2), and applicable regulations regarding the placement, type, size, and color of the warnings.

Appendix A – Example Cigarette Warning Plan

Note: This document is intended to serve as an example of a plan that FDA believes would meet the applicable requirements for approval and provide information that would help facilitate FDA's review; however, alternative approaches may also satisfy the applicable requirements.

I. Cover Letter (Cigarette Sample)

Date

Office of Compliance and Enforcement
FDA Center for Tobacco Products
c/o Document Control Center
9200 Corporate Boulevard
Rockville, Maryland 20850

RE: WARNING PLAN FOR CIGARETTES
([***INSERT*** *"Original," "Amendment," or "Supplement"*])

To Whom It May Concern:

Pursuant to Section 4 of the Federal Cigarette Labeling and Advertising Act (FCLAA), as amended by section 201 of the Family Smoking Prevention and Tobacco Control Act of 2009 (Tobacco Control Act), [***INSERT*****:** *company name*] submits this proposed warning plan covering *[**INSERT**: packaging and advertising or packaging or advertising]* for cigarettes. See attached.

This plan is being submitted by:
- Company Name:
- Name of most responsible individual:
- Company Role (manufacturer, distributor, importer, or retailer):
- Street Address:
- City, State, and Zip Code:
- Phone Number:
- DUNS Number:

Contact information
- Name of contact for the warning plan:
- Street Address (if different):
- City, State, and Zip Code (if different):
- Phone Number:
- Fax Number:
- Email Address:

Transmitter information (if different from the submitter)
- Name of person transmitting the warning plan on behalf of the submitter:
- Company Name:
- Street Address:
- City, State, and Zip Code:
- Phone Number:
- Fax Number:
- Email Address:

Previous Related Warning Plan Number(s) (if applicable):

Appendix A – Example Cigarette Warning Plan

This plan covers the following cigarette products:

Brand Name	Product (Subbrand)	Unique Identifier	Type of Unique Identifier (SKU, Catalog #, UPC)
1. Brand x	*Blues 100 Hard Pack*	*12345*	*Catalog #*
2.			

If you have any questions regarding the attached warning plan, please contact [***INSERT*: *name of company contact listed above***].

Sincerely,

Name, Title

CERTIFICATION

This certifies that all of the information submitted in the attached Warning Plan dated [***INSERT:*** *date*] which covers cigarettes [***SELECT****: packaging and/or advertising*] was reviewed by me [***IF APPLICABLE:*** and [***INSERT***: name of person transmitting warning plan] has the authority to transmit it on my behalf].

_____

Printed Name of official of company who is authorized to submit plan

_____

Signature of official of company who is authorized to submit plan

II. Warning Plan for Cigarette Packaging

In accordance with Section 4 of the FCLAA, each cigarette package must bear one of nine warning statements and its accompanying graphic on the front and rear panels of the package. Additionally, the warning statement must appear in black text if on a white background, or white text if on a black background, in a manner that contrasts, by typography, layout, or color, with all other printed material on the package.

This plan provides the manner by which the required warnings on packages will be:

- randomly displayed in each 12-month period on each brand of the product;
- randomly displayed in as equal a number of times as is possible on each brand of the product;
- randomly distributed in all areas of the United States in which the product is marketed; and
- displayed on product packages at the same time.

To ensure display of required warnings in as equal a number of times as is possible on packaging for each brand, we will:

1. Produce a total of 9,000 packages for each print run.
2. Print each of the nine required warnings on packages in sequential order (1, 2, 3, 4, 5, 7, 8, 9 and 1, 2, 3, 4, 5, 7, 8, 9 and 1, 2, 3, 4, 5, 7, 8, 9, etc.), for a total of 9,000 (1,000 each).

OR

2. Print 1,000 of each of the nine required warnings on batches of packages simultaneously (1,000 of warning 1, 1,000 of warning 2, etc.).

This should result in an equal display of each of the nine different required warnings for each brand of product, subject to minor variations due to normal commercial printing and manufacturing practices.

To ensure that the required warnings are randomly displayed in as equal a number of times as is possible on each brand during a 12-month period, that all nine required warnings are displayed at the same time, and that the required warnings are randomly distributed in all areas of the United States in which the product is marketed, we will:

Upon cigarettes being manufactured, store products in shipping containers. Each container will include all required warnings in as equal numbers as possible. When an order is placed, we will distribute such container(s).

OR

Separate cigarette packages by required warning at the time of manufacture. When an order is placed, we will fill the order with as equal a number of packages as is possible from each separate inventory of these warnings.

Appendix A – Example Cigarette Warning Plan

III. Warning Plan for Cigarette Advertising

In accordance with Section 4 of FCLAA, each cigarette advertisement must bear one of the nine required warnings. Additionally, the warning statement must appear in black text if on a white background or white text if on a black background.

This plan provides the manner by which the required warnings on cigarette advertising will be rotated quarterly in alternating sequence in advertisements for each brand of cigarettes.

Our advertisements will rotate the nine required warnings according to the following schedule for each brand of product:

	Jan 1 – March 31	April 1 – June 30	July 1 – Sept 30	Oct 1 – Dec 31	Jan 1 – March 31	April 1 – June 30	July 1 – Sept 30	Oct 1 – Dec 31	Jan 1 – March 31
Brand A	*1*	*2*	*3*	*4*	*5*	*6*	*7*	*8*	*9*
Brand B	*9*	*1*	*2*	*3*	*4*	*5*	*6*	*7*	*8*
Brand C	*8*	*9*	*1*	*2*	*3*	*4*	*5*	*6*	*7*

1=WARNING: Cigarettes are addictive.
2=WARNING: Tobacco smoke can harm your children.
3=WARNING: Cigarettes cause fatal lung disease.
4=WARNING: Cigarettes cause cancer.
5=WARNING: Cigarettes cause strokes and heart disease.
6=WARNING: Smoking during pregnancy can harm your baby.
7=WARNING: Smoking can kill you.
8=WARNING: Tobacco smoke causes fatal lung disease in nonsmokers.
9=WARNING: Quitting smoking now greatly reduces serious risks to your health.

Cigarette brands will be advertised using the following media and the rotation of the nine required warnings will be based on the date indicated in the table below:

Type of Advertising	**Start of Quarterly Rotation**
Advertising in periodicals (newspapers, magazines)	[*Cover date*] *or* [*closing date of publication*]
Posters and placards	[*Date of scheduled appearance of the advertisement.*]
Other Advertisements	[*Order date*] *or* [*date of material dissemination*]

Appendix B – Example Smokeless Tobacco Warning Plan

Note: This document is intended to serve as an example of a plan that FDA believes would meet the applicable requirements for approval and provide information that would help facilitate FDA's review; however, alternative approaches may also satisfy those requirements.

I. Cover Letter (Smokeless Sample)

Date

Office of Compliance and Enforcement
FDA Center for Tobacco Products
c/o Document Control Center
9200 Corporate Boulevard
Rockville, Maryland 20850

RE: WARNING PLAN FOR SMOKELESS TOBACCO PRODUCTS
([***INSERT:*** *"Original," "Amendment," or "Supplement"*])

To Whom It May Concern:

Pursuant to Section 3 of the Comprehensive Smokeless Tobacco Health Education Act of 1986 (Smokeless Tobacco Act), as amended by section 204 of the Family Smoking Prevention and Tobacco Control Act of 2009 (Tobacco Control Act), [***INSERT:*** *company name*] submits the attached proposed warning plan covering [***INSERT:*** *packaging and advertising or packaging or advertising*] for smokeless tobacco products. See attached.

This plan is being submitted by:
- Company Name:
- Name of most responsible individual:
- Company Role (manufacturer, distributor, importer, or retailer):
- Street Address:
- City, State, and Zip Code:
- Phone Number:
- DUNS Number:

Contact information
- Name of contact for the warning plan:
- Street Address (if different):
- City, State, and Zip Code (if different):
- Phone Number:
- Fax Number:
- Email Address:

Transmitter information (if different from the submitter)
- Name of person transmitting the warning plan on behalf of the submitter:
- Company Name:
- Street Address:
- City, State, and Zip Code:
- Phone Number:
- Fax Number:
- Email Address:

Previous Related Warning Plan Number(s) (if applicable):

Appendix B – Example Smokeless Tobacco Warning Plan

This plan covers the following smokeless tobacco products:

Brand Name	Product (Subbrand)	Type of Smokeless Tobacco	Unique Identifier	Type of Unique Identifier (SKU, Catalog #, UPC)
1. Brand x	*Long Cut Mint*	*Chew*	*12345*	*Catalog #*
2.				

If you have any questions regarding the attached warning plan, please contact [***INSERT:*** *name of company contact listed above*].

Sincerely,

Name, Title

CERTIFICATION

This certifies that all of the information submitted in the attached Warning Plan dated [***INSERT:*** *date*] which covers *smokeless tobacco products* [***SELECT:*** *packaging and/or advertising*] was reviewed by me [***IF APPLICABLE:*** and [***INSERT***: name of person transmitting warning plan] has the authority to transmit it on my behalf].

_____

Printed Name of official of company who is authorized to submit plan

_____

Signature of official of company who is authorized to submit plan

II. Warning Plan for Smokeless Tobacco Product Packaging

In accordance with Section 3 of the Smokeless Tobacco Act, each smokeless tobacco product package must bear one of four required warning statements on its two principal display panels. Additionally, the warning statement must appear in black text if on a white background, or white text if on a black background, in a manner that contrasts by typography, layout, or color, with all other printed material on the package.

This plan provides the manner by which the required warning statements on packages will be:

- randomly displayed in each 12-month period on each brand of the product;
- randomly displayed in as equal a number of times as is possible on each brand of the product;
- randomly distributed in all areas of the United States in which the product is marketed; and
- displayed on product packages at the same time.

To ensure display of the four required warning statements in as equal a number of times as is possible on packaging for each brand, we will:

1. Produce a total of 4,000 packages for each print run.
2. Print each of the four required warning statements on packages in sequential order (1, 2, 3, 4, and 1, 2, 3, 4, and 1, 2, 3, 4, etc.), for a total of 4,000 (1,000 each).

OR

2. Print 1,000 of each of the four required warning statements on batches of packages simultaneously (1,000 of warning 1, 1,000 of warning 2, etc.).

This should result in an equal display of the four different required warning statements for each brand of product, subject to minor variations due to normal commercial printing and manufacturing practices**.**

To ensure that the required warning statements are randomly displayed and in as equal a number of times as is possible on each brand during a 12-month period, that all four required warning statements are displayed at the same time, and that the required warning statements are randomly distributed in all areas of the United States in which the product is marketed, we will:

Upon smokeless tobacco product being manufactured, store products in shipping containers. Each container will include all required warning statements in as equal a number as possible. When an order is placed, we will ship such container(s).

OR

Separate smokeless tobacco product packages by required warning statement at the time of manufacture. When an order is placed, we will fill the order with as equal a number of packages as is possible from each separate inventory of these warning statements.

Appendix B – Example Smokeless Tobacco Warning Plan

III. Warning Plan for Smokeless Tobacco Product Advertising

In accordance with Section 3 of the Smokeless Tobacco Act, each smokeless tobacco advertisement must bear one of the four required warning statements. Additionally, the warning statement must appear in black text if on a white background or white text if on a black background.

This plan provides the manner by which the required warning statements on smokeless tobacco product advertising will be rotated quarterly in an alternating sequence in advertisements for each brand of smokeless tobacco product.

Our advertisements will rotate the four required warning statements according to the following schedule for each brand of product:

	Jan 1 – March 31	April 1 – June 30	July 1 – Sept 30	Oct 1 – Dec 31
Brand A	*1*	*2*	*3*	*4*
Brand B	*2*	*3*	*4*	*1*
Brand C	*3*	*4*	*1*	*2*

1 = WARNING: This product can cause mouth cancer.
2 = WARNING: This product can cause gum disease and tooth loss.
3 = WARNING: This product is not a safe alternative to cigarettes.
4 = WARNING: Smokeless tobacco is addictive.

Smokeless tobacco brands will be advertised using the following media and the rotation of the four required warning statements will be based on the date indicated in the table below.

Type of Advertising	**Start of Quarterly Rotation**
Advertising in periodicals (newspapers, magazines)	[*Cover date*] or [*closing date of publication*]
Posters and placards	[*Date of scheduled appearance of the advertisement.*]
Other Advertisements	[*Order date*] or [*date of material dissemination*]