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Draft – Not for Implementation

Submission of Plans for Cigarette Packages and Cigarette Advertisements

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DRAFT GUIDANCE

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For questions regarding this draft guidance, contact the Center for Tobacco Products at (Tel) 1-877-CTP-1373 (1-877-287-1373) Monday-Friday, 9 a.m. – 4 p.m. EDT.

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

December 2019

Table of Contents

Submission of Plans for Cigarette Packages and Cigarette Advertisements[1]

Guidance for Industry[2]

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or Agency) on this topic.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 assist persons (you) submitting cigarette plans[3] for cigarette packages and cigarette advertisements, as required by the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (Public Law 111-31), amending the Federal Cigarette Labeling and Advertising Act (FCLAA) (15 U.S.C. 1333). This guidance provides recommendations related to the FCLAA requirements regarding the submission of cigarette plans for cigarette packages and advertisements. This guidance document also discusses, among other things:

- The regulatory requirements to submit cigarette plans
- Definitions
- Who submits a cigarette plan
- The scope of a cigarette plan

[1] This draft guidance, when finalized, will supersede the portion of the 2011 Draft Guidance, "Submission of Warning Plans for Cigarettes and Smokeless Tobacco Products," that relates to cigarette health warnings (i.e., the submission of plans for cigarettes).

[2] This guidance was prepared by the Office of Compliance and Enforcement and the Office of Regulations in the Center for Tobacco Products at FDA.

[3] As described in Section II, for the purposes of this draft guidance, "cigarette plan" or "cigarette plans" refers to the plan that provides for the random and equal display and distribution of the required warnings on cigarette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.

- When to submit a cigarette plan
- What information should be submitted in a cigarette plan
- Where to submit a cigarette plan
- What approval of a cigarette plan means

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 that something is suggested or recommended, but not required.

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 regulations requiring color graphics depicting the negative health consequences of smoking to accompany new textual warning statements (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). Section 201(b) of the Tobacco Control Act provides that the warning requirements are to become effective 15 months after the date the final rule publishes in the *Federal Register*.[4]

The Tobacco Control Act also modified the FCLAA's requirements regarding the submission of cigarette plans for cigarette packages and advertisements and requires that such cigarette 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).

FDA issued a proposed rule on required warnings for cigarette packages and advertisements on August 16, 2019 (84 FR 42754). The proposed rule, once finalized, would specify the textual warning label statements that will be required and the color graphics that must accompany them. FCLAA establishes marketing requirements that include the random and equal display and distribution of the required warnings for cigarette packages and quarterly rotation of the required warnings in cigarette advertisements. The statutory marketing requirements also require submission of a cigarette plan 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. The proposed rule proposes

[4] In the *Federal Register* of June 22, 2011 (76 FR 36628), FDA issued a final rule entitled "Required Warnings for Cigarette Packages and Advertisements," which specified nine images to accompany the nine textual warning statements for cigarettes set out in the Tobacco Control Act. However, the final rule was challenged in court and on August 24, 2012, the U.S. Court of Appeals of the District of Columbia vacated the rule. In the following years, FDA conducted comprehensive research and development activities in support of the new cigarette health warnings proposed rule issued in August 2019.

requiring that cigarette plans be submitted to FDA no later than five months after the date of publication of the final rule. For efficiency of review, FDA requests that, to the extent possible, manufacturers, distributors, and retailers submit a single cigarette plan that covers both packaging and advertising. This guidance provides recommendations related to preparing and submitting those cigarette plans.

A. Definitions

For purposes of this guidance, FDA intends to use the following definitions. When the proposed rule is finalized, FDA may add definitions from the final rule when finalizing this guidance.

Amendment. FDA considers a submission to be an amendment if the tobacco product manufacturer, distributor, or retailer is submitting additional information to a cigarette plan that is currently under review at FDA.

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.

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.

Distributor. As defined in section 900(7) of the FD&C Act, any person who furthers the distribution of a tobacco product, 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 purposes of this chapter.

Original submission. FDA considers the submission of a cigarette plan for a specific brand(s) to be an original submission if it is the first time the tobacco product manufacturer, distributor, or retailer has submitted a cigarette plan for cigarette packaging and advertising to FDA for that brand.

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.

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

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.

Retailer. As defined in section 900(14) of the FD&C Act, any person, government, or entity who sells tobacco products to individuals for personal consumption, or who operates a facility where self-service displays of tobacco products are permitted.

Supplement. FDA considers a submission to be a supplement if the tobacco product manufacturer, distributor, or retailer is seeking approval of a change to an FDA-approved cigarette plan.

Tobacco Product Manufacturer. As defined in section 900(20) of the FD&C Act, any person, including any repacker or relabeler, who manufactures, fabricates, assembles, processes, or labels a tobacco product; or imports a finished tobacco product for sale or distribution in the United States.

United States. As defined in section 3(3) of the FCLAA, the term "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.

B. Overview of Required Warnings

Under section 4 of the FCLAA, each cigarette package and advertisement must bear a textual warning label statement accompanied by a color graphic depicting the negative health consequences of cigarette smoking. The proposed rule on required warnings for cigarette packages and advertisements contains 13 proposed required warnings, consisting of textual warning label statements and concordant photorealistic images, and explains that FDA proposes to finalize some or all of the 13 required warnings.

Under section 4 of the FCLAA, the required warnings must comprise the top 50 percent of the front and rear panels of cigarette packages and at least 20 percent of the area of the advertisement in a conspicuous and prominent format and location at the top of each cigarette advertisement within the trim area, if any.

According to section 201(b) of the Tobacco Control Act, if a cigarette product was manufactured prior to the effective date of the final rule (i.e., 15 months from the date that the final rule publishes in the *Federal Register*), but its package does not contain a required warning, the product may be introduced into commerce in the United States within 30 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.

C. Overview of Cigarette Plan Requirements

The requirement for submission of cigarette plans for cigarette packages and advertisements, and the specific requirements relating to the random and equal display and distribution of required warnings on cigarette packaging and quarterly rotation of required warnings in cigarette advertising, appear at section 4(c) of the FCLAA. Pursuant to section 201(b) of the Tobacco Control Act, packages and advertisements of cigarettes will be required to bear the required warnings beginning 15 months after the date of publication of the final rule. In addition, section 201(c) of the Tobacco Control Act requires the agency to review and approve cigarette plans in advance of any person marketing products that are required to carry the warnings on packages and advertisements.

If the rule is finalized as proposed, each person required to submit a cigarette plan to FDA would be required to do so no later than 5 months after the final rule publishes in the *Federal Register*. This will facilitate timely FDA review prior to the effective date, which is 15 months from the date that the final rule publishes in the *Federal Register*. (84 FR 42754). Given the initial bolus 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 original submissions. FDA will complete its review of plans timely submitted (i.e., no later than 5 months after the date of publication of the final rule) before the effective date of the required cigarette health warnings. FDA will ensure that its review of cigarette plans will be completed no later than 6 months after receipt of an adequate plan for persons who are responsive and work diligently with FDA to complete its review (e.g., persons should submit any requested information in a timely manner).

More specifically, under Section 4(c)(1) of the FCLAA, cigarette plans for cigarette packaging must provide that all of the required warnings are:

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

In reviewing the cigarette plans, FDA will apply the criteria specified in Section 4(c)(3) of FCLAA. 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.

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

III. DISCUSSION

A. Who Submits a Cigarette Plan?

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

1. Packages

As explained above, when the cigarette plan requirements are in 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 product unless the product package bears one of the required warnings set forth in section 4 of the FCLAA. In addition, required warnings on packages must be randomly and equally displayed on each brand and randomly distributed in all areas of the United States in accordance with a cigarette plan submitted to, and approved by, FDA. Section 4(c) of the FCLAA.

For a particular brand, this cigarette plan may be submitted by the tobacco product manufacturer, distributor, or retailer. Although the cigarette 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, to ensure you are in compliance with FCLAA, it is important that you make sure there is an applicable FDA-approved cigarette plan for that cigarette brand and that you comply with the approved plan.

Based on FDA's experience reviewing similar plans for other tobacco products, we believe it is likely that for domestic products only one cigarette plan will be submitted for each brand and that the brand's manufacturer will submit this plan. One plan may also be submitted for multiple brands. In most circumstances, the brand's manufacturer is the entity most able to ensure that a cigarette plan meets the relevant requirements.

The brand's manufacturer is also typically the entity responsible, either directly or through a contractor or other agent, for placing or directing the placement of the required warnings on the brand's cigarette packages and for directing distribution of the packages. The cigarette plan should describe how the required warnings will be placed on packages and how the required warnings on packages will be randomly distributed to all areas in the U.S. where the product is marketed.

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 required warnings on the product package. Therefore, in these situations, FDA believes the private label brand distributor would be best suited to submit the cigarette plan.

Consistent with section 900(20) of the FD&C Act, the definition of manufacturer includes any person who imports any cigarette for sale or distribution to consumers in the United States. The importer usually directs distribution of the packages after they are imported. If this definition is adopted in the final rule, for finished cigarettes that are imported, we would recommend that the person who is importing cigarettes submit the plan.

Under section 4 of the FCLAA, retailers are not in violation of the requirements of section 4 of the FCLAA for cigarette packaging that (1) contains a warning; (2) is supplied to the retailer by a license- or permit-holding tobacco product manufacturer or distributor; and (3) is not altered by the retailer in a way that is material to the requirements of section 4 of the FCLAA. 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. We note that retailers who are also manufacturers would be subject to both the requirements for retailers and manufacturers, as applicable.

2. Advertisements

When the required warnings are in effect, it will be unlawful for any tobacco product manufacturer, distributor, or retailer to advertise or cause to be advertised within the United States any cigarette product unless its advertising bears one of the required warnings in accordance with the requirements of section 4 of the FCLAA. Under these requirements, the required warnings in advertisements must be rotated quarterly in alternating sequence for each brand in accordance with a cigarette plan submitted to, and approved by, FDA (see section 4 of the FCLAA).

For a particular brand, the cigarette plan may be submitted by the tobacco product manufacturer, distributor, or retailer. Thus, although the cigarette plan may be submitted to FDA by someone other than you, before you advertise a brand of cigarettes, it is important that you make sure there is an applicable FDA-approved cigarette plan for the quarterly rotation of the required warnings for cigarette advertisements and that you comply with the approved plan. 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. Retailers would also need to ensure that the advertisements contain a warning and that the warning has not been altered by the retailer in a way that is material to the requirements of section 4 of the FCLAA.

In most circumstances, the person who creates advertising, causes advertising to be created, or is otherwise responsible for inclusion of the required warnings in advertising for a brand of cigarettes is most able to ensure a cigarette plan contains sufficient information for approval by FDA. FDA recommends such responsible persons submit a cigarette plan that covers all of the brands it advertises.

A retailer typically would not submit a cigarette plan for advertising supplied by the manufacturer of a tobacco product if the advertising is already covered by an FDA-approved cigarette plan submitted by the manufacturer. The retailer should comply with the cigarette plan, such as by following the manufacturer's instructions for displaying advertising. However, under section 4 of the FCLAA, a retailer would not be relieved of liability if the retailer displays, in a location open to the public, an advertisement that does not contain a warning or that contains a warning that has been altered by the retailer in a way that is material to the requirements of section 4 of the FCLAA.

B. What is the Scope of a Cigarette Plan?

For efficiency of review, FDA asks that, to the extent possible, each cigarette plan cover both packaging and advertising, rather than submitting each plan separately. The cigarette manufacturer, distributor, or retailer should describe its plan to achieve the random and equal display and distribution of the required warnings on packages and the quarterly rotation of the required warnings on advertisements.

A cigarette plan may cover a single brand or multiple brands. Manufacturers may state in their original submission that the plans apply to all brands in their product listing(s) under section 905(i) of the FD&C Act. For retailer generated advertising, retailers may list "all brands," which will cover future brands, so long as the plan provides for the same schedule for quarterly rotation of the required warnings for all brands.

C. When Should a Cigarette Plan Be Submitted?

If the rule is finalized as proposed, each person required to submit a cigarette plan to FDA would be required to do so no later than 5 months after the final rule publishes in the *Federal Register* to ensure timely FDA review prior to the effective date. (84 FR 42754). Cigarette plans that are submitted as soon as possible after the publication of the final rule are likely to be reviewed by FDA promptly. Given the potential volume of submissions FDA may initially receive, our best estimate is that it will take up to 6 months for the Agency to review the initial bolus of original submissions. 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 cigarette plan to facilitate adequate time to obtain FDA approval of the cigarette plan prior to the date by which the required warnings are to become effective.

FDA will complete its review of plans timely submitted (i.e., no later than 5 months after the date of publication of the final rule) before the effective date of the required cigarette health warnings. FDA will ensure that its review of cigarette plans will be completed no later than 6 months after receipt of an adequate plan for persons who are responsive and work diligently with FDA to complete its review (e.g., persons should submit any requested information in a timely manner).

Once FDA approves a cigarette plan, a supplement to the approved cigarette plan must be submitted to FDA and approved before making changes to the distribution or display of required warnings on packages or the rotation of required warnings in advertisements. After the effective date of the final rule, for a new brand, a new cigarette plan or a supplement to an approved cigarette plan must be submitted and approved before distributing or displaying packages and advertisements for that new brand.

However, in lieu of a supplement to an approved cigarette plan to cover a new brand, a manufacturer's original cigarette plan may state that it applies to all brands in their product listing(s) under section 905(i) of the FD&C Act. A supplement would not be required to cover a new brand if manufacturers reference in their original cigarette plans all brands in their product listing(s) under section 905(i) of the FD&C Act, so long as no other changes are made to the plan. For retailer-generated advertising, retailers may list "all brands" in their cigarette plan, which will cover future brands, so long as the plan provides for the same schedule for quarterly rotation of the required warnings for all brands.

For planning purposes, as with original submissions, we recommend that you allow up to 6 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 quality of the submission.

During the course of a review of a cigarette plan, FDA may request an amendment to a cigarette plan under review if FDA needs clarification of information in the plan or other additional information to determine whether FDA can approve the plan. The need for any such amendments will likely increase the overall review time.

D. What Information Should Be Submitted as Part of a Cigarette Plan?

The following information should be submitted to FDA as part of a cigarette plan. The appendix to this guidance provides an example of what FDA considers to be an acceptable cigarette plan.

1. Cover Letter

To facilitate FDA's review, FDA requests that your cigarette plan be accompanied by a cover letter. Section I of the appendix provides an example of a cover letter that would accompany the submission of a cigarette plan, which includes information such as:

- The date of the submission;

- The following subject line: "RE: CIGARETTE PLAN FOR CIGARETTES ("Original," "Amendment," or "Supplement");
- A list of any previous submissions made to FDA relating to the cigarette plan, identified by the Submission Track Number (STN) and the date of submission, if applicable;
- A statement as to whether the cigarette plan covers packaging only, advertising only, or both packaging and advertising;
- The name, address, and phone number of the person making the submission;
- The name of the most responsible official if the submitter is a company;
- Identification of the submitter as the manufacturer, distributor, or retailer of the tobacco products covered by the cigarette plan;
- 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 individual authorized to act as the contact point for the cigarette plan;
- A list of all cigarette brands covered by the plan, preferably identifying cigarettes 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 FD&C Act (21 U.S.C 387e). Alternatively, if desired, a manufacturer may refer to "all brands in its product listing(s) under section 905(i) of the FD&C Act" and state that the cigarette plan incorporates any and all future brands listed with FDA. Likewise, a retailer may state, "all brands";
- A certification by the most responsible official, if the submitter is a company, that all information submitted has been reviewed prior to filing; and
- A certification by the most responsible company official authorizing an agent to submit the cigarette plan on their behalf (if applicable).

2. Information to Include in the Cigarette Plan for Packaging

Section II of the appendix provides an example of a cigarette plan for cigarette packaging that FDA believes would meet the applicable requirements for approval.

The submitter must ensure that a cigarette plan:

- Contains sufficient information for approval by FDA;
- Provides for the random and equal display and distribution of the required warnings on cigarette packages; and
- Assures that all required warnings will be displayed at the same time.

For each cigarette brand (or for a set of brands), your plan should list each specific element of the cigarette plan requirement and provide a detailed description of how each element will be met. Specifically, you should explain how:

- Each of the required warnings will be randomly displayed during each 12-month period on each brand of the product;

- Each of the required warnings will be displayed on each brand of the product in as equal a number of times as possible during each 12-month period;
- Product packages will be randomly distributed in all areas of the United States in which the product is marketed; and
- Each of the required 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 "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 an acceptable deviation (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).

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

3. Information to Include in the Cigarette Plan for Advertising

Section III of the appendix provides an example of a cigarette plan for cigarette advertisements that FDA believes would meet the applicable requirements for approval.

The submitter must ensure that a cigarette plan:

- Contains sufficient information for approval by FDA;
- Provides for the quarterly rotation of required warnings, in alternating sequence, in advertisements for each brand; and
- Assures that all required warnings will be displayed at the same time.

Your plan should state the specific applicable cigarette plan requirements. Then, for each cigarette brand (or a set of brands), your plan must provide a description of how the required warnings will be rotated quarterly in advertisements (section 4 of the FCLAA).

Among other things, your cigarette plan should specify the start 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 the required warnings for each brand. A cigarette plan may consider practical constraints on the production and distribution of advertising. FDA does not consider a cigarette plan that merely restates the statutory requirements for quarterly rotation of the required warnings in advertisements to be sufficiently detailed to enable FDA to determine whether it can approve the cigarette plan.

4. Representative Packaging and Advertising

FDA requests that your cigarette plan include representative samples of packages and advertisements with each of the required warnings. Such samples would place the cigarette plan in context and, therefore, facilitate FDA's review of the plan, which does not include a review of the content of the package labels and advertisements. By representative samples, we mean different types of cigarette product packaging and a range of package sizes for each type of product. Samples of advertising could include examples of different types of advertising materials for various brands, prototypes of actual advertising materials, the required warning as it would appear in different sizes of advertisements, or acetates or other facsimiles for the required warning as it would appear in different sizes of advertisements.

E. Where Should a Cigarette Plan Be Submitted?

Although electronic submission is not mandatory, FDA strongly encourages electronic submission to facilitate efficiency and timeliness of submission and processing. To submit your cigarette plan electronically, please use FDA's Electronic Submissions Gateway, available at http://www.fda.gov/ForIndustry/ElectronicSubmissionsGateway/default.htm.

For cigarette plans submitted in electronic format, we recommend that all content (including the cover letter), be a Portable Document Format (PDF) file compatible with Adobe Acrobat 6.0 or higher. Files should not be password protected or encrypted. In preparing your submission in PDF format, we recommend that you:

- Create PDF files directly from an electronic source such as a word processing file or spreadsheet;
- If you scan a document to create a PDF file, we recommend that you capture text by optical character recognition (OCR) software so that the text of the resulting electronic documents is reasonably accessible and searchable. (Avoid image-only based PDF files whenever possible because scanned images are more difficult to read and search); and
- Create a submission table of contents and format it using bookmarks designed to help the reader navigate through the document efficiently.

Written submissions should be addressed to the Office of Compliance and Enforcement and 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

F. What Does It Mean to Receive FDA Approval of a Cigarette Plan?

FDA's review of a cigarette plan is only for the purpose of determining compliance with the criteria for approval of a cigarette plan, as set forth in section 4(c)(3) of the FCLAA. Approval of a cigarette plan does not represent a determination by FDA that any specific package or advertisement complies with any of the other requirements regarding the placement, font type, size, and color of the required warnings found in section 4 of FCLAA and its implementing regulations, or any other requirements under the FD&C Act and its implementing regulations.

Appendix – Example Cigarette 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

Date

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

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

Previously Related Original/Amendment/Supplement Cigarette Plan Number(s) (*if applicable*):
[**insert:** RPXXXXXXX]

Pursuant to section 4 of the FCLAA, [**insert:** *"Company Name"*] submits the attached proposed cigarette plan covering [**insert:** *"packaging and advertising" or "packaging" or "advertising"*] for cigarettes. See attached.

Submitter Information:

Company Name:	
Name of Most Responsible Official:	
Title/Position/Authority of Most Responsible Individual	
Company Role (manufacturer (including importer), distributor, or retailer):	
Street Address:	
City, State, and Zip Code:	
Phone Number:	
DUNS Number:	

Company Contact Individual (*if different from the submitter information)*:

Name of Contact for the Cigarette Plan:	
Title/Position/Authority of Contact	
Street Address (*if different*):	
City, State, and Zip Code:	
Phone Number:	

Fax Number:	
Email Address:	

Transmitter Information (*if different from the submitter and company contact individual*):

Name of Individual Transmitting the Cigarette plan on Behalf of the Submitter:	
Title/Position/Authority of Transmitter	
Company Name:	
Street Address:	
City, State, and Zip Code:	
Phone Number:	
Fax Number:	
Email Address:	

This plan covers the following cigarettes:

	Brand Name	**Product (Subbrand)**	**Unique Identifier/Number**	**Type of Unique Identifier (SKU, Catalog #, UPC)**
1	Brand X	Silver 100s Hard Pack	99999 99999	UPC
2				

If you have questions regarding the attached cigarette plan submission, contact [**insert:** *name of company contact person provided above*].

Sincerely,

Name / Title of Submitting Individual

CERTIFICATION

This certifies that I, **[name of most responsible company official],** reviewed the attached Cigarette Plan submission, dated [**insert:** *date*], which covers cigarette [**select:** *packaging and/or advertising*].

Printed Name of Most Responsible Company Official	Signature of Most Responsible Company Official
Title of Most Responsible Company Official	Date

[If applicable, insert: This certifies that I, **[name of most responsible company official]**, authorize **[name of agent authorized to submit Cigarette plan submission]** to submit the attached Cigarette Plan submission on my behalf**]**.

Printed Name of Most Responsible Company Official	Printed Name of Agent Authorized to Submit Cigarette Plan Submission
Title of Most Responsible Company Official	Title of Agent Authorized to Submit Cigarette Plan Submission
Signature of Most Responsible Company Official	Signature of Agent Authorized to Submit Cigarette Plan Submission
Date	Date

II. Cigarette Plan for Cigarette Packaging

In accordance with Section 4 of the FCLAA, each cigarette package will bear one of the required warning statements and its accompanying color graphic on the front and rear panels of the package. Each required warning, comprising a combination of a textual warning label statement and its accompanying color graphic, will be obtained and accurately reproduced as specified from the electronic files contained in "Required Cigarette Health Warnings."

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 on each brand of the product in as equal a number of times as possible during each 12-month period;
- Randomly distributed in all areas of the United States in which the product is marketed; and
- Assure that all required warnings are displayed at the same time.

Plan for Random and Equal Display of Required Warnings:

To ensure that the required warnings are randomly and equally displayed in as equal a number of times as possible on each brand during a 12-month period (e.g., based on the date of manufacture), and that all required warnings are displayed at the same time, we will:

1. Produce a total of 13,000[5] packages for each print run.
2. Print each of the required warnings on packages in sequential order (i.e., 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13), for a total of 13,000 (1,000 of each required warning).

OR ALTERNATIVELY

2. Equally print 1,000 of each of the required warnings on batches of packages simultaneously (1,000 of required warning 1, 1,000 of required warning 2, etc.) for each print run.

This should result in an equal display of each of the different required warnings for each brand of product during a 12-month period, subject to minor variations due to normal commercial printing and manufacturing practices.

Plan for Random Distribution of Required Warnings:

To ensure that the required warnings are randomly distributed in all areas of the United States in which the product is marketed:

[5] For illustrative purposes, 13,000 is based on the base number 13, which is the number of proposed required warnings in the proposed rule. FDA will revise the examples provided in the final guidance as appropriate, based on the number of required warnings in the final cigarette health warning rule.

Upon cigarettes being manufactured, we will 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) on a first in, first out basis.

OR ALTERNATIVELY

We will 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 required warnings.

III. Cigarette Plan for Cigarette Advertising

In accordance with Section 4 of the FCLAA, each cigarette advertisement will bear one of the required warnings. Each required warning, comprising a combination of a textual warning label statement and its accompanying color graphic, will be obtained and accurately reproduced as specified from the electronic files contained in "Required Cigarette Health Warnings."

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.

The required warnings will be quarterly rotated in advertisements according to the following schedule for each brand of product.[6] For each subsequent quarter beyond the schedule below, we will continue, in perpetuity, the quarterly rotation of the required warnings in the established order for each brand (*e.g.*, required warning 1 will be used for the quarter beginning April 1, Year (D), for Brand X).

Schedule of Quarterly Rotation of Required Warnings on Cigarette Advertisements (Table 1 – All Brands)

	Jan 1 – Mar 31 (Year A)	Apr 1 – Jun 30	Jul 1 – Sep 30	Oct 1 – Dec 31	Jan 1 – Mar 31 (Year B)	Apr 1 – Jun 30	Jul 1 – Sep 30	Oct 1 – Dec 31	Jan 1 – Mar 31 (Year C)	Apr 1 – Jun 30	Jul 1 – Sep 30	Oct 1 – Dec 31	Jan 1 – Mar 31 (Year D)
All Brands	1	2	3	4	5	6	7	8	9	10	11	12	13

Alternative Schedule of Quarterly Rotation of Required Warnings on Cigarette Advertisements (Table 2 – By Each Brand)

	Jan 1 – Mar 31 (Year A)	Apr 1 – Jun 30	Jul 1 – Sep 30	Oct 1 – Dec 31	Jan 1 – Mar 31 (Year B)	Apr 1 – Jun 30	Jul 1 – Sep 30	Oct 1 – Dec 31	Jan 1 – Mar 31 (Year C)	Apr 1 – Jun 30	Jul 1 – Sep 30	Oct 1 – Dec 31	Jan 1 – Mar 31 (Year D)
Brand x	1	2	3	4	5	6	7	8	9	10	11	12	13
Brand Y	4	5	6	7	8	9	10	11	12	13	1	2	3
Brand Z	11	12	13	1	2	3	4	5	6	7	8	9	10

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

Type of Advertising	**Start Date of Quarterly Rotation** *(do not provide a calendar date; use below or similar terms to identify start date)*

[6] For illustrative purposes, we specify 13 quarters here, because that is the number of proposed required warnings in the proposed rule. FDA will revise the examples provided in the final guidance as appropriate, based on the number of required warnings in the final cigarette health warning rule.

Advertising in periodicals (newspapers, magazines)	[“cover date”], [“periodical publication date”], or [“date of publication”]
Posters and placards	[“scheduled ad appearance date”]
Email advertisements, direct mail advertisements, and mobile coupons	[“date of dissemination”], [“campaign start state”]
Digital media, including websites, banner ads, mobile applications, and social media	[“date of posting”], [“scheduled ad appearance date”]
Other advertisements (*describe intended advertisement, e.g., Billboard, Point of Sale Shelf Talker)*	[“date of issuance”], [“order date”], [“date of dissemination”], [“campaign start state”], [“air date”], [“date of posting”], [“date of production"]