**Contains Nonbinding Recommendations**

# Submission of Plans for Cigarette Packages and Cigarette Advertisements (Revised)*

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# 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. EDT.

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

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**See additional PRA statement in Section IV of the guidance**

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

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# Submission of Plans for Cigarette Packages and Cigarette Advertisements (Revised)[1]

## Guidance for Industry[2]

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 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 21 CFR 1141 and 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
- When to submit a cigarette plan

[1] This guidance supersedes 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 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 and 21 CFR 1141.

- What information should be submitted as part of 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 final rule[5] on required warnings for cigarette packages and advertisements on March 18, 2020 (85 FR 15638). The rule specifies the textual warning label statements that are required and the color graphics that must accompany them. The final rule 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 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

[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 final rule issued in March 2020.

[5] 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. FDA also issued a proposed rule on required warnings for cigarette packages and advertisements on August 16, 2019 (84 FR 42754).

quarterly rotation of the required warnings in cigarette advertising, as described under section 4 of the FCLAA.

On April 3, 2020, the final rule was challenged in the U.S. District Court for the Eastern District of Texas.[6] Due to the COVID-19 pandemic and its impacts, 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.[7] The new effective date of the final rule is October 16, 2021. 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 date. As such, 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 date of publication of the final rule (i.e., by December 16, 2020). 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.

> **Amendment.** FDA considers a submission to be an amendment if the 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. (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

[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. filed April 3, 2020).
[7] *R.J. Reynolds Tobacco Co. et al.*, No. 6:20-cv-00176 (E.D. Tex. May 8, 2020) (order granting joint motion and establishing schedule), Doc. No. 33.

(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** means 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 purposes of this part. (21 CFR 1141.3)

**Manufacturer** means 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)

**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 manufacturer, distributor, or retailer has submitted a cigarette plan for cigarette packaging or advertising to FDA for that brand(s).

**Package** or **packaging** 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 and 21 CFR 1141.

**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. (21 CFR 1141.3)

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

**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. (21 CFR 1141.3)

## 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 final rule on required warnings for cigarette packages and advertisements contains 11 required warnings, consisting of textual warning label statements paired with concordant photorealistic images.

Under the final rule, the required warnings must comprise at least 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. 21 CFR 1141.10(c) and (d). Required warnings must be indelibly printed on or permanently affixed to cigarette packages and cigarette advertisements. 21 CFR 1141.10(e).

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, 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 and 21 CFR 1141.10. Pursuant to section 201(b) of the Tobacco Control Act and the May 8, 2020, court order described above, packages and advertisements of cigarettes will be required to bear the required warnings beginning 15 months and 120 days after the date of publication of the final rule (i.e., by October 16, 2021). In addition, under section 201(c) of the Tobacco Control Act and 21 CFR 1141.10(g), the Agency must review and approve cigarette plans in advance of any person displaying or distributing packages or advertisements for products that are required to carry the required warnings on packages and in advertisements.

FDA strongly encourages entities to submit cigarette plans 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., by December 16, 2020). Early submission will facilitate timely FDA review of plans prior to the effective date of the required warnings, encourage dialogue with entities regarding any implementation concerns, and provide time 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 (October 16, 2021).

More specifically, under section 4(c)(1) of the FCLAA and 21 CFR 1141.10(g), cigarette plans for cigarette packages 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
- Displayed at the same time.

In reviewing the cigarette plans, FDA will apply the criteria specified in section 4(c)(3) of the FCLAA and 21 CFR 1141.10(g)(3). For FDA to approve a cigarette plan for cigarette packaging, the plan must provide that all of the required warnings are randomly displayed in each 12-month period, in as equal a number of times as is possible on each brand of the product and randomly distributed in all areas of the United States in which the product is marketed; and the plan must assure that all of the required warnings will be displayed by the manufacturer, distributor, or retailer at the same time. Sections 4(c)(1) and (c)(3) of the FCLAA and 21 CFR 1141.10(g)(1) and (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. Sections 4(c)(2) and (c)(3) of the FCLAA and 21 CFR 1141.10(g)(2) and (g)(3). 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 cigarettes unless the package bears one of the required warnings in accordance with section 4 of the FCLAA and 21 CFR 1141. In addition, required warnings on 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 be randomly distributed in all areas of the United States in which the product is marketed in accordance with a cigarette plan submitted by the manufacturer, distributor, or retailer to, and approved by, FDA. Section 4(c)(1) of the FCLAA and 21 CFR 1141.10(g)(1).

For a particular brand, this cigarette plan may be submitted by the 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 the FCLAA and 21 CFR 1141, 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 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 (because, in most instances, the brand's manufacturer is the entity best able to ensure that a plan meets the relevant requirements). One plan may also be submitted for multiple brands.

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. The cigarette plan should describe how the required warnings will be randomly placed, in as equal a number of times as possible, on packages and how the required warnings on packages will be randomly distributed to all areas in the United States 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.

For cigarettes that are imported, the importer (included in the definition of manufacturer) usually directs distribution of the packages after they are imported. Therefore, for imported cigarettes, the importer is likely best-positioned to submit the plan.

Under section 4 of the FCLAA and 21 CFR 1141.1(c), retailers are not in violation of the requirements of section 4 of the FCLAA or 21 CFR 1141.10 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 or 21 CFR 1141. We believe most, if not all, retailers

would fall under this scenario. 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 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 and 21 CFR 1141.[8] 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 by the tobacco product manufacturer, distributor, or retailer to, and approved by, FDA. Section 4(c)(2) of the FCLAA and 21 CFR 1141.10(g)(2).

For a particular brand, the cigarette plan may be submitted by the 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.

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 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 and 21 CFR 1141.1(d), 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 or the requirements of 21 CFR 1141.

[8] For advertisements, Section 1141.10(d)(1) of the final rule states as follows: "(1) For print advertisements and other advertisements with a visual component (including, for example, advertisements on signs, retail displays, internet web pages, digital platforms, mobile applications, and email correspondence), the required warning must appear directly on the advertisement." Further, the preamble to the final rule also explains that "[t]he final rule applies to advertisements appearing in or on, for example, promotional materials (point-of-sale and non-point-of-sale), billboards, posters, placards, published journals, newspapers, magazines, other periodicals, catalogues, leaflets, brochures, direct mail, shelf-talkers, display racks, internet web pages, electronic mail correspondence, or be communicated via mobile telephone, smartphone, microblog, social media website, or other communication tool; websites, applications, or other programs that allow for the sharing of audio, video, or photography files; video and audio promotions; and items not subject to the sale or distribution restriction in § 1140.34."

## 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 packages and advertisements, 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 in 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 and incorporate any new brands into their approved plan, so long as no other changes are made to the plan. For retailer-generated advertising, retailers may list "all brands" in their plan, which would 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?

FDA strongly encourages entities to submit cigarette plans 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., by December 16, 2020). 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 time 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 (October 16, 2021).

After FDA approval of an initial plan, a supplement to the approved plan should be submitted to FDA for review and approval before making changes to the random and equal display or distribution of required warnings on packages or the quarterly rotation of required warnings in advertisements. For a new brand, a new plan or a supplement to an FDA-approved plan is required to be submitted and approved before displaying or distributing packages and advertisements for that new brand.

However, in lieu of a supplement to an FDA-approved plan for a new brand, manufacturers may reference in their initial plan all brands in their product listing(s) under section 905(i) of the FD&C Act and incorporate any new brands into their approved plan, so long as no other changes are made to the plan.

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 and the diligence and responsiveness of the submitter.

FDA intends to request an amendment to a 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 adequate 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. Please note that these are suggested elements of the cover letter and any omissions will not prevent the plan from being accepted and approved. However, FDA encourages the submission of the following suggested elements to facilitate timely FDA review of your cigarette plan:

- 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"; and

- If the submitter is a third party, FDA recommends that the cover letter also include a statement by an authorized official of the manufacturer, distributor, or retailer that the third-party agent is authorized to submit the cigarette plan on its behalf. If a statement is not included in the cover letter, FDA will confirm with the manufacturer, distributor, or retailer that the submitter is an authorized third-party agent before reviewing the plan.

*2. Information to Include in the Cigarette Plan for Packaging*

Section II of the appendix provides an example of a cigarette plan for cigarette packages 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 cigarette plan for packaging should include a discussion of how the requirements are to be implemented based on the specific manufacturing processes and distribution procedures to ensure random display, in as equal a number of times as is possible, in each 12-month period on each brand of the product. We recognize and understand that achieving conformity with the narrowest possible reading of the random and equal display requirement within a 12-month period would pose some difficulties, and we agree that allowing some level of deviation is appropriate particularly given the language of the FCLAA, which includes the phrase "as equal a number of times as is possible." As described in the final rule, different required warnings may be placed on the front and rear panels of the cigarette package, which may facilitate achieving the random display of the required warnings, in as equal a number of times as is possible.

Manufacturers with concerns about complying with this requirement for their products should promptly 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 this requirement.

We encourage manufacturers to submit their cigarette plans to FDA as soon as possible so that we can discuss these concerns and consider proposals with manufacturers in a timely manner.

FDA expects that a plan for random and equal display and distribution of warnings on packages will ordinarily be based on the date of manufacture or shipment of the product. FDA would not consider a plan that merely restated the regulatory requirements to be sufficiently detailed to enable FDA to approve the 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 and how the quarterly rotations will occur in alternating sequence. Section 4 of the FCLAA and 21 CFR 1141.10(g)(2).

Among other things, the plan should specify the initial rotation timeframe on which quarterly rotation is based and, if the rotation timeframe varies for different types/forms of advertising, specify the reference date(s) that will be used to select the required warning for each type of advertising in each quarter, and describe the quarterly schedule for rotating each of the required warnings for each cigarette brand. A cigarette plan may consider practical constraints on the production and distribution of advertising. FDA would not consider a plan that merely restated the regulatory requirements to be sufficiently detailed to enable FDA to approve the plan.

*4. Representative Packaging and Advertising*

FDA requests that plans submitted for review include representative samples of packages and advertisements with each of the required warnings. Such samples would place the plan in context and, therefore, facilitate FDA's review of the plan; FDA's review would 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 https://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
- You 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 statutory and regulatory criteria for approval of a cigarette plan, as set forth in section 4(c)(3) of the FCLAA and 21 CFR 1141.10(g)(3). 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 the FCLAA and 21 CFR 1141, or any other requirements under the FD&C Act and its implementing regulations.

## IV. PAPERWORK REDUCTION ACT OF 1995

This guidance contains information collection provisions that are subject to review by The Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520).

The time required to complete this information collection is estimated to average 153 hours per response, including the time to review instructions, search existing data sources, gather the data needed, and complete and review the information collection. Send comments regarding this burden estimate or suggestions for reducing this burden to:

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

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this information collection is 0910-0877 (expires April 30, 2023).

## V. 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., by December 16, 2020).
- Section IV – Added OMB control number and information related to the Paperwork Reduction Act of 1995.

# Appendix – Cigarette Plan Example

**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 and 21 CFR 1141, [**insert:** *"Company Name"*] submits the attached proposed Cigarette Plan covering [**insert:** *"packages and advertisements" or "packages" or "advertisements"*] 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

## AUTHORIZATION

All information submitted in the attached Cigarette Plan dated ***[INSERT date*]**, which covers cigarette [**select:** packaging and/or advertising] was authorized by me.

Printed Name of Authorized Company Official

Signature of Authorized Company Official

Title of Authorized Company Official

Date

**[If applicable, insert: [Name and title of agent authorized to submit Cigarette Plan submission]** is authorized to submit the attached Cigarette Plan submission on behalf of **[name of company]**.

| | |
|---|---|
| Printed Name of Authorized Company Official | Printed Name of Agent Authorized to Submit Cigarette Plan Submission |
| Title of Authorized Company Official | Title of Agent |
| Signature of Authorized Company Official | Signature of Agent |
| Date | Date |

## II. Cigarette Plan for Cigarette Packages

In accordance with section 4 of the FCLAA and 21 CFR 1141, 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. Under 21 CFR 1141.10(b), each required warning, comprising a combination of a textual warning label statement and its accompanying color graphic, will 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. The cigarette packages will bear the required warnings in accordance with 21 CFR 1141.10(c).

This plan provides the manner by which the 11 required warnings on packages will be:

- Randomly displayed during each 12-month period on each brand of the product;
- Displayed in each 12-month period, 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 at the same time.

**[Example 1]**

Plan for Random and Equal Display of Required Warnings (Hardpacks):

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

1. Utilize an 8x3 cylinder layout (i.e., 8 columns with 3 rows each).
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), with different required warnings on the front and rear panels of each package. The last two package impressions (see shaded cells in the grid below) will display four of the eleven required warnings. The four required warnings will be randomly selected without replacement (i.e., the additional randomly selected required warnings will not repeat, to avoid increasing over-representation), for each brand as illustrated in the grid below (represented as A, B, C, and D). [Alternatively: The last two package impressions will be left blank; therefore, the required warnings will all be equally printed.]
3. Produce a total of 12,000 package labels displaying 24,000 required warnings for hardpack packages for each print run, with four of the eleven required warnings (represented as A, B, C, and D in the grid below) being produced 2,500 times each and seven of the eleven required warnings being produced 2,000 times each. [Alternatively: The last two package impressions are left blank; therefore, the required warnings will all be equally printed.]

The required warnings will be arranged on the 8x3 cylinder layout as follows:

8x3 – Hardpack Cylinder Layout of the 11 Required Warnings
Each Side of the Package Displays a Different Required Warning
(number represents the corresponding required warning*)

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| 1<br>2 | 7<br>8 | 2<br>3 | 8<br>9 | 3<br>4 | 9<br>10 | 4<br>5 | 10<br>11 |
| 3<br>4 | 9<br>10 | 4<br>5 | 10<br>11 | 5<br>6 | 11<br>1 | 6<br>7 | A+<br>B+ |
| 5<br>6 | 11<br>1 | 6<br>7 | 1<br>2 | 7<br>8 | 2<br>3 | 8<br>9 | C+<br>D+ |

*+Note: Each box in the grid above represents one package. The two different numbers in each box represent that different required warnings will be printed on the front and rear panels of each package. Letters A-D in these shaded cells represent the four randomly selected required warnings without replacement for each brand.*

*Required Warning Statements (to include the accompanying color graphics):

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

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:

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

**[Example 2]**

Plan for Random and Equal Display of Required Warnings (Softpacks):

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

1. Utilize an 9x5 cylinder layout (i.e., 9 columns with 5 rows each).
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), with the same warning on the front and rear panels of each package. The last package impression (see shaded cell in the grid below) will display one of the eleven required warnings. The one required warning will be randomly selected without replacement (i.e., the additional randomly selected required warning will not repeat, to avoid increasing over-representation) for each brand, as illustrated in the grid below (represented as A). [Alternatively: The last package impression will be left blank; therefore, the required warnings will all be equally printed.]
3. Produce a total of 11,250 package labels displaying 22,500 required warnings for softpack packages for each print run, with one of the eleven required warnings (represented as A in the grid below) being produced 2,500 times each and ten of the eleven required warnings being produced 2,000 times each. [Alternatively: The last package impression is left blank, therefore, the required warnings will all be equally printed.]

The required warnings will be arranged on the 9x5 cylinder layout as follows:

9x5 – Softpack Cylinder Layout of the 11 Required Warnings
Each Side of the Package Displays the Same Required Warning
(number represents the corresponding required warning*)

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 1<br>1 | 6<br>6 | 11<br>11 | 5<br>5 | 10<br>10 | 4<br>4 | 9<br>9 | 3<br>3 | 8<br>8 |
| 2<br>2 | 7<br>7 | 1<br>1 | 6<br>6 | 11<br>11 | 5<br>5 | 10<br>10 | 4<br>4 | 9<br>9 |
| 3<br>3 | 8<br>8 | 2<br>2 | 7<br>7 | 1<br>1 | 6<br>6 | 11<br>11 | 5<br>5 | 10<br>10 |
| 4<br>4 | 9<br>9 | 3<br>3 | 8<br>8 | 2<br>2 | 7<br>7 | 1<br>1 | 6<br>6 | 11<br>11 |
| 5<br>5 | 10<br>10 | 4<br>4 | 9<br>9 | 3<br>3 | 8<br>8 | 2<br>2 | 7<br>7 | A+<br>A+ |

*+Note: Each box in the grid above represents one package. The two identical numbers in each box represent that the same required warning will be printed on the front and rear panels of the package. Letter A in this shaded cell represents the one randomly selected required warning without replacement for each brand.*

*Required Warning Statements (to include the accompanying color graphics):

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

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:

Upon cigarettes being manufactured, we will store products in shipping containers. Each container will include all required warnings in as equal numbers as is 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.

**[Example 3]**

Plan for Random and Equal Display of Required Warnings:

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

Plan for producing and displaying the required warnings on as equal a number of packages as possible for each product during a 12-month period:

1. Produce a total of 11,000 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), for a total of 11,000 required warnings (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 during a 12-month period, subject to minor variations due to normal commercial printing and manufacturing practices.[9]

*Required Warning Statements (to include the accompanying color graphics):

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

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:

Upon cigarettes being manufactured, we will store products in shipping containers. Each container will include all required warnings in as equal numbers as is 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.

[9] FDA recognizes and understands that achieving conformity with the narrowest possible reading of the random and equal display requirement within a 12-month period would pose some difficulties, and we agree that allowing some level of deviation is appropriate particularly given the language of the FCLAA, which includes the phrase "as equal a number of times as is possible."

## III. Cigarette Plan for Cigarette Advertisements

In accordance with Section 4 of the FCLAA and 21 CFR 1141, each cigarette advertisement will bear one of the required warnings. Under 21 CFR 1141.10(b), each required warning, comprising a combination of a textual warning label statement and its accompanying color graphic, will 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. The cigarette advertisements will display the required warnings in accordance with 21 CFR 1141.10(d).

This plan provides the manner by which the 11 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. 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.

Schedule of Quarterly Rotation:

**[Example1]**

Schedule of Quarterly Rotation of the 11 Required Warnings (number represents the corresponding required warnings*) on Cigarette Advertisements
(Table 1 – Schedule is Applicable to All Brands)

| Quarterly Period | Jun 1 – Aug 31 (Year 2021) | Sept 1 – Nov 30 | Dec 1 – Feb 28 | Mar 1 – May 31 | Jun 1 – Aug 31 | Sept 1 – Nov 30 | Dec 1 – Feb 28 | Mar 1 – May 31 | Jun 1 – Aug 31 | Sept 1 – Nov 30 | Dec 1 – Feb 28 | Mar 1 – May31[10] |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| All Brands | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 1 |

[10] Will continue in perpetuity for subsequent quarters

**[Example 2]**

Schedule of Quarterly Rotation of the 11 Required Warnings (number represents the corresponding required warnings*) on Cigarette Advertisements
(Table 2 – Schedule Varies for Each Brand)

| Quarterly Period | Jun 1 – Aug 31 (Year 2021) | Sept 1 – Nov 30 | Dec 1 – Feb 28 | Mar 1 – May 31 | Jun 1 – Aug 31 | Sept 1 – Nov 30 | Dec 1 – Feb 28 | Mar 1 – May 31 | Jun 1 – Aug 31 | Sept 1 – Nov 30 | Dec 1 – Feb 28 | Mar 1 – May31[11] |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Brand X | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 1 |
| Brand Y | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 1 | 2 | 3 | 4 |
| Brand Z | 7 | 8 | 9 | 10 | 11 | 1 | 2 | 3 | 4 | 5 | 6 | 7 |

*Required Warning Statements (to include the accompanying color graphics):

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

Reference Date(s) for Quarterly Rotation for Each Type of Advertising

Cigarette brands will be advertised using the types of media listed in the table below. Each type of advertising media will display the required warning in accordance with the schedule of quarterly rotation of the required warnings noted above. The reference date(s) will be used to select the appropriate quarter and corresponding required warning for each medium, as indicated in the table below:

[11] Will continue in perpetuity for subsequent quarters

| **Type of Advertising** | **Reference Date(s) for Quarterly Rotation**** |
|---|---|
| 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"] |

*(**Note: Do not provide a calendar date in this column; use the examples provided or similar terms to identify the reference date(s) that will be used to assign the corresponding required warning, as described above in Tables 1 and 2, Schedule of Quarterly Rotation.)*