Submission of Warning Plans for Cigars (Revised)*

Guidance for Industry

Comments may be submitted at any time for Agency consideration. Electronic comments may be submitted to http://www.regulations.gov. Alternatively, submit written comments to the Division of Dockets Management (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.

Additional copies are available online at http://www.fda.gov/TobaccoProducts/Labeling/RulesRegulationsGuidance/default.htm. You may send an e-mail request to SmallBiz.Tobacco@fda.hhs.gov to receive an electronic copy of this guidance. You may send a request for hard copies to U.S. Food and Drug Administration, Center for Tobacco Products, Attn: Office of Small Business Assistance, Document Control Center, Bldg. 71, Rm. G335, 10903 New Hampshire Ave., Silver Spring, MD 20993-2000.

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

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*This is the first revision to this guidance. The first edition was published in December 2016.

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Submission of Warning Plans for Cigars

Guidance for Industry[1]

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

This guidance document is intended to assist persons submitting warning plans for cigars, as required by Title 21, Code of Federal Regulations (CFR), part 1143 (21 CFR part 1143). This guidance document discusses, among other things:

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

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.

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

II. BACKGROUND

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

The Tobacco Control Act also gave FDA the authority to issue a regulation deeming all other products that meet the statutory definition of a tobacco product as subject to FDA regulatory authority (deeming) (section 901(b) of the Federal Food, Drug, and Cosmetic Act (FD&C Act)) (21 U.S.C. 387a(b))). On May 10, 2016, FDA issued the deeming rule, extending FDA's tobacco product authority to cigars, among other products (81 FR 28973). Among the requirements that now apply to newly deemed products such as cigars are health warning statements prescribed under section 906(d) of the FD&C Act (21 U.S.C. 387f(d)), which permits restrictions on the sale and distribution of tobacco products that are "appropriate for the protection of public health."

Under § 1143.5, each cigar package and advertisement must bear one of six textual warning statements.

Packages. Once the required warning statements take effect, it will be unlawful for any person to manufacture, package, sell, offer to sell, distribute, or import for sale or distribution within the United States any cigar unless the product package bears one of the following required warning statements listed in § 1143.5(a):[2]

- WARNING: This product contains nicotine. Nicotine is an addictive chemical.
- WARNING: Cigar smoking can cause cancers of the mouth and throat, even if you do not inhale.
- WARNING: Cigar smoking can cause lung cancer and heart disease.
- WARNING: Cigars are not a safe alternative to cigarettes.
- WARNING: Tobacco smoke increases the risk of lung cancer and heart disease, even in nonsmokers.
- WARNING: Cigar use while pregnant can harm you and your baby.

  Or

  SURGEON GENERAL WARNING: Tobacco Use Increases the Risk of Infertility, Stillbirth and Low Birth Weight.

You may choose to display either one of the warning statements regarding reproductive health. FDA is allowing the use of the reproductive health warning statement as required

[2] Retailers may continue to sell and distribute tobacco products with packaging that does not bear the required health warning statements after the effective date, but only if the products were manufactured before the effective date of the warning statement requirements. *See* 21 CFR1143.13(a). For more information on compliance dates, see FDA's guidance for industry, Extension of Certain Tobacco Product Compliance Deadlines Related to the Final Deeming Rule (August, 2018), available at: https://www.fda.gov/TobaccoProducts/Labeling/RulesRegulationsGuidance/ucm557714.htm.

by the Federal Trade Commission (FTC) consent decrees as an optional alternative to the FDA warning, "WARNING: Cigar use while pregnant can harm you and your baby." FDA expects that providing this optional alternative will benefit entities bound by the FTC consent decrees, and the statement is appropriate for the protection of public health.

In certain situations described in § 1143.5(a)(4), retailers of cigars are exempt from this requirement. The retailer will not be in violation of this section for cigar packaging that: (1) contains a health warning; (2) is supplied to the retailer by the tobacco product manufacturer, importer, or distributor who has the required state, local, or Alcohol and Tobacco Tax and Trade Bureau (TTB)-issued license or permit, if applicable; and (3) is not altered by the retailer in a way that is material to the requirements of § 1143.5(a) (§ 1143.5(a)(4)). However, a retailer is still responsible for complying with other applicable requirements relating to cigars, including those contained in part 1143.

Cigars that are sold individually, without any packaging, are exempt from the packaging requirements. In this circumstance, retailers must post a warning sign that lists all six of the required warning statements at the point-of-sale, in accordance with the requirements set forth in § 1143.5(a)(3). Retailers of cigars sold individually and not in product packaging are not required to submit a warning plan for warnings on packages, because the warning signs posted at the retailer's point-of-sale will include all six warnings applicable to cigars. Cigar retailers are responsible for creating and posting these signs in accordance with § 1143.5(a)(3)(i)-(iv).

Advertisements. Once the required warning statements take effect, it will be unlawful for any cigar manufacturer, packager, importer, distributor, or retailer to advertise or cause to be advertised within the United States any cigar unless the advertising bears one of the required warning statements, in accordance with an FDA-approved warning plan (§ 1143.5(b)(1) and (b)(2)). As with packaging, retailers may be exempt from this requirement under certain circumstances, which are described in § 1143.5(b)(3). Specifically, the warning statement requirements for advertisements outlined in § 1143.5(b) apply to a retailer only if that retailer is responsible for or directs the required warning statements. However, this does not relieve a retailer of liability if the retailer displays, in a location open to the public, an advertisement that does not contain a health warning or contains a health warning that has been altered by the retailer in a way that is material to the requirements of § 1143.5.

Warning Plans. The requirement for submission of warning plans to FDA for cigars and the specific requirements relating to random display and distribution of required warning statements on cigar packaging and quarterly rotation of required warning statements in cigar advertising appear at § 1143.5. The requirement to submit a warning plan to FDA will take effect 12 months after May 10, 2016 (§ 1143.13(b)). Twenty-four months after May 10, 2016, the requirement to carry warning statements on cigar packages and advertising becomes effective (§ 1143.13(a)). Under the warning plan requirements set forth in § 1143.5, each person required to randomly display and distribute or rotate warnings in accordance with an FDA-approved plan under this part shall submit a proposed warning plan to FDA no later than either 12 months after May 10, 2016, or 12 months before advertising or commercially marketing a product that is subject to such requirement, whichever is later (§ 1143.5(c)(3)).

In particular, in accordance with (§ 1143.5(c)(1), warning plans for cigar packaging must provide that all of the required warning statements:

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

For FDA to approve a warning plan, the plan must provide for the required random distribution and display of required warning statements on packaging, in a 12-month period, and must ensure that all of the required warning statements will be displayed by the manufacturer, importer, distributor, or retailer (§ 1143.5(c)).

Warning plans for cigar advertising must provide that all of the required warning statements are rotated quarterly in alternating sequence in advertisements for each brand of cigar (§ 1143.5(c)(2)).

III. DISCUSSION

A. What Definitions Apply to This Guidance?

For purposes of this guidance, FDA intends to use the following definitions, some of which are included in § 1143.1:

Cigar means a tobacco product that: (1) is not a cigarette; and (2) is a roll of tobacco wrapped in leaf tobacco or any substance containing tobacco.

Package or *packaging* means a pack, box, carton, or container of any kind or, if no other container, any wrapping (including cellophane), in which a tobacco product is offered for sale, sold, or otherwise distributed to consumers.

Principal display panels means the panels of a package that are most likely to be displayed, presented, shown, or examined by the consumer.

Required warning statement means a textual warning statement required to be on packaging and in advertisements for cigarette tobacco, RYO, cigars, and other covered tobacco products.

Original submission: FDA considers the submission of a warning plan to be an original submission if it is the first time the submitter has provided to FDA a warning plan for the cigar products.

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

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

B. Who Submits a Warning Plan?

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

1. Packaged Cigars

As explained above, when the warning statement 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 cigar unless the package bears one of the required warning statements set forth in § 1143.5(a)(1). In addition, required warning statements on packages must be randomly displayed on each brand and randomly distributed in all areas of the United States in accordance with a warning plan submitted to, and approved by, FDA (§ 1143.5(c)(1)). For a particular brand, this warning plan may be submitted by the tobacco product manufacturer, importer, distributor, or retailer. Although the warning plan may be submitted by someone other than you, before you "manufacture, package, sell, offer to sell, distribute, or import for sale or distribution within the United States" a brand of cigar product, it is important that you make sure there is an applicable FDA-approved warning plan for that cigar brand and you comply with the approved plan.

Based on FDA's experience reviewing warning plans for smokeless tobacco products, we believe it is likely that, for domestic products, only one plan will be submitted for each brand, and that the brand's manufacturer will submit this plan.

In most circumstances, the brand's manufacturer is the entity most able to ensure that a warning plan:

- contains sufficient information for approval by FDA
- provides for random distribution and random display of warning statements on packaging
- demonstrates that all of the required warning statements will be displayed in each 12-month period

The brand's manufacturer is also usually the entity responsible, either directly or through a contractor or other agent, for placing or directing the placement of the required warning statements on the brand's packages and for directing distribution of the packages. Placing the required warning statements on the packages and directing distribution of the packages are the key elements of a warning plan.

If a product is manufactured under contract, such as for a private label brand, it is likely that the contracting entity, typically the private label brand's distributor, specifies or otherwise directs the placement of the required warning statements on the product package.

In these situations, FDA believes the private label brand distributor would be best suited to submit the warning plan.

A retailer typically would not submit a warning plan for cigar packaging that is supplied by a manufacturer, importer, or distributor who has the required state, local, or Alcohol and Tobacco Tax and Trade Bureau (TTB)-issued license or permit, if applicable. In this case, the retailer would need to ensure that the package displays a health warning and that the retailer does not alter the warning in a material way (e.g., the retailer cannot cover up the warning label) (§ 1143.5(a)(4)). If a retailer is responsible for or directs the placement of required warning statements on packaging, the retailer would be best suited to submit the warning plan.

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

2. Advertisements

When the required warning statements are in effect, it will be unlawful for any tobacco product manufacturer, importer, distributor, or retailer to advertise or cause to be advertised within the United States any cigar unless its advertising bears one of the required warning statements in accordance with § 1143.5(b)(1) and (b)(2). The regulation specifies that the required warning statements in advertisements be rotated quarterly in alternating sequence for each brand in accordance with a warning plan submitted to, and approved by, FDA (§ 1143.5(c)(2)). For a particular brand, this warning plan may be submitted by the tobacco product manufacturer, importer, distributor, or retailer. Although the warning plan may be submitted by someone other than you, before you advertise a brand of cigar, it is important that you make sure there is an applicable FDA-approved warning plan, and your actions in rotating the required warning statements in advertising 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 warning statements on advertising for a brand of cigars is most able to ensure a warning plan contains sufficient information for approval by FDA — that it provides for quarterly rotation of required warning statements in advertising for the brand. FDA recommends that each manufacturer, importer, distributor, and retailer who creates advertising, causes advertising to be created, or is otherwise responsible for inclusion of the warning on advertising for a brand of cigar submit a warning plan that covers all of the brands it advertises. A retailer typically would not submit a warning plan for advertising supplied by the manufacturer of a tobacco product if the advertising is already covered by a plan submitted by the manufacturer. However, the retailer would be held responsible for the requirements if the retailer is responsible for or directs the warning label statement on the advertisements, publicly displays an advertisement that does not contain a warning label statement, or alters a

required warning statement in a material way (e.g., covers up the warning label) (§ 1143.5(b)(3)).

C. What Is the Scope of a Warning Plan?

For the efficiency of review, FDA asks that each warning plan cover both packaging and advertising to the extent applicable. The cigar product manufacturer, distributor, importer, or retailer should demonstrate how they plan to achieve the random distribution and random display of the required warning statements on packages and the quarterly rotation on advertisements.

D. When Should a Warning Plan Be Submitted?

Required warning statements for cigars must be randomly distributed and randomly displayed on packages, and rotated quarterly in advertisements, *in accordance with an approved warning plan* (§ 1143.5(c)(1) and (2) (emphasis added)).

- Warning plans should be submitted to FDA no later than either 12 months after May 10, 2016, or 12 months before advertising or commercially marketing a product that is subject to such requirement, whichever is later (§ 1143.5(c)(3)). On May 10, 2017, FDA issued a guidance, which, among other things, provided a compliance date of August 10, 2017 for the warning plan requirement. Therefore, warning plans for tobacco products on the market as of August 8, 2016 that are subject to these requirements were expected to be submitted to FDA by August 10, 2017.
- Cigars will be required to carry warnings beginning 24 months after May 10, 2016. FDA issued a guidance on May 10, 2017 which, among other things, provided a compliance date of August 10, 2018 for this requirement. On July 5, 2018, the U.S. District Court for the District of Columbia enjoined FDA from enforcing the warning requirements for cigars and pipe tobacco (21 CFR §§ 1143.3 and 1143.5) until 60 days after the final disposition of the plaintiffs' appeal in the case: *Cigar Ass'n of America v. FDA*, No. 1:16-cv-01460 (D.D.C.) (order granting injunction pending appeal); *see also Cigar Ass'n of America v. FDA*, No. 18-5195 (D.C. Cir.). FDA will not seek to enforce the warning requirements for cigars and pipe tobacco until that order is lifted.

After FDA approval of an initial cigar warning plan, a supplement to the approved warning plan must be submitted to FDA and approved before making changes to the distribution or display of required warning statements on packages or the rotation of required warning statements in advertisements. For a new brand, a new warning plan or a supplement to an approved warning plan must be submitted and approved before distributing or displaying packages and advertisements for that new brand. For retailer-generated advertising, retailers may list "all brands" in their warning plan, which will cover future brands, so long as the plan provides for the same schedule for quarterly rotation of the required warning statements for all brands.

To afford FDA sufficient time to review a supplement to an approved warning plan, FDA strongly recommends 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 volume and quality of the submissions.

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

E. What Information Should Be Submitted as Part of a Warning Plan?

The following information should be submitted to FDA. Appendix A provides an example of what FDA considers to be an acceptable warning plan for cigars.

1. Cover Letter

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

- Date of the submission.
- The following subject line: "RE: WARNING PLAN FOR CIGARS ("Original," "Amendment," or "Supplement").
- A statement as to whether the warning plan covers packages, advertising, or both packages and advertising.
- The name, address, and phone number of the person making the submission; the name of the most responsible individual if the submitter is a company; identification of the person as the manufacturer, distributor, retailer, or importer of the tobacco products covered by the warning plan; and the Data Universal Numbering System (D-U-N-S®) number of the person making the submission.
- The name, address, phone number, fax number, and email address of the person authorized to act as the FDA contact point for the warning plan.
- A list of any previous submissions made to FDA relating to the warning plan, identified by CTP-assigned reference number and the date of submission, if applicable.
- A list of all cigars covered by the plan, preferably identified using the unique name and identifying number (e.g., SKU, catalog number, UPC) that was provided when the product was listed under section 905 of the FD&C Act (21 U.S.C 387e).
- A certification by an authorized official of the company making the submission that all information submitted has been reviewed prior to filing.

Section I of Appendix A provides an example of a cover letter to accompany the submission of a warning plan.

2. Information to Include in the Warning Plan for Packaging

For each cigar brand, your plan should list each specific element of the warning plan requirement and provide a detailed description of how each element will be met. Specifically, you should explain how:

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

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

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

Section II of Appendix A provides an example of a warning plan for cigar packaging that FDA believes would meet the applicable requirements for approval.

3. Information to Include in the Warning Plan for Advertising

Your plan should list each specific element of the warning plan requirement. Then, for each cigar brand, your plan should provide a sufficiently detailed description of how the required warning statements will be rotated quarterly in advertisements and how the quarterly rotations will occur in alternating sequence.

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

Section III of Appendix A provides an example of a warning plan for cigar advertisements that FDA believes would meet the applicable requirements for approval.

4. Representative Packaging and Advertising

FDA requests that your warning plan include representative samples of packages and advertisements with each of the required warning statements. Such samples will place the

warning plan in context and, therefore, facilitate FDA's review. By representative samples, we mean different types of cigar packaging and a range of package sizes and colors, if applicable. Samples of advertising could include examples of different types of advertising materials for various brands, prototypes of actual advertising materials, the required warning statement as it would appear in different sizes and colors of advertisements, or acetates or other facsimiles for the warning as it would appear in different sizes and colors of advertisements.

F. Where Should a Warning Plan Be Submitted?

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

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

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

For warning plans submitted in electronic format, we recommend that all content (including the cover letter), be in Portable Document Format (PDF) files 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;
- Avoid image-only based PDF files whenever possible because scanned images are more difficult to read and search. 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;
- Create a submission table of contents and format it using bookmarks designed to help the reader navigate through the document efficiently.

G. What Does It Mean to Get FDA Approval of a Warning Plan?

FDA's review of a warning plan is only for the purpose of determining compliance with the regulatory criteria for approval of a warning plan, as set forth in § 1143.5(c). Approval of a warning plan does ***not*** represent a determination by FDA that any specific package or

advertisement complies with any of the other requirements regarding the placement, font type, size, and color of the warnings found in part 1143.

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 120 hours per response, including the time to review instructions, search existing data sources, gather the data needed, and complete and review the warning plan. Send comments regarding this burden estimate or suggestions for reducing this burden to:

PRAStaff@fda.hhs.gov

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 0910-0768 (expires 08/31/2019).

V. DOCUMENT HISTORY

December 2016 — First edition of guidance issued.

August 2018 — Section III.D of guidance is revised to reflect a stay of enforcement of the warning requirements for cigars and pipe tobacco (21 CFR §§ 1143.3 and 1143.5) after the United States District Court for the District of Columbia granted plaintiffs' motion for an injunction pending appeal. *Cigar Ass'n of America v. FDA*, No. 1:16-cv-01460 (D.D.C.) (order granting injunction pending appeal). Clarifying and corrective edits made throughout the guidance.

APPENDIX A – EXAMPLE CIGAR WARNING PLAN

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

I. Cover Letter (Cigar Sample)

Date

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

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

To Whom It May Concern:

Pursuant to 21 CFR part 1143, [***INSERT:*** *company name*] submits the attached proposed warning plan covering [***INSERT: "*** *packaging and advertising" or "packaging" or "advertising"*] for cigars. See attached.

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

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

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

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

APPENDIX A – EXAMPLE CIGAR WARNING PLAN

This plan covers the following cigars:

Brand Name	Product (Subbrand)	Unique Identifier	Type of Unique Identifier (SKU, Catalog #, UPC)
1. Brand x	*Churchill, Gordo, Corona*	*12345*	*Catalog #*
2.			

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

Sincerely,

Name, Title

CERTIFICATION

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

_____

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

_____

Signature of official of company who is authorized to submit plan and Date

APPENDIX A – EXAMPLE CIGAR WARNING PLAN

II. Warning Plan for Cigar Product Packaging

In accordance with 21 CFR part 1143, each cigar package must bear one of six required warning statements on its two principal display panels. Additionally, the following warning statements must appear in black text if on a white background, or white text if on a black background, in a manner that contrasts by typography, layout, or color, with all other printed material on the package:

1 = WARNING: Cigar smoking can cause cancers of the mouth and throat, even if you do not inhale.
2 = WARNING: Cigar smoking can cause lung cancer and heart disease.
3 = WARNING: Cigars are not a safe alternative to cigarettes.
4 = WARNING: Tobacco smoke increases the risk of lung cancer and heart disease, even in nonsmokers.
5 = WARNING: Cigar use while pregnant can harm you and your baby. [*or* SURGEON GENERAL WARNING: Tobacco Use Increases the Risk of Infertility, Stillbirth and Low Birth Weight.[3]]
6 = WARNING: This product contains nicotine. Nicotine is an addictive chemical.

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

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

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

1. Produce a total of 6,000 packages for each print run.
2. Print each of the six required warning statements on packages in sequential order (1, 2, 3, 4, 5, 6 and 1, 2, 3, 4, 5, 6 and 1, 2, 3, 4, 5, 6 etc.), for a total of 6,000 (1,000 each).

OR

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

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

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

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

OR

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

[3] You may choose to display either one of the warning statements regarding reproductive health. FDA is allowing the use of the reproductive health warning statement as required by the Federal Trade Commission (FTC) consent decrees as an optional alternative to the fifth FDA warning, "WARNING: Cigar use while pregnant can harm you and your baby." FDA expects that providing this optional alternative will benefit entities bound by the FTC consent decrees, and the statement is appropriate for the protection of public health.

Appendix A – Example Cigar Warning Plan

III. Warning Plan for Cigar Product Advertising

In accordance with 21 CFR 1143.5, each cigar advertisement must bear one of six required warning statements. Additionally, the required warning statement must appear in black text if on a white background or white text if on a black background.

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

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

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

1 = WARNING: Cigar smoking can cause cancers of the mouth and throat, even if you do not inhale.
2 = WARNING: Cigar smoking can cause lung cancer and heart disease.
3 = WARNING: Cigars are not a safe alternative to cigarettes.
4 = WARNING: Tobacco smoke increases the risk of lung cancer and heart disease, even in nonsmokers.
5 = WARNING: Cigar use while pregnant can harm you and your baby.; or
SURGEON GENERAL WARNING: Tobacco Use Increases the Risk of Infertility, Stillbirth and Low Birth Weight[4].
6 = WARNING: This product contains nicotine. Nicotine is an addictive chemical.

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

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

[4] You may choose to display either one of the warning statements regarding reproductive health. FDA is allowing the use of the reproductive health warning statement as required by the Federal Trade Commission (FTC) consent decrees as an optional alternative to the fifth FDA warning, "WARNING: Cigar use while pregnant can harm you and your baby." FDA expects that providing this optional alternative will benefit entities bound by the FTC consent decrees, and the statement is appropriate for the protection of public health.