



September 1, 2016

Dear Cigar Manufacturer:

On May 10, 2016, the Food and Drug Administration (FDA) issued the final rule “Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products” (“Deeming Rule”) extending its authority to all “tobacco products” as defined under section 201(rr) of the Federal Food, Drug, and Cosmetic Act (FD&C Act). The regulation also provides for additional restrictions on the sale and distribution of newly deemed tobacco products, including the requirement to place warning statements on cigar packaging and advertising. The agency is sending this letter to inform cigar manufacturers, including importers of finished cigars, about the requirement to submit a warning plan for cigar packages and advertisements to FDA for review and approval under 21 C.F.R. § 1143.5(c)(3). Specifically, warning plans must be submitted to FDA by **May 10, 2017** or 12 months before advertising or commercially marketing a product that is subject to such requirement, whichever is later.

In addition, the requirement that new health warnings be placed on cigar packages and advertisements, as described under 21 C.F.R. § 1143.5, “Required warning statements for cigars,” will become effective 24 months after the publication date of the Deeming Rule or **May 10, 2018**. The required warning statements on cigar packaging must be randomly displayed in each 12-month period, in as equal a number of times as possible on each brand of cigar. Additionally, the required warning statements on packaging must be randomly distributed in all areas of the United States in which the product is marketed. For advertisements, the required warning statements must be rotated quarterly, in alternating sequence, in each advertisement for each brand of cigar. See 21 CFR §1143.5(c)(1) and (c)(2). Also, among the requirements in 21 C.F.R. § 1143.5 is that the display, distribution, and rotation of required warning statements on packaging and advertisements for each brand of cigar must be done “in accordance with a plan submitted by the cigar manufacturer, importer, distributor, or retailer” to, and approved by, FDA. See 21 CFR §1143.5(c)(1) and (c)(2). Therefore, if you are required to submit a warning plan for cigar packaging and/or advertising, we encourage you to submit your proposed warning plan to FDA as soon as possible so that your plan may be reviewed and approved before the new health warnings take effect.

Please see enclosed examples of a cover letter and examples of what FDA considers to be acceptable warning plans for cigar packaging and advertising. In addition, FDA published the Draft Guidance for Industry on the Submission of Warning Plans for Cigars (August, 2016), <http://www.fda.gov/TobaccoProducts/Labeling/RulesRegulationsGuidance/ucm517680.htm> , which, when final, will reflect FDA’s current thinking on this requirement. The comment period is open until September 30, 2016, and we welcome comments and feedback on the Draft Guidance.

Here are links to additional information about the Deeming Rule:

- **Final Rule:** Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products
- **Small Entity Compliance Guide:** FDA Deems Certain Tobacco Products Subject to FDA Authority, Sales and Distribution Restrictions, and Health Warning Requirements for Packages and Advertisements

We encourage you to subscribe to FDA's "This Week in CTP." By subscribing, you'll receive information on FDA's compliance webinars, including a webinar that will cover cigar warning plan requirements, as well as updates about regulatory activities, retailer notices, upcoming events, and public education campaigns.

If you have questions about submitting warning plans for cigar packaging or advertisements or questions on these provisions of the new regulation, please contact us at 1-877-CTP-1373 or AskCTP@fda.hhs.gov. Thank you for your cooperation in this matter.

Sincerely,

/s/ _____
Ann Simoneau
Director
Office of Compliance and Enforcement
Center for Tobacco Products

Enclosures: Example Cover Letter for a Cigar Warning Plan
 Example Warning Plan for Cigar Packaging
 Example Warning Plan for Cigar Advertising

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. <i>Brand x</i>	<i>Churchill, Gordo, Corona</i>	<i>12345</i>	<i>Catalog #</i>
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.²]
- 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.

² 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
<i>Brand A</i>	1	2	3	4	5	6
<i>Brand B</i>	1	2	3	4	5	6
<i>Brand C</i>	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 Weight³.

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]

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.