

# **Compliance Training for Small Manufacturers**

## **Cigarettes and Smokeless Tobacco Warning Plans**

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# Agenda

## Cigarette and Smokeless Tobacco Warning Plans

- Background: Applicable Law
- Warning Plan Requirements
  - Packages
  - Advertising
- Draft Guidance for Industry on Warning Plans
  - Who, what, when, and where to submit
- Questions

# Background—Applicable Law

- On June 22, 2009, the President signed into law the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act).
- Tobacco Control Act granted FDA new authority to regulate the manufacture, marketing, and distribution of tobacco products to protect public health and to reduce tobacco use by minors.
- Smokeless Tobacco warning plan requirements are prescribed under the Comprehensive Smokeless Tobacco Health Education Act of 1986 (Smokeless Tobacco Act), as amended by section 204 of the Tobacco Control Act.
- Cigarette warning plan requirements are prescribed under the Federal Cigarette Labeling and Advertising Act (FCLAA), as amended by section 201 of the Tobacco Control Act.

# Effective Dates for Smokeless Tobacco

- *Packages:* Effective June 22, 2010, no person may manufacture for sale or distribution within the United States any smokeless tobacco product the package of which does not comply with the Smokeless Tobacco Act amendments.
- *Advertisements:* Effective June 22, 2010, no manufacturer, packager, importer, distributor, or retailer may advertise or cause to be advertised any smokeless tobacco product within the U.S. if the advertisement does not comply with the Smokeless Tobacco Act amendments.
- *Warning Plans:* The Smokeless Tobacco Act now requires that smokeless warning plans for packages and advertisements be submitted to FDA for review and approval, rather than to the FTC.
- FDA has issued Guidance for Industry stating that FDA will exercise enforcement discretion for those entities who are implementing a warning plan that was submitted to FDA by July 22, 2010, even if the warning plan has not yet been approved by FDA.

# Anticipated Effective Dates for Cigarettes

- FCLAA, as amended, will take effect 15 months after issuance of the graphic health warnings rule for cigarettes (September 22, 2012).
- *Packages:* Starting September 22, 2012, no person may manufacture for sale or distribution within the U.S. any cigarette the package of which does not comply with FCLAA, as amended.
- *Advertisements:* Effective September 22, 2012, no manufacturer, importer, distributor, or retailer may advertise or cause to be advertised any cigarette within the U.S. if the advertisement does not comply with FCLAA, as amended.
- *Warning Plans:* FCLAA requires that, as of the effective date, cigarette warning plans for packages and advertisements be submitted to FDA for review and approval, rather than to the Federal Trade Commission (FTC). These plans may now be submitted to FDA for review and approval.

# Retailer Exemption

- Retailers may be exempt from the packaging and advertising requirements set forth under FCLAA and the Smokeless Tobacco Act for cigarettes and smokeless tobacco products, respectively, under certain circumstances.\*

\*Sections 4(a)(4) and 4(c)(4) of FCLAA and Sections 3(a)(5) and 3(b)(3)(D) of the Smokeless Tobacco Act.

# Manufacturer Responsibilities - Warning Plans for Packages and Advertising

Cigarette and smokeless tobacco packages and advertisements that do not comply with the requirements can violate

- Food, Drug, and Cosmetic Act (FD&C Act);
- Federal Cigarette Labeling and Advertising Act (FCLAA);  
and/or
- Comprehensive Smokeless Tobacco Health Education Act of 1986 (Smokeless Tobacco Act).

# Required Warning Statements for Smokeless Tobacco Packaging and Advertising

- Sections 3(a)(1) and 3(b)(1) of the Smokeless Tobacco Act require packaging and advertisements to bear one of the warning statements:
  - **WARNING:** This product can cause mouth cancer.
  - **WARNING:** This product can cause gum disease and tooth loss.
  - **WARNING:** This product is not a safe alternative to cigarettes.
  - **WARNING:** Smokeless tobacco is addictive.

# Textual Warning Statements for Cigarettes Packaging and Advertising

Sections 4(a)(1) and 4(b)(1) of FCLAA will require packaging and advertisements to bear one of the warning statements:

- WARNING: Cigarettes are addictive.
- WARNING: Tobacco smoke can harm your children.
- WARNING: Cigarettes cause fatal lung disease.
- WARNING: Cigarettes cause cancer.
- WARNING: Cigarettes cause strokes and heart disease.
- WARNING: Smoking during pregnancy can harm your baby.
- WARNING: Smoking can kill you.
- WARNING: Tobacco smoke causes fatal lung disease in nonsmokers.
- WARNING: Quitting smoking now greatly reduces serious risks to your health.

# Warning Plan Requirement for Cigarettes and Smokeless Tobacco

- The required warnings shall be equally and randomly displayed and randomly distributed on **packages**, in accordance with an FDA-approved plan.

(Sec. 4(c)(1) of FCLAA and Sec. 3(b)(3)(A) of the Smokeless Act.)

- The required warnings shall be rotated quarterly in alternating sequence in **advertisements** for each brand of product, in accordance with an FDA-approved plan.

(Sec. 4(c)(2) of FCLAA and Sec. 3(b)(3)(B) of the Smokeless Tobacco Act).

# Warning Plan Requirements for Packaging

- It is unlawful for any person to manufacture, package, sell, offer to sell, distribute, or import for sale or distribution within the United States any smokeless tobacco product or cigarette unless the product package bears one of the required warnings in accordance with the requirements set forth under the Smokeless Tobacco Act or FCLAA.\*

\*Sec. 3(a)(1) of the Smokeless Tobacco Act and Sec. 4(a)(1) of FCLAA.

# Warning Plan Requirements

## Packaging – Display and Distribution

- Warning plans must provide that all of the required warnings on packages are\*:
  - randomly displayed in each 12 month period, in as equal a number of times as is possible on each brand of product, and
  - randomly distributed in all areas of the United States in which the product is marketed.

\*Sec. 3(b)(3)(A) of the Smokeless Tobacco Act and Sec. 4(c)(1) of FCLAA

# Warning Plan Review and Approval for Packaging

- FDA reviews each plan submitted and approves it if the plan\*:
  - provides for the required equal distribution and display of required warnings on packaging, as required under FCLAA and the Smokeless Tobacco Act; and
  - assures that all of the required warnings will be displayed by the tobacco product manufacturer, importer, distributor, or retailer at the same time within the United States.

\*Sections 3(b)(3)(A) and 3(b)(3)(C) of the Smokeless Tobacco Act and Sections 4(c)(3)(A) and 4(c)(3)(B) of FCLAA

# Warning Plan Requirements for Advertising (Smokeless Tobacco)

- It is unlawful for any tobacco product manufacturer, packager, importer, distributor, or retailer to advertise or cause to be advertised within the United States any smokeless tobacco product unless the advertising bears one of the required warnings.\*

\*Sec. 3(b)(1) of the Smokeless Tobacco Act.

# Warning Plan Requirements for Advertising (Cigarettes)

- It is unlawful for any tobacco product manufacturer, importer, distributor, or retailer of cigarettes to advertise or cause to be advertised within the United States any cigarette unless the advertising bears one of the required warnings.\*

\*Sec. 4(b)(1) of FCLAA

# Warning Plan Requirements for Advertising

- Warning plan for advertising must provide for the required quarterly rotation of warning statements, in alternating sequence in advertisements, for each brand of cigarette or smokeless tobacco product.\*

\*Sec. 4(c)(2) of FCLAA and Sec. 3(b)(3)(B) of the Smokeless Tobacco Act.

# Warning Plan Review and Approval for Advertising

- FDA reviews each plan submitted and approves it if the plan provides that all of the warnings are rotated quarterly in alternating sequence in advertising for each brand of cigarettes and smokeless tobacco products, as required by FCLAA and the Smokeless Tobacco Act.\*

\*Sec. 4(c)(3)(A) and (B) of FCLAA and Sec. 3(b)(3)(C) of the Smokeless Tobacco Act.

# Draft Guidance for Industry: Submission of Warning Plans for Cigarettes and Smokeless Tobacco Products

- FDA issued draft guidance on warning plans for comment on September 9, 2011.
- When finalized, this guidance will represent FDA's current thinking on this topic.
- Written comments may be submitted to FDA within 60 days of publication.
  - Address: Division of Dockets Management (HFA-305), FDA, 5630 Fishers Lane, Room 1061, Rockville, MD 20852
  - Web page: <http://www.regulations.gov>
  - All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

# Draft Guidance:

## Example Package--Equal/Random Display

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

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

OR

- 2. Print 1,000 of each of the nine cigarette (or four for smokeless tobacco) required warnings on batches of packages simultaneously (1,000 of warning 1, 1,000 of warning 2, etc.).*

*This should result in an equal display of each of the nine different required warnings for cigarettes (or four for smokeless tobacco products) for each brand of product, subject to minor variations due to normal commercial printing and manufacturing practices.*

# Draft Guidance: Example Packaging-- Random Display and Distribution

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

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

OR

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

## Draft Guidance: Example of a Quarterly Rotation Schedule or Smokeless Tobacco Advertising

	Jan 1–Mar 31	Apr 1– Jun 30	Jul 1–Sep 30	Oct 1-Dec 31
Brand A	I	II	III	IV
Brand B	II	III	IV	I
Brand C	III	IV	I	II

I = WARNING: This product can cause mouth cancer.

II = WARNING: This product can cause gum disease and tooth loss.

III = WARNING: This product is not a safe alternative to cigarettes.

IV = WARNING: Smokeless tobacco is addictive.

# Draft Guidance: Example of a Quarterly Rotation Schedule or Cigarette Advertising

	Jan 1– Mar 31	Apr 1– Jun 30	Jul 1– Sep 30	Oct 1– Dec 31	Jan 1– Mar 31	Apr 1– Jun 30	Jul 1– Sep 30	Oct 1– Dec 31	Jan 1– Mar 31
Brand A	1	2	3	4	5	6	7	8	9
Brand B	9	1	2	3	4	5	6	7	8
Brand C	8	9	1	2	3	4	5	6	7

1=WARNING: Cigarettes are addictive.

2=WARNING: Tobacco smoke can harm your children.

3=WARNING: Cigarettes cause fatal lung disease.

4=WARNING: Cigarettes cause cancer.

5=WARNING: Cigarettes cause strokes and heart disease.

6=WARNING: Smoking during pregnancy can harm your baby.

7=WARNING: Smoking can kill you.

8=WARNING: Tobacco smoke causes fatal lung disease in nonsmokers.

9=WARNING: Quitting smoking now greatly reduces serious risks to your health.

# Draft Guidance: Example of a Quarterly Rotation schedule for Advertising

*Tobacco products will be advertised using the following media, and the rotation of the warning statements will be based on the date indicated in the table below:*

<b><i>Type of Advertising:</i></b>	<b><i>Start of Quarterly Rotation:</i></b>
<i>Advertising in periodicals (newspapers, magazines)</i>	<i>Cover date or closing date of publication.</i>
<i>Posters and placards</i>	<i>Date of scheduled appearance of the advertisement.</i>
<i>Other Advertisements</i>	<i>Order date or date of material dissemination.</i>

# Draft Guidance: Who Submits a Warning Plan?

- Warning plans may be submitted by the tobacco product manufacturer, importer, distributor, or retailer.
- The warning plan may be submitted by someone other than the manufacturer (e.g., contract manufacturers, importers, distributor).
- Before you manufacture, package, sell, offer to sell, distribute, or import for sale or distribution within the United States, it is important that you make sure a warning plan has been approved covering your actions and you comply with an FDA-approved plan.

# Draft Guidance: Who Submits a Warning Plan?

- Generally, the entity that is ultimately responsible for placing or directing the placement of the warnings on the packages and for directing distribution of the packages would be best suited to submit the warning plan for packaging.
- The 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 is generally best suited to submit a warning plan for advertising that ensures quarterly rotation of required warnings for that brand.

# Draft Guidance: What to Submit

- Cover Letter (Guidance’s Appendixes A and B)
  - Subject line: “RE: WARNING PLAN FOR CIGARETTES or SMOKELESS TOBACCO PRODUCTS (Original, Amendment, or Supplement)”
  - Detailed information of the contents of your submission
  - Contact information for the warning plan
  
- Proposed Warning Plan
  - Cigarette Packaging and/or Advertising
  - Smokeless Tobacco Product Packaging and/or Advertising

# Draft Guidance: What to submit

- Warning plans may include representative samples of packaging and advertising.
  - Representative samples of packaging and advertising are not required. Firms may voluntarily submit different types of packaging and a range of package sizes for each type of product (e.g., multi-pack sleeves) and different types of advertisements.

Note: Such samples will place the warning plan in context and, therefore, facilitate FDA's review.

# Draft Guidance: When to Submit a Warning Plan?

- Because warnings must be equally distributed and displayed on packages, and rotated quarterly in advertisements, in accordance with an approved warning plan, a warning plan must be submitted and approved before the distribution or display of warnings on packages or rotation of warnings in advertisements.
- A supplement to an approved warning plan (or a new plan) must be submitted and approved before making changes to the distribution or display of warnings on packages or rotation of warnings in advertisements, or before distributing or displaying packages and advertisements for a new brand.

# Draft Guidance: When to Submit

- *Smokeless warning plans*: Smokeless warning plans should have been submitted to the FDA by July 22, 2010, and implemented. New plans or modifications are submitted to FDA before implementation.
- *Cigarette warning plans*: In order to afford FDA sufficient time to review and approve proposed warning plans for cigarettes before the anticipated effective date (September 22, 2012), FDA recommends that proposed warning plans be submitted to the agency as soon as possible.

# Draft Guidance: Where to Submit Warning Plans

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

# More Information on the Draft Guidance

Draft Guidance for Industry Submission of  
Warning Plans for Cigarettes and Smokeless  
Tobacco Products (Issued on 9/9/2011):

Web page link:

<http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/ucm271265.htm>