



Warning Plans & Warning Labels:

IPCPR Guidance for Manufacturers (Updated)

In May 2016, the FDA finalized and enacted the so-called “Deeming Rule,” enacting a series of requirements on several tobacco products, including Premium Cigars. This document focuses on the new requirements relating to warning label requirements and warning plans for packaging and advertising. Specifically, this document will review the following:

- Warning Plans –
 - What is a warning plan,
 - What are the six required warnings,
 - What should a warning plan look like,
 - Warning plans and advertisements, and
 - How to submit a warning plan

- Warning Labels -
 - August 10th, 2018 Deadline and Sell Through Provisions

New Requirements under the FDA Deeming Rule

Beginning on August 10th, 2018, cigar packaging and advertisements must contain 1 of 6 specific warning statements (some cigars already have warning statements as a result of a June, 2000 consent decree with the Federal Trade Commission). In addition, FDA needs to approve a “warning plan” that was submitted to FDA 12 months before the warning statements are used showing how the six required warning statements will be displayed on packaging (and advertising) and rotated quarterly. Thus, the warning plans should be submitted by August 10th, 2017. Warning plans can be submitted after that date, but you will need to wait 12 months before you can use the packaging or advertisement that is subject to a warning statement. Here’s what you need to know about the new requirements under the warning plan and warning label provisions in the rule.

Warning Plans

What is a warning plan?

A warning plan is a plan submitted to FDA that demonstrates how you will display the six required warning statements on packaging and advertisements so that they are:

- 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
- Are randomly distributed in all areas of the United States in which the product is marketed.

On August 10, 2018, the requirement to carry warning statements on cigar packages and advertising becomes effective. The requirement to submit a warning plan to FDA then is August 10, 2017. You can submit a warning plan later, but if you are required to have a warning plan, you need to submit a proposed warning plan to FDA 12 months before advertising or commercially marketing a product that is subject to the requirement for a warning statement.

By definition, packaging (or package) 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.

As a Manufacturer, do I need a warning plan for packaging?

Simply put, yes. If you are a manufacturer responsible for the packaging of your product, then you must submit a warning plan to the FDA.

What are the six required warnings for warning plans and warning labels?

For products manufactured after May 10, 2018, manufacturers must apply one of six warning statements to each cigar package.

- 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.

What should my warning plan submission look like?

[The FDA draft guidance last December describes what warning plan submissions should include.](#) It details what should be included in the plan and provides a 3-page template for manufacturers to follow.

According to the guidance, a warning plan should include the following:

- Cover Letter (page 11 & 12)
- Information about the Warning Plan for Packaging And/Or Advertising (Page 13 & 14)
- Representative Packaging or Advertising (Page 9)

How the regulatory requirements will be met

According to [FDA's guidance \(page 8\)](#), the warning plan should explain the following:

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

IPCPR recommends that manufacturers refer to [FDA's template \(page 13\)](#) for how best to demonstrate and meet these requirements.

Representative Materials

FDA strongly recommends but does not require representative materials for packaging and advertisements. These materials place the warning plan in context and may help facilitate FDA's review. Representative samples of packaging could be 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, and the required warning statement

as it would appear in different sizes and colors of advertisements. For example, you could submit a mock-up showing how the packaging (or advertisement) will look including content and graphics placement, warning label placement, etc. The warning statements must meet the specific requirements (font, size, look) [described in FDA regulations](#).

What can be advertised without the need of warnings and a warning plan?

IPCPR is of the opinion that only those advertisements with a particular “brand” of cigar will likely need a warning plan. In this case, *a brand represents a specific cigar product rather than a cigar manufacturer*. For example, take the case of the fictional DT Cigar Company. Simply advertising “DT Cigar Company” advertises a cigar manufacturer, but does not advertise a particular “brand” and would not need a warning plan. However, if the manufacturer or a retailer were to advertise a special deal for DT Cigar Company’s “Alpha Belicoso Maduro Wrapper Cigar,” then they would be advertising a “brand” and will need to submit a warning plan.

For manufacturers with retail locations, FDA has said that you can advertise the name of your store if it is not also a brand of cigar. IPCPR is of the opinion that you can advertise the name of a person from a cigar manufacturer.

Manufacturers can also provide advertisements (covered by a warning plan) to retailers for use. This includes an advertisement displaying a specific cigar brand which retailers will feature in their store. If a retailer were to simply run that advertisement and include their logo and details (location, contact info etc.) then the manufacturer’s warning plan for that advertisement is sufficient.

How do I submit a plan?

Manufacturers can submit plans through snail-mail or online.

IPCPR recommends retailers & manufacturers submit their plans physically through a trackable/traceable shipping method (i.e. fedex, UPS, certified USPS)

Snail-Mail Submissions

Manufacturers wishing to physically mail their submissions can do so to the following address.

Address:

**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

IPCPR recommends retailers submit their plans physically through a trackable/traceable shipping method (i.e. fedex, UPS, certified USPS)

Electronic Submissions

Manufacturers can submit their warning plans and representative materials as PDF documents through FDA's [Electronic Submissions Gateway](#) WebTrader Production Software. [Instructions on signing up for an account can be found here](#). The sign-up process can be cumbersome so we recommend you allow plenty of time to set up the account and submit your materials.

Warning Labels

The deadline for warning labels is August 10, 2018. So can retailers still sell non-labeled product after that date?

For retailers, the short answer to this question is yes, they can still sell products without the required labeling, ***BUT ONLY IF THE PRODUCT WAS MANUFACTURED BEFORE August 10, 2018 and introduced into “domestic commerce” by September 10, 2018.***

As long as the manufacturer and by extension the retailer can show that the cigars meet both these requirements, no label is required. One option may be to have manufacturers stamp Lading Documents or Invoices for shipments from August 10th through September 10th, 2018 with: “These Products were manufactured on or before August 10, 2018 and were introduced into domestic commerce of the United States.”

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