



Warning Labels & Advertising Plans: IPCPR Guidance for Manufacturers

In 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, and
 - When a warning plan is required for advertising.

- Warning Labels -
 - Deadlines for sale of non-labeled products.

New Requirements under the FDA Deeming Rule

By May 10, 2017, manufacturers are required to submit to the FDA for review a plan for how they will display the six required warning statements on tobacco product packaging. One year later, as of May 10, 2018, FDA will require the inclusion of specified warnings on packaging and advertisements for premium cigars. After that date, cigar manufacturers must begin labeling products with a required warning statement (some cigars already have warning statements as a result of a June, 2000 consent decree with the Federal Trade Commission). Here’s what you need to know about the new requirements under the warning plan and warning label provisions in the rule.

Warning Plans

1) 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.

The requirement to submit a warning plan to FDA takes effect May 10, 2017. On May 10, 2018, the requirement to carry warning statements on cigar packages and advertising becomes effective. If you are required to have a warning plan, you need to 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.

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.

If you think you need to submit a warning plan for packaging or advertising, [FDA provides a good template for submission that can be found here. \(pages 14-17\)](#)

2) 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.

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

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 any cigar unless the advertising bears one of the six required warning statements listed above.

FDA has said that you need warnings (and a warning plan) for a brand of cigar. However, “brand” is not defined in the Tobacco Control Act, and it is probably a lot narrower than you might think it is. The word “brand” is defined by law as “a variety of tobacco product distinguished by the tobacco used, tar content, nicotine content, flavoring used, size, filtration, packaging, logo, registered trademark, brand name, identifiable pattern of colors, or any combination of such attributes.”

FDA has said that you can advertise the name of your store as long as that is not also a brand of cigar. We believe you can advertise the name of a person from a cigar manufacturer. We also believe you can advertise a cigar manufacturer without mentioning a specific brand of cigar. We have asked FDA to provide more guidance around exactly what a retailer might advertise.

Warning Labels

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

There are two important dates to keep in mind here (both dates apply to manufacturers, but indirectly apply to retailers too). Any product manufactured after May 10, 2018 must include the appropriate warning label. However, on June 8, 2018, manufacturers must apply warnings to all products, no matter when they were manufactured.

So 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 MAY 10, 2018 and introduced into “domestic commerce” by June 8, 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 May 10 through June 8, 2018 with: “These Products were manufactured on or before May 10, 2018 and were introduced into domestic commerce of the United States

5) When can I expect additional clarity on these issues?

That is a hard question for us to answer. The law is confusing enough to begin with, but even then a provision that might make sense when applied to cigarettes does not make sense when applied to premium cigars. The law is new for manufacturers, retailers and for FDA so there is not a lot of history to help us with interpretation. It is unlikely that we will get clear answers from FDA to all our questions but if we do, we will let you know. In the meantime, we will continue to give our interpretation of the requirements when we can, and point out to you and FDA where we think the law is unclear.

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