



Warning Plans: An IPCPR Guidance for Retailers

Beginning on August 10, 2018, cigar packaging and advertisements must contain 1 of 6 specific warning statements. Before August 10, 2018, you can continue to advertise as you always have. However, after August 10, 2018, you cannot advertise a “cigar brand” unless that advertisement has a warning, and the advertisement is covered by a warning plan that was submitted to FDA at least 12 months before you use the advertisement.

What is a Warning Plan?

A warning plan is a plan submitted to FDA that [demonstrates how the six required warning statements](#) will be displayed 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.

FDA recently extended the compliance deadline by 90 days for several requirements, including the requirement to submit a warning plan to FDA. As noted above, if you want to advertise cigars on August 10, 2018, you must submit a warning plan by August 10, 2017. You can submit your plan after that date, but then you cannot advertise a “cigar brand” after August 10, 2018 unless you submit a warning plan to FDA and wait 12 months before you use the advertisement.

As a retailer – do I need to submit a warning plan for packaging?

For warning labels displayed on cigar packaging/cigar boxes – the responsibility for warning plans will almost always rest with the manufacturer. However, a retailer may also be a manufacturer if, for example, the retailer produces their own unique products in-house, or they use a contract manufacturer to produce private label tobacco products. For cigars or pipe tobacco provided by an outside manufacturer in packaging, then, IPCPR advises that you should work with your manufacturing partner to make sure that one of you has submitted a plan that covers your private label cigars. *So for packaging, most retailers do not need to submit a plan!*

What about for Advertising?

The question gets a little more complicated when considering advertising. Unfortunately, the answer is unclear, and it probably depends on what your advertisement looks like.

Definition of “Cigar Brand” Vs. “Cigar Manufacturer”

As we previously discussed, IPCPR is of the opinion that only those advertisements with a particular “brand” of cigar will likely need a warning plan for that advertisement. 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 the fictional “DT Cigar Company” advertises a cigar manufacturer, but it does not advertise a particular “brand” and would not need a warning plan. However, if a retailer were to advertise a special deal for DT Cigar Company’s “Alpha Belicoso Maduro Wrapper Cigar,” then that retailer is advertising a “brand” and will need to submit a warning plan.

IPCPR RECOMMENDS THAT RETAILERS DO NOT SUBMIT A WARNING PLAN AND AVOID ADVERTISING SPECIFIC “BRANDS” OF CIGARS IN ADVERTISING.

It is important to remember that if you submit an advertising warning plan, then you are telling the FDA that your advertising is subject to all of FDA’s requirements (the warning font, font size, placement on the advertisement, etc.), including the FDA’s 12-month submission requirement.

Private Labels

The requirement for a packaging warning plan for private label cigars is discussed above. For advertising, IPCPR recommends that retailers submit a warning plan if they source and sell private label brands and advertise that private label. For instance, the MP Cigar Store sells a cigar blend made by a manufacturer but branded as the MP Especial Cigar – the retailer should submit a warning plan. IPCPR is of the opinion that the “All Brands” approach discussed later in this document also covers retailer-specific private label cigars.

If I do choose to submit a Warning Plan, what would it look like?

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

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

- Cover Letter
- Information about the Warning Plan for Packaging And/Or Advertising
 - How the regulatory requirements will be met
- Representative Packaging or Advertising

If you know exactly what advertisements you will be running in 2018 and beyond, FDA's template is easy to follow. Basically, for each "brand" you will advertise, use the FDA template to show which required warning will be used in the advertisement and when they will be rotated. Unfortunately, most retailers don't know 12 months in advance which cigars they will be advertising, and don't run advertisements over the course of multiple quarters. FDA's template and guidance do not address these common situations.

[To address this scenario, IPCPR has provided a semi-completed template incorporating the information detailed below.](#) Retailers can review and utilize this template along with the advice provided here to determine what needs to be submitted in an advertising warning plan.

"All Brands" Approach

The FDA guidance does state that a "warning plan may take into account practical constraints on the production and distribution of advertising." Therefore, In IPCPR's opinion, one option may be to inform FDA that you are using FDA's template to provide a warning plan that you intend to be applied as broadly as possible. A retailer could explain in the cover letter that the warning plan applies to "all brands." Examples of a "all brands" approach can be found in this linked template as well in the examples below.

However, without further information from FDA – IPCPR cannot guarantee this approach will be accepted following submission.

This plan covers the following cigars:

Brand Name	Product (Subbrand)	Unique Identifier	Type of Unique Identifier (SKU, Catalog #, UPC)
All Brands	All Subbrands	N/A	N/A

Practical constraints on the production and distribution of advertising: I do not know 12 months in advance which cigars a manufacturer will provide, or which cigars I will be advertising. I do not run the same advertisement over the course of multiple quarters. Therefore the attached warning plan covers all advertisements that I may run after August 10, 2018. Any brand/subbrand that I advertise in the first quarter will include the first of the six warning statements. The next quarter, the next warning statement would be included in all brand/subbrand advertisements. The same warning statement would be used for all brand/subbrands advertised in that period, and the warning statements will rotate in subsequent quarters according to the attached warning plan.

OPTIONAL: A retailer could also list all cigar brands in inventory with a unique identifier in an attachment, however it would seem that in such a case, the warning plan would cover only those brands. Any new brands that might be introduced after the warning plan was submitted would need to be included in a supplement or amendment to the warning plan.

For any brand the retailer might advertise in the first quarter, one of the six warning statements would be applied to all advertisements. The next quarter, the next warning statement would be applied. As shown in the figure below, retailers could simply indicate that all brands advertised will receive the same warning statement per quarter.

“Our advertisements will rotate the six required warning statements according to the following schedule for all brand(s) of product advertised during the period shown. This schedule assumes a calendar start date of January 1, 2018:”

	Jan 1 – March 31	April 1 – June 30	July 1 – Sept 30	Oct 1 – Dec 31	Jan 1 – March 31	April 1 – June 30
All Brands	1	2	3	4	5	6

As you'll see above, the template assumes a quarterly rotation start date of January 1, 2018. This is for simplicity. So if a retailer were to produce advertising on August 11th, 2018, that would be firmly in the third quarter warning statement time frame.

Additionally, IPCPR provided the option that retailers could list all their cigar "brands" in inventory on an attachment, however it would seem that in such a case, the warning plan would cover only those brands, and not any new brands that might be introduced after the warning plan was submitted. Retailers run the risk of pigeonholing their future advertising should they choose to advertise new "brands."

Additional Information

FDA recommends but does not require retailers submit "representative material" of planned advertisements. Retailers should be prepared to respond to requests for additional information from the FDA, including providing representative samples of advertising and the design and display of the required warning statements(s) in those advertisements.

How do I submit a plan?

Retailers can submit plans through snail-mail or electronically.

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

Snail-Mail Submissions

Retailers 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

Electronic Submissions

Retailers 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.

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