

FDA ALERT

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Reminder: Cigar Warning Statements and Warning Plans

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The Deeming Regulations enacted by the Food and Drug Administration (FDA) on May 10, 2016, expanded the agency's tobacco regulatory authority to **cigars** and certain other tobacco products. Among the regulatory provisions made applicable to cigars, were requirements related to the inclusion of health warning statements on packaging and advertisements. These warning statement requirements must be implemented pursuant to a warning plan approved by the FDA.

Key Dates

- *Warning Plans* – Warning plans for cigars must be submitted to the FDA no later than **May 10, 2017**, or twelve (12) months before advertising or commercially marketing a cigar product that is subject to the warning statement requirements, whichever is later.
- *Warning Statement Requirements* – The warning statement requirements for cigar packaging and advertisements take effect on **May 10, 2018**.
- The FDA anticipates receiving a large volume of cigar warning plans by the **May 10, 2017** deadline and estimates that it will take up to twelve (12) months for the agency to review a submission. Therefore, the FDA encourages businesses to submit their cigar warning plans as soon as possible.

Cigar Warning Statements

The Deeming Regulations require the use of the following warning statements on the packages and in the advertisements for all cigars:

- 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, as an alternative statement)
SURGEON GENERAL WARNING: Tobacco Use Increases the Risk of Infertility, Stillbirth and Low Birth Weight.
- WARNING: This product contains nicotine. Nicotine is an addictive chemical.

General Requirements

- *Warning Statements* – The Deeming Regulations require that the warning statements on both cigar packaging and advertisements satisfy a series of formatting requirements, such as size, location, placement, font style and size, and certain other requirements. In addition, the Deeming Regulations require that for cigar **packaging**, all six (6) warning statements be randomly displayed in each twelve (12) month period, in as equal a number of times as possible on each brand of cigar sold in product packaging and be randomly distributed in all areas of the United States in which the product is marketed. The warning statements for **advertisements** must be rotated quarterly, in alternating sequence, in each advertisement for each brand of cigar.

- *Warning Plans* – The package and advertisement warning statement requirements must be implemented in accordance with a warning plan or plans approved by the FDA. Generally, a warning plan should include the following: background and identifying information about the submitter, the plan type and scope, and the cigar brands covered (in cover letter form); a listing of the specific element of the warning plan requirements being addressed and a detailed description of how the element will be met; and, representative samples of packages and advertisements with each of the required warning statements.
- *Exemptions* – Cigars sold individually, without any packaging, are exempt from the packaging requirements. When sold in this manner, retailers are required to post all six (6) of the cigar warning statements on a sign, at the point-of-sale, at each cash register in any retail establishment in which the cigars are sold. The point-of-sale warning statement signs must satisfy various formatting and location requirements. Retailers of cigars sold individually and not in product packages are not required to submit a warning plan for warning statements on packages, because the warning signs posted at the retailer's point-of-sale will include all six (6) warning statements applicable to cigars.

For further information regarding cigar warning statement requirements, cigar warning plans, or the Deeming Regulations, please contact one of the listed Roetzel attorneys.

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