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CAA Member Companies

Re: FDA's Final Deeming Regulation

Dear Member:

I am writing to inform you about the U.S. Food and Drug Administration's ("FDA's") recently issued final rule that deems cigars a tobacco product subject to the requirements of the Federal Food, Drug, and Cosmetic Act ("FD&C Act"). The rule establishes requirements for a number of "deemed" tobacco products, including cigars, the focus of this letter.

In the proposed rule, FDA offered two options for cigar regulation, one that would make all cigars (including small, large, and premium) subject to regulation and the other that would exclude premium cigars from regulation. In the final rule, FDA chose Option 1 deeming all cigars, including premium cigars, subject to the final rule. Under the final rule, cigars as deemed products are automatically subject to a number of "deeming provisions"[1] of the FD&C Act. In addition, FDA is proposing three additional requirements for newly deemed tobacco products.

Below is a high level summary of the main provisions of the final rule applicable to cigars and a discussion of the likely implications of the rule for CAA members. Also, attached is a side-by-side comparison of the proposed and final rules[2] and a schedule of effective and compliance dates that, in addition to the main provisions discussed below, includes items of lesser significance we will take up later[3].

[1] FDA refers to existing law applicable to all tobacco products as deeming provisions.
[2] *See* Attachment A, a chart showing the differences between the proposed and final rules.
[3] *See* Attachment B, a chart showing effective and compliance dates for requirements applicable to cigars.

SUMMARY OF FINAL RULE

***a. Deeming provisions*:** The following FD&C Act provisions automatically apply to cigars as of the effective date of the final rule[4]:

- Enforcement action against adulterated or misbranded products (FD&C Act Sections 902 and 903): Products that are "adulterated" or "misbranded" are subject to FDA enforcement action. Under the FD&C Act, there are a number of ways that a product could become adulterated or misbranded, for example, through contamination from insanitary production conditions, non-compliance with Good Manufacturing Practices ("GMPs"), or false or misleading labeling or advertising.

  Implications: The principal implication is that FDA can initiate an enforcement action such as a seizure, injunction, or criminal prosecution if the product is adulterated or misbranded. Currently, there are no GMP requirements for tobacco products that could create the basis for an adulteration finding. However, there are many other bases for a finding of adulteration or misbranding. Examples of adulteration are the failure to pay user fees; non-compliance with an applicable tobacco product standard; and product contamination from being prepared, packed or held under insanitary conditions. Examples of misbranding are false or misleading labeling or advertising and non-compliance with labeling requirements.

- Requirement to submit ingredient lists and report harmful and potentially harmful constituents (FD&C Act Section 904): Cigar manufacturers are required to submit a listing of all ingredients, including tobacco, substances, compounds, and additives that are used to manufacture cigars. Manufacturers are also required to report harmful or potentially harmful constituents (HPHCs) of cigars.

  Implications: Because there is currently no HPHC list for cigars, nor a testing methodology for cigars that enables manufacturers to evaluate the HPHC levels in their products, the requirement for HPHC reporting could be quite troubling and potentially burdensome. However, FDA does not intend to enforce the HPHC reporting requirements for newly deemed products prior to the close of the 3-year compliance period. FDA also intends to issue a guidance regarding HPHC reporting and a testing and reporting regulation. It therefore appears that FDA intends to clarify HPHC testing requirements within the 3-year compliance timeframe. Through the notice and comment process, CAA will have an opportunity to represent member concerns with FDA on this very challenging issue.

[4] The date for compliance may not be the effective date of the rule if FDA provides a compliance period during which it will exercise enforcement discretion.

- Requirement to register and list products with FDA (FD&C Act Sections 905(a) through (i)): Cigars manufacturers are required to register their establishments engaged in the manufacture, preparation, compounding, or processing of a tobacco product with FDA and to submit product lists to the agency. This requirement does not apply to foreign establishments; however, FDA plans to issue a proposed registration and listing rule that would extend these requirements to foreign tobacco product establishments.

  Implications: Registration and listing is a low burden undertaking and should not affect cigar manufacturers in a significant way.

- Prohibition against sale and distribution of modified risk products (FD&C Act Section 911): Cigar manufacturers are prohibited from marketing products with modified risk descriptors (e.g., "light", "low" or "mild") or making direct or implied claims of reduced/modified risk, unless FDA issues an order authorizing the marketing of the modified risk product following the submission of a modified risk tobacco product application.

  Implications: Currently, modified risk descriptors or claims have not been identified as a significant issue by the members. Accordingly, this requirement should have minimal immediate effects.

- Prohibition against the distribution of free samples (Tobacco Control Act Section 102 and 21 CFR 1140.16(d)): Cigar manufacturers are prohibited from distributing, or causing to be distributed, free cigar samples.

  Implications: CAA members currently rely on in-store events at which they can provide samples and offer discounts. This prohibition results in a significant limitation on one of the industry's core cigar promotion practices.

- Requirement for premarket review (FD&C Act Sections 905(j) and 910): Under the FD&C Act, tobacco products, including cigars, introduced into the U.S. market before February 15, 2007 may remain on the market without premarket review. Cigars and other tobacco products introduced after that date require premarket review and authorization[5] from FDA prior to marketing because they are considered "new" products. The final rule states that February 15, 2007 is the date that separates the newly deemed products from older products that do not require premarket review unless changed. This means that cigars that were not on the U.S. market as of February 15, 2007 would be considered new tobacco products requiring approval of a premarket application prior to marketing, unless the product is found "substantially equivalent" to a predicate product or is exempt from the substantial equivalence requirement. A predicate

[5] Authorization refers to an exemption from substantial equivalence requirements, a substantial equivalence order, or a marketing order.

product is a tobacco product that was commercially marketed in the U.S. as of February 15, 2007, or a tobacco product that was determined by FDA to be substantially equivalent to such a tobacco product and in compliance with the FD&C Act.

Implications: The requirements for premarket review will have significant impact on members not only because of the need to make submissions to FDA and be subject to agency reviews, but because of the February 15, 2007 date will have the tendency through the passage of time to eliminate "predicate" cigars and thereby greatly lessen members' ability to compare newer to "older" cigars to establish substantial equivalence (SE). Natural variation remains an important concept because FDA reiterates in the preamble to the final rule that it does not intend to enforce the premarket authorization requirements where manufacturers make tobacco blending changes to address the natural variation of tobacco to maintain a consistent product. Nonetheless, the scope of the natural variation likely will require interaction with FDA to obtain clarification of that term. Also, FDA generally expects that cigars with blending changes that are intended to alter the chemical or perception properties of the new product will be able to successfully use the substantial equivalence pathway so long as the blending change does not significantly raise the HPHC levels in the tobacco product over its predicates.

FDA is providing staggered compliance periods for currently marketed products that were introduced into commerce after February 15, 2007 of 12, 18 and 24 months following the effective date of the final rule based on the complexity of the submission: SE exemption requests will receive 12 months; SE reports 18 months; and premarket tobacco applications 24 months. Moreover, unless FDA issues an order denying or refusing to accept the submission, those products for which timely premarket submissions are made will be granted an additional continued compliance period of 12 months, resulting in compliance periods of 24, 30 and 36 months for the above-referenced submissions, respectively. If, at the time of the conclusion of the continued compliance period, FDA determines that the applicant has provided the necessary information and substantial progress is made towards completing the review, FDA may consider, on a case-by-case basis, whether to defer enforcement of the premarket authorization requirements for a reasonable additional time period. However, concern remains that if FDA falls behind in its reviews, the agency could force SE Report submitters to remove product from the market, claiming that the submitter failed to respond to agency information requests adequately.

b. Additional provisions: The final rule imposes three additional requirements on cigars:

- Minimum age and identification restrictions (21 CFR § 1140.14(b)(1) and (2)): Cigar retailers are prohibited from selling products to any person under the age of 18. Retailers are required to verify through photo identification that customers are not younger than 18 years of age, but are not required to verify age for persons over the age of 26. While mail order sales are permitted,

FDA states in the preamble to the final rule that it will continue to actively enforce the minimum age restriction for mail order and internet sales. FDA states that mail order retailers may choose any method of identification verification that complies with the minimum age and identification provision in the final rule, *i.e.*, the requirement of verification through photo identification.

- Requirement to include health warnings (21 CFR § Part 1143): Cigar packages and advertisements are required to bear health warnings that must be randomly displayed on cigar product packages and rotated in advertisements. FDA requires the use of four current FTC warnings[6], plus two others, including a fifth warning regarding reproductive health effects. The fifth warning may read: "WARNING: Cigar use while pregnant can harm you and your baby" or, alternatively, may mirror the warning required by the FTC consent decree: "Tobacco Use Increases The Risk of Infertility, Stillbirth And Low Birth Weight". FDA is also requiring the following addictiveness warning: "WARNING: This product contains nicotine. Nicotine is an addictive chemical."

  The required warning must appear directly on the package and be conspicuously and prominently placed on two principal display panels, with the warning covering at least 30 percent of each of the principal display panels. For advertisements, the required warning must occupy at least 20 percent of the area of the advertisement. There are size, font and contrast requirements for the warnings on both the packaging and advertising, including that it appear in black text on white background or white text on black background in a manner that contrasts by typography, layout, or color with the other material on the packaging/advertisement. Individually sold cigars that are not in product packages must have the warning statements posted at the retailer's point-of-sale; no warnings are required on individual cigars.

  Implications: Under the consent decree, the required size of the warning on both labels and packages is determined by, and relative to, the size of the advertisement or package and generally speaking, the size requirement is less than that required by FDA. As a result, members will have to redesign their packaging to comply with the FDA warning requirements. Additionally, members will be required to add the required addictiveness warning. Although the requirements entail the need for new packaging and advertising, there should be sufficient time to implement the requirements. The health warning requirements become effective 24 months from the date of publication of the final rule, with an additional 30-day period during which manufacturers may continue to introduce into interstate commerce existing inventory without the required warning statements on packaging that was manufactured before the effective date.

[6] The four warnings are:
(i) WARNING: Cigar smoking can cause cancers of the mouth and throat, even if you do not inhale.
(ii) WARNING: Cigar smoking can cause lung cancer and heart disease.
(iii) WARNING: Cigars are not a safe alternative to cigarettes.
(iv) WARNING: Tobacco smoke increases the risk of lung cancer and heart disease, even in nonsmokers.

Nonetheless, concern exits because rotation plans for warning statements must be submitted to FDA within 12 months of the effective date of the rule. Member experience with preparing and submitting warning rotation plans to FTC suggests that complying with the one year requirement may be a challenge that may require communications with FDA to ensure adequate time to achieve acceptable plans.

- Prohibition of vending machine sales, unless in a facility that excludes youth (21 CFR § 1140.14(b)(3)): Cigar retailers are prohibited from selling cigars through vending machines unless the vending machines are located in a facility where the retailer ensures that no one under the age of 18 is present, or permitted to enter, at any time. In other words, vending machine sales are permitted as long as it can be ensured that no one under the age of 18 is present or permitted entry.

  Implications: Because the final rule permits vending machines under certain circumstances, and does not require face-to-face sales for cigars, this provision should have modest impact on members.

c. (Potential) Future Requirements: Although not part of the final rule, FDA provided information in the preamble regarding potential future requirements:

- Ban on Flavored Tobacco Products. FDA announced in the final rule that it intends to issue a proposed product standard that would prohibit characterizing flavors in all cigars, including cigarillos and little cigars. This potential rule would be very troubling and would likely require full CAA engagement with FDA and elsewhere.

- Additional Access Restrictions: FDA will monitor whether a requirement for face-to-face sales is necessary for deemed tobacco products. If FDA determines that it is appropriate for the protection of the public health to extend the self-service display prohibition to newly deemed tobacco products, the agency will issue a Notice of Proposed Rulemaking.

d. Effective Date

The self-executing provisions are effective 90 days from the date of publication of the final rule. However, FDA is providing compliance periods for a number of the requirements in the final rule. For example, for premarket review the agency is providing staggered compliance periods following the effective date of the final rule based on the type of submission. Similarly, FDA is providing a 3-year compliance period for HPHC reporting. The minimum age and identification requirements and vending machine restrictions are effective 90 days from the date of publication of the final rule. The health warning requirements are effective 24 months from the date of publication of the final rule, with an additional 30-day period to distribute non-compliant existing inventory manufactured before the effective date. Attached is a list of effective and compliance dates applicable to each provision.

e. User Fees

In a separate rule, FDA announced that it is requiring domestic manufacturers and importers of cigars and pipe tobacco to submit information needed to calculate the amount of user fees assessed under the FD&C Act. Domestic manufacturers and importers of cigars and pipe tobacco must begin submitting the required information no later than August 20, 2016.

Along with the final rule FDA issued a number of guidance documents to explain to the industry how the agency will implement the requirements in the new regulation. We can provide these guidance documents to interested members upon request. We will continue to update you as the agency releases further guidelines and notices.

Sincerely,

Craig Williamson
President
Cigar Association of America, Inc.

Attachments