

April 25, 2014

FDA Proposes Tobacco Products Rule; E-Cigarettes, Cigars To Be Regulated

The rule would ban the sale of e-cigarettes, cigars, pipe tobacco, and other products to those under 18; would require warning statements on product packages and in advertisements; and would require manufacturers to register and list products with the Agency and submit new products for premarket review.

On April 25, the U.S. Food and Drug Administration (FDA or the Agency) published a proposed rule (the Rule) in the *Federal Register*, establishing, for the first time, federal regulatory authority over electronic cigarettes (e-cigarettes), cigars, pipe tobacco, dissolvable tobacco products, and nicotine gels (deemed tobacco products).¹

Key Takeaways from the Rule, if Finalized

The following would apply to the newly deemed tobacco products:

- No sales to those younger than 18 years of age and requirements for verification by means of photographic identification
- Requirements to include health warnings on product packages and in advertisements
- Prohibition of vending machine sales unless in an adult-only facility

In addition, per the Rule, manufacturers of newly deemed tobacco products would be subject to the following requirements, among others:

- Register with, and report product and ingredient listings to, the Agency
- Market new tobacco products only after FDA review
- Not make direct and implied claims of reduced risk unless FDA confirms (1) that scientific evidence supports the claim and (2) that marketing the product will benefit public health
- Not distribute free samples

Background

The Tobacco Control Act provides FDA with the authority to regulate cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco. Section 901 of the Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Tobacco Control Act, permits FDA to issue regulations deeming other tobacco products not named in the tobacco control statute (e.g., e-cigarettes) to be subject to the FD&C Act. Section 906(d) provides FDA with the authority to propose restrictions on the sale and distribution of tobacco products, including restrictions on access to, and advertising and promotion of, tobacco products if FDA determines that such

1. Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Regulations on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products, 79 Fed. Reg. 23,142 (proposed April 25, 2014) (to be codified at 21 C.F.R. pts. 1100, 1140, 1143), available at <http://www.gpo.gov/fdsys/pkg/FR-2014-04-25/pdf/2014-09491.pdf>.

regulation would protect public health.

The Rule would extend FDA's existing authority over cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco to include e-cigarettes, cigars, pipe tobacco (including hookah [water pipe] tobacco), dissolvable tobacco products, and nicotine gels. This latter group of tobacco products, deemed by FDA to be subject to the Tobacco Control Act, was not named in such legislation.

Scope of the Rule

Broadly, the Agency has proposed the following two alternatives for the scope of the deeming provisions and, consequently, the application of the Rule:

- **Option 1** would extend the Agency's authority to all tobacco products not previously regulated by FDA that meet the statutory definition of "tobacco product,"² **except** accessories of such products
- **Option 2** would extend the Agency's authority to all tobacco products not previously regulated by FDA that meet the statutory definition of "tobacco product," **except** premium cigars³ and the accessories of products not previously regulated by FDA

FDA is seeking comment on the relative merits of Option 1 versus Option 2, based primarily on the public health consequences of adopting one option or the other.

The principal difference between the two options is the scope of cigar regulation. Under Option 1, all cigars would be covered. Under Option 2, only a subset of cigars (i.e., "everything but "premium" cigars) would be covered by the Rule.

As noted above, accessories of proposed deemed tobacco products are outside the scope of the Rule. FDA considers accessories of proposed deemed products to be those items that are **not** included as part of a finished tobacco product or items that are intended or expected to be used by consumers in the consumption of a tobacco product. For example, FDA considers accessories to be those items that may be used in the storage or personal possession of a proposed deemed product (e.g., hookah tongs, bags, cases, charcoal burners and holders, cigar foil cutters, humidors, carriers, and lighters). However, e-cigarettes, and the components thereof, and hookah pipes are covered by the Rule.

Requirements; Implications for Retailers and Manufacturers

Generally, deemed tobacco products would be subject to the same FD&C Act provisions that apply to cigarettes. These include, but are not limited to the following:

- Prohibition on selling (at a retail counter or via a vending machine) these products to persons under 18 years of age and verification by means of photographic identification related to the same
- Enforcement action against products determined to be adulterated and misbranded
- Required submission of ingredient listing and reporting of harmful and potentially harmful constituents (HPHCs) for all tobacco products
- Required registration and product listing for all tobacco products

2. Section 201(rr) of the FD&C Act (21 U.S.C. 321(rr)), as amended by the Tobacco Control Act, defines the term "tobacco product" to mean "any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product)." FDA notes in the Rule that products falling within the FD&C Act's definition of "tobacco product" may not be considered tobacco products for federal excise tax purposes. See 26 U.S.C. § 5702(c).

3. The Rule defines "premium cigars" as cigars that are wrapped in whole tobacco leaf; contain a 100% leaf tobacco binder; contain primarily long filler tobacco; are made by manually combining the wrapper, filler, and binder; have no filter, tip, or non-tobacco mouthpiece and are capped by hand; do not have a characterizing flavor other than tobacco; weigh more than 6 pounds per 1,000 units; and sell for \$10 or more per cigar.

- Prohibition against use of modified risk descriptors (e.g., “light,” “low,” and “mild” descriptors) and claims unless FDA issues an order permitting their use
- Prohibition on the distribution of free samples
- Premarket review requirements

Display of Health Warnings on Deemed Tobacco Product Packages and Advertisements

The Rule would require the following health warning on packages of cigarette tobacco, roll-your-own tobacco, and deemed tobacco products other than cigars sold, distributed, or imported for sale within the United States: “WARNING: This product contains nicotine derived from tobacco. Nicotine is an addictive chemical.” Regarding cigars, the Rule would require that any cigar sold, distributed, or imported for sale within the United States must bear one of the following warning statements on each product package:

- “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: This product contains nicotine derived from tobacco. Nicotine is an addictive chemical.”⁴

These warning statement requirements also apply to advertisements of cigarette tobacco, roll-your own tobacco, and deemed tobacco products, regardless of form, which could encompass retail or point-of-sale displays (including functional items, such as clocks or change mats), magazine and newspaper ads, pamphlets, leaflets, brochures, coupons, catalogues, posters, billboards, direct mailers, and Internet advertising (e.g., websites, banner ads, etc.).

New Requirements for Deemed Tobacco Products; Implications for E-Cigarettes and Hookahs

Significantly, the Rule would require manufacturers of deemed tobacco products to meet new additional requirements. In addition to the deemed tobacco products themselves, the scope of the Rule also includes components and parts sold separately or as parts of kits sold or distributed for consumer use or further manufacturing or included as part of a finished tobacco product. Such examples would include, but are not limited to, the following:

- Air/smoke filters
- Tubes
- Papers
- Pouches
- Flavorings used for any of the proposed deemed tobacco products (such as flavored hookah charcoals and hookah flavor enhancers)
- Cartridges for e-cigarettes (including the liquid contained therein)

The Rule would require manufacturers of deemed tobacco products that were not on the market in the United States by February 15, 2007 to only market such products after FDA premarket clearance. The review process adopts a system similar to the medical device regulatory process. Manufacturers may submit either (1) a premarket tobacco product application (PMTA) to, and receive a marketing authorization order from, FDA or (2) a substantial equivalence (SE) report if the new product is substantially equivalent to a predicate product (i.e., a

4. In 2000, in settlements with the Federal Trade Commission (FTC), the seven largest U.S. cigar manufacturers agreed to include warnings about significant adverse health risks of cigar use in their advertising and packaging. See, e.g., *In re Swisher International, Inc.*, Docket No. C-3964 (FTC Aug. 25, 2000). Under the 2000 FTC consent orders, virtually every cigar package and advertisement is required to clearly and conspicuously display one of several warnings on a rotating basis. FDA is proposing to adopt these four cigar warning statements from the FTC consent orders, which the vast majority of cigars already use.

product commercially marketed in the United States as of February 15, 2007) at least 90 days prior to introducing or delivering for introduction into interstate commerce for commercial distribution of the product.⁵

A PMTA may require one or more types of studies, including chemical analysis, nonclinical studies, and clinical studies. To demonstrate substantial equivalence, an SE notice must compare a new product to a predicate product to demonstrate that the products have the same characteristics or, if there are differences between such products, that the differences do not raise different questions of public health.

The Agency intends to continue to allow the marketing of such products pending FDA's review of either a PMTA or SE notice, presuming such application or notice is submitted within 24 months after publication of the final Rule. It is unclear whether most e-cigarette products commercially marketed in the United States could be eligible for an SE report or if they would be required to go through the PMTA process.

Although the PMTA and SE requirements do not take effect until 24 months after publication of the final Rule, we would expect manufacturers to begin, in the near term, to gather the necessary information and prepare the necessary applications/notifications to come into compliance. Those manufacturers that submit their PMTAs or SE reports early within the 24-month window presumably will receive clearance before the close of the window. Retailers should be aware of supply chain issues and possible disruptions in the marketplace because of the Rule and should work with suppliers to understand the continued availability of deemed tobacco products.

What Is Not in the Rule; No Impact on Internet Sales or Flavored Products

The Rule's prohibition on sales from vending machines is not intended to impact the sale of any tobacco product via the Internet, and the Rule does not otherwise address Internet sales. Note, however, that state laws would continue to apply to Internet sales.

Moreover, the Rule does not restrict the sale of deemed tobacco products that are flavored. FDA specifically notes in the Rule that the prohibition against the use of characterizing flavors established in the Tobacco Control Act applies to cigarettes only (i.e., it does not apply to e-cigarettes, pipe tobacco, cigars, dissolvable tobacco products, or nicotine gels). However, FDA requests comments on the characteristics or other factors it should consider in determining whether a particular tobacco product is a "cigarette" as defined in section 900(3) of the FD&C Act and, consequently, subject to the prohibition against characterizing flavors. FDA's request for comments in this area is in response to the proliferation of products marketed as "little cigars" or "cigarillos" (allegedly to get around the flavored cigarette ban), but which the Agency has indicated are truly cigarettes.

Compliance Dates

The age restrictions in the Rule would take effect 30 days after publication of the final Rule, whereas the proposed health warning requirements would take effect 24 months after publication of the same. The PMTA and SE requirements would also take effect 24 months after publication of the final Rule.

Comments on the Rule

Interested parties are encouraged to submit comments on the Rule, identified by Docket No. FDA-2014-N-0189 and/or Regulatory Information Number (RIN) 0910-AG38 by July 9, 2014.

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5. FDA states in the Rule that it is aware of new product category entrants into the market after the February 15, 2007 reference date and that the SE pathway may not be available to these newer products.

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