

BRIEF SUMMARY OF THE PROPOSED DEEMING RULE
ASSERTING FDA’S JURISDICTION OVER OTHER TOBACCO PRODUCTS, SUCH AS
CIGARS, PIPE TOBACCO AND E-CIGARETTES

The Family Smoking Prevention and Tobacco Control Act of 2009 (Tobacco Control Act or TCA) gave FDA immediate jurisdiction over cigarettes, cigarette tobacco, smokeless tobacco, and roll-your-own tobacco. It also gave FDA authority to extend its jurisdiction over “other tobacco products” by issuing a regulation “deeming” those products subject to the statute. The TCA defines “tobacco product” broadly to include products made from or derived from tobacco, including their components, parts and accessories except for products already regulated as drugs (i.e., nicotine replacement therapy products).

In April, 2011, following an unsuccessful attempt to regulate e-cigarettes as drugs,¹ FDA indicated its intent to issue a regulation deeming all “tobacco products” subject to the TCA, but it did not issue a proposed “deeming” regulation until three years later, on April 25, 2014. FDA has established a seventy-five day period for public comment, expiring July 9, 2014. There is no statutory deadline for FDA to issue a final deeming rule.

What Products Does FDA Propose to Regulate?

The principal products that would be made subject to FDA regulation by the proposed rule are cigars and e-cigarettes, but the proposed rule would also cover all other tobacco products, including pipe tobacco, hookah tobacco, dissolvable tobacco products, gels, and any future products containing or derived from tobacco.

The proposed rule contains two alternative proposals for coverage of cigars and asks for public comment on which alternative FDA should adopt. Under one option, all cigars would be made subject to FDA jurisdiction. Under the other option, cigars designated as “premium cigars” would not be made subject to FDA jurisdiction at all. FDA notes that some have suggested that, although all cigars are harmful and potentially addictive, different kinds of cigars “may have the potential for varying effects on public health,” particularly if there are differences in youth initiation and frequency of use by youth and young adults. The proposed rule defines “premium cigars” as cigars which meet all of the following criteria: (1) wrapped in tobacco leaf; (2) contains 100% leaf tobacco binder; (3) contains primarily long filler tobacco; (4) is made by combining manually the wrapper, filler, and binder; (5) has no filter, tip, or non-tobacco mouthpiece and is capped by hand; (6) has a retail price (after any discounts or coupons) of no less than \$10 per cigar (subject to inflation adjustment); (7) does not have a characterizing flavor other than tobacco; and (8) weighs more than six pounds per 1000 units.

¹ FDA first attempted to assert jurisdiction over e-cigarettes as drugs but the Court of Appeals for the District of Columbia Circuit ruled that e-cigarettes containing nicotine derived from tobacco could only be regulated as “other tobacco products” unless therapeutic claims were made for them and therefore that they could not be regulated until FDA issued a rule asserting jurisdiction over them. *Sottera, Inc. v. FDA*, 627 F.3d 891(D.C. Cir. 2010).

The proposal also seeks comments on whether some products currently marketed as “cigars” in fact meet the definition of “cigarettes” under the statute and ought to be regulated as cigarettes rather than cigars.²

The proposed rule provides FDA with the same general authority over newly-deemed tobacco products in sections 901-919 that it currently has over cigarettes, smokeless and roll-your-own tobacco products.³ It also would subject the deemed products to several additional regulations which FDA has discretion to impose on such products, including (1) requirement for a minimum age for purchase, (2) health warnings for product packages and advertisements, and (3) prohibition of vending machine sales.

Substantive Provisions that Would be Applied to Deemed Products

A. Regulations restricting sale and distribution

When FDA first (and unsuccessfully) asserted jurisdiction over tobacco in 1996, it promulgated regulations containing restrictions on the sale and distribution of cigarettes. The Tobacco Control Act directed FDA to promulgate a rule identical to the 1996 rule (with certain specified exceptions) and FDA did so. 21 CFR Part 1140. The proposed deeming rule would apply many, but not all, of these provisions, now applicable to cigarettes, to the sale and distribution of the newly-deemed products:

1. The proposed rule would prohibit retailers from selling any of the deemed products to persons younger than 18 and would require age verification. 21 CFR 1140.14(a)-(c)
2. The proposed rule would prohibit the sale of deemed products through vending machines except in facilities restricted to persons 18 and older. 21 CFR 1140.16
3. The distribution of free samples of deemed products would be prohibited. 21 CFR 1140.16(d)

² The proposed rule notes that the TCA prohibits the use of characterizing flavors (other than menthol) in cigarettes but not other tobacco products and seeks comments on the extension of this prohibition to the newly- deemed products. If some or all little cigars were regulated as cigarettes, the prohibition on characterizing flavors would immediately apply to them.

³ FDA describes those provisions that apply “automatically” as the following: (1) enforcement action against products determined to be adulterated and misbranded; (2) required submission of ingredient listing and reporting of harmful and potentially harmful constituents; (3) required registration and product listing for all tobacco products; (4) prohibition of modified risk descriptors and claims unless FDA issues an order permitting their use; (5) prohibition on the distribution of free samples (as with cigarettes); and (6) premarket review requirements for new products. 79 Fed. Reg. 23143.

There are several provisions of the rule governing sales and distribution applicable to cigarettes and smokeless tobacco products that the deeming rule would *not* apply to the deemed products. These include:

1. Provisions barring self-service displays. (21 CFR 1140.16(c))
2. Provisions requiring manufacturers, distributors, or retailers intending to disseminate certain advertising or labeling to notify FDA 30 days prior to dissemination and describe the extent to which the advertising may be seen by persons younger than 18. (21 CFR 1140.30)
3. Provisions requiring minimum pack sizes. (21 CFR 1140.14(d))
4. Provisions prohibiting the distribution of any non-tobacco merchandise containing the name or logo of a cigarette or smokeless tobacco product. (21 CFR 1140.34(a))
5. Provisions prohibiting manufacturers, distributors or retailers of cigarettes or smokeless tobacco products from sponsoring athletic or musical events or teams using a brand name of a cigarette or smokeless tobacco product. (21 CFR 1140.34(c))

B. Warning Labels

1. The proposed rule would require newly-deemed products other than cigars to carry the following warning label covering at least 30 percent of each principal display panel on product packaging: “This product contains nicotine derived from tobacco. Nicotine is an addictive chemical.” In addition, advertisements for these products would have to carry the warning placed in the upper portion of the advertisement and large enough to occupy at least 20 percent of the area of the advertisement. These are the same sizes required for smokeless products.
2. The proposed rule would require packages and advertisements for deemed cigars to have warning labels occupying the same area and bearing one of the following five warnings:
 - (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.

- (v) WARNING: This product contains nicotine derived from tobacco. Nicotine is an addictive chemical.

For cigars sold individually and not in a product package, no warning needs to be placed on the products. Instead, the warning statements must be posted at the retailer's point-of-sale.

C. Application of other provisions of the Tobacco Control Act

1. Adulteration and Misbranding – Sections 902 and 903

The Tobacco Control Act amended the Food, Drug and Cosmetic Act to make the provisions of the Act defining adulteration and misbranding applicable to cigarettes and smokeless tobacco products. The proposed deeming rule would apply these standards to other tobacco products to the extent they are covered.

2. Ingredient and constituent listing – Section 904

The provisions of Section 904 would become applicable to deemed tobacco products to the same extent they apply to cigarettes and smokeless tobacco. Section 904 requires manufacturers of cigarettes and smokeless tobacco products to provide FDA with information, on a brand-by-brand basis, on all ingredients, including a description of the content, delivery and form of nicotine, in their products, and requires provision of information on all constituents identified by the Secretary as harmful and potentially harmful in such products, information FDA is directed to publish in a manner that is not confusing or misleading to consumers. This section also gives FDA comprehensive authority to require provision of virtually all information in the possession or control of the manufacturer regarding its products, including marketing and consumer acceptance studies.

3. Registration and product listing – Section 905

The provisions of Section 905 would become applicable to other tobacco products to the same extent they apply to cigarettes and smokeless tobacco. Section 905 requires manufacturers to register with FDA, identify their products, and permit inspections of their facilities.

4. Good manufacturing practices – Section 906 (e)

The provisions of Section 906, authorizing FDA to establish good manufacturing practices, would be applied to the manufacture of other tobacco products.

5. New tobacco products – Sections 905/910

FDA proposes to apply the provisions of the Tobacco Control Act regarding the introduction of new products to the newly-deemed tobacco products, but to do so in a significantly different manner from that applied to cigarettes and smokeless tobacco.

a. Provisions of the Tobacco Control Act regarding new products

Under the Tobacco Control Act, any product not commercially marketed on or before February 15, 2007 is defined as a “new tobacco product.” Any modification of the product after February 15, 2007 also makes the product a “new tobacco product.” No new tobacco product may be marketed until a manufacturer has filed an application with FDA and FDA has issued a marketing order for that product.

There are two primary paths to market for a new tobacco product. First, manufacturers can file a “new product” application under Section 910, in which they must demonstrate that the marketing of the product would be “appropriate for the protection of the public health.” The requirements for such a showing are stringent. Second, manufacturers can avoid having to meet this public health standard by filing a “substantial equivalence” application, in which they must show that the new product is “substantially equivalent” to a product marketed on or before February 15, 2007. Under the TCA, manufacturers filing substantial equivalence applications by March 22, 2011 could keep their products on the market while their applications are pending. Manufacturers who filed a substantial equivalence application after March 22, 2011 cannot introduce the product until FDA issues a marketing order. See note at the bottom of the page for experience to date with new product and substantial equivalence applications under the TCA.*

b. Provisions of the proposed deeming rule with regard to newly-deemed products

The proposed deeming rule proposes to apply the new product provisions of the statute to the newly-deemed products. However, if the provisions of the Act were applied literally to deemed products that were not commercially marketed on February 15, 2007, none of them could remain on the market because no new product or substantial equivalence applications for such products were submitted by March 22, 2011.

FDA proposes to permit manufacturers of newly-deemed tobacco products to keep their current products on the market, as well as to introduce new products without FDA marketing orders provided that the manufacturer files a new product application or a substantial equivalence application for that product within two years of the date the proposed rule is finalized.⁴ Thus, if FDA issues a final rule on May 1, 2015, manufacturers would be free to keep current new products on the market and introduce additional new products into the market until at least May 1, 2017, provided that they file an application by that date. In addition, such

* No manufacturer has yet filed a new product application. In contrast, manufacturers submitted approximately 3,100 substantial equivalence applications by the March, 2011 deadline. The only decision FDA has rendered to date on these application was to reject one set of applications. Despite the fact that none of the remaining 3,100 products has been found to meet the statutory standard, all of those products remain on the market to this day. FDA has given no indication as to its schedule for reviewing these applications.

⁴ The Tobacco Control Act also provides for an exemption from the substantial equivalence requirements, but such exemptions are available only in a narrow range of circumstances and no exemption has yet been granted.

products would stay on the market unless and until FDA denied such an application. The result is that products for which applications are filed pursuant to this procedure are likely to stay on the market for years before FDA completes its review.

It is reasonable to expect that many substantial equivalence applications will be filed for cigars as well as for e-cigarettes. Numerous brands of cigars have long been on the market and there may well be relevant predicate products. It is uncertain how e-cigarettes would qualify for treatment under the substantial equivalence pathway and many such products may be the subject of new product applications.

6. Modified risk tobacco products – Section 911

Under the proposed rule, newly-deemed tobacco products covered by the rule will be subject to the provisions of section 911 regarding modified risk tobacco products. Under section 911, a manufacturer may not make a claim that a tobacco product presents a lower risk of harm than other tobacco products unless FDA has first determined that such a claim would be appropriate for the protection of the public health. Manufacturers of some e-cigarettes seeking to make such claims may file applications under this section.

7. Product standards and flavorings – Section 907

Section 907 gives the FDA the authority to issue product standards governing what is put into a cigarette; smokeless tobacco products and roll-your-own cigarettes and the emissions from those products. When a final deeming rule is promulgated, FDA will have the same authority to issue product standards applicable to the newly-deemed tobacco products, including flavorings. Thus, while FDA has the statutory authority to issue a product standard prohibiting flavorings in the newly-deemed products that make them very appealing to young people, the proposed rule does not prohibit flavorings in any deemed tobacco products. Section 907 already prohibits characterizing flavors other than menthol in cigarettes.

8. Advertising and Marketing

The FDA has specific rules restricting the advertising and marketing of cigarettes and smokeless tobacco products (Section 102) and the authority to further restrict the advertising and marketing of these products to protect the public health to the full extent permitted by the First Amendment (section 906(d)). When a final deeming rule is promulgated, FDA will have the authority over the advertising and marketing of newly-deemed products, but FDA did not exercise that authority in the proposed regulation. Therefore, the proposed rule does not address the advertising and marketing of cigars or e-cigarettes.

D. Other significant issues

The proposed rule does not address the problem that liquid nicotine is currently being sold in both retail outlets and over the internet in uncontrolled quantities with packaging that doesn't contain childproof lids.