The FDA Takes Small Steps to Expand Tobacco Regulation

The Family Smoking Prevention Tobacco Control Act grants the U.S. Food and Drug Administration the authority to regulate all tobacco products.[1] However, the Tobacco Control Act only required the FDA to regulate cigarettes, cigarette tobacco, smokeless tobacco, and roll your own tobacco. [2] In order to regulate all other products, the agency must first issue a rule that "deems" those products to be within FDA authority.

Almost five years after Congress authorized action, the FDA finally issued a proposed Deeming Regulation that will eventually bring all tobacco products under its authority. This factsheet will explain what products the FDA will be regulating and how those products will be regulated.

Although the FDA has taken an important step to regulate new and novel tobacco products, it has not acted as boldly as it could have, and its efforts fall short of those of many state and local governments. Regardless of FDA action to regulate all tobacco products, state and local governments still have broad authority to regulate these products. The FDA proposal will complement – not replace – local action.

What products will the FDA begin regulating?

The Deeming Regulation will allow the FDA to begin regulating any product that is "made or derived from tobacco that is intended for human consumption." [3] This includes cigars, e-cigarettes, hookah, pipe tobacco, dissolvable tobacco products and any other product containing tobacco, or nicotine derived from tobacco. Unfortunately, this definition prohibits the FDA from regulating products that do not contain nicotine. Some e-cigarette liquid is labeled nicotine-free, and, therefore, might be outside the reach of the FDA. However, if the liquid does contain nicotine, and claims not to, it will be subject to FDA enforcement action as a "misbranded tobacco product," because the FDA now regulates the labeling of all tobacco products.

The FDA's proposal also includes two options for regulating cigars. Option 1 would allow the FDA to regulate all cigars, while Option 2 would exempt premium cigars that are wrapped in whole tobacco leaf, are not filtered, are manually constructed, contain no characterizing flavor other than tobacco, and meet minimum price and weight requirements.

How will tobacco product parts and accessories be regulated?

The Tobacco Control Act definition of tobacco products includes any component, part, or accessory. However, the proposed deeming regulation would treat the newly-covered tobacco

products differently, specifically excluding "any component or part that does not contain tobacco or nicotine." The FDA's decision to exclude all accessories as well as most components or parts could leave significant gaps in the federal restrictions for the newly-covered products, especially e-cigarettes. For example, as proposed, there would be no minimum age for purchase of the actual electronic cigarette device if it is not sold with liquid nicotine.

Will the FDA restrict or prohibit advertising of e-cigarettes?

While the advertising of cigarettes and smokeless tobacco on television and radio was prohibited in 1971[4] and 1986[5] respectively, there are no restrictions on the advertising of e-cigarettes. The FDA has broad authority to restrict the advertising and marketing of all tobacco products.[6] However, the proposed Deeming Regulation would not limit the advertising and marketing of e-cigarettes or other newly-covered tobacco products. The FDA retains the authority to restrict advertising and marketing in the future but the proposal does not include any such restrictions.

Will flavored tobacco products be prohibited?

The Tobacco Control Act prohibits characterizing flavors in cigarettes, with the exception of menthol and tobacco, but the FDA proposal would not extend that provision to any other products. All other tobacco products, including e-cigarettes and little cigars, known for their use of youth-attractive flavors, can continue to be sold with any fruit or candy flavor. The FDA can prohibit flavors in the future but it has not proposed to do so at this time.

Will newly-covered products be subject to premarket review by the FDA?

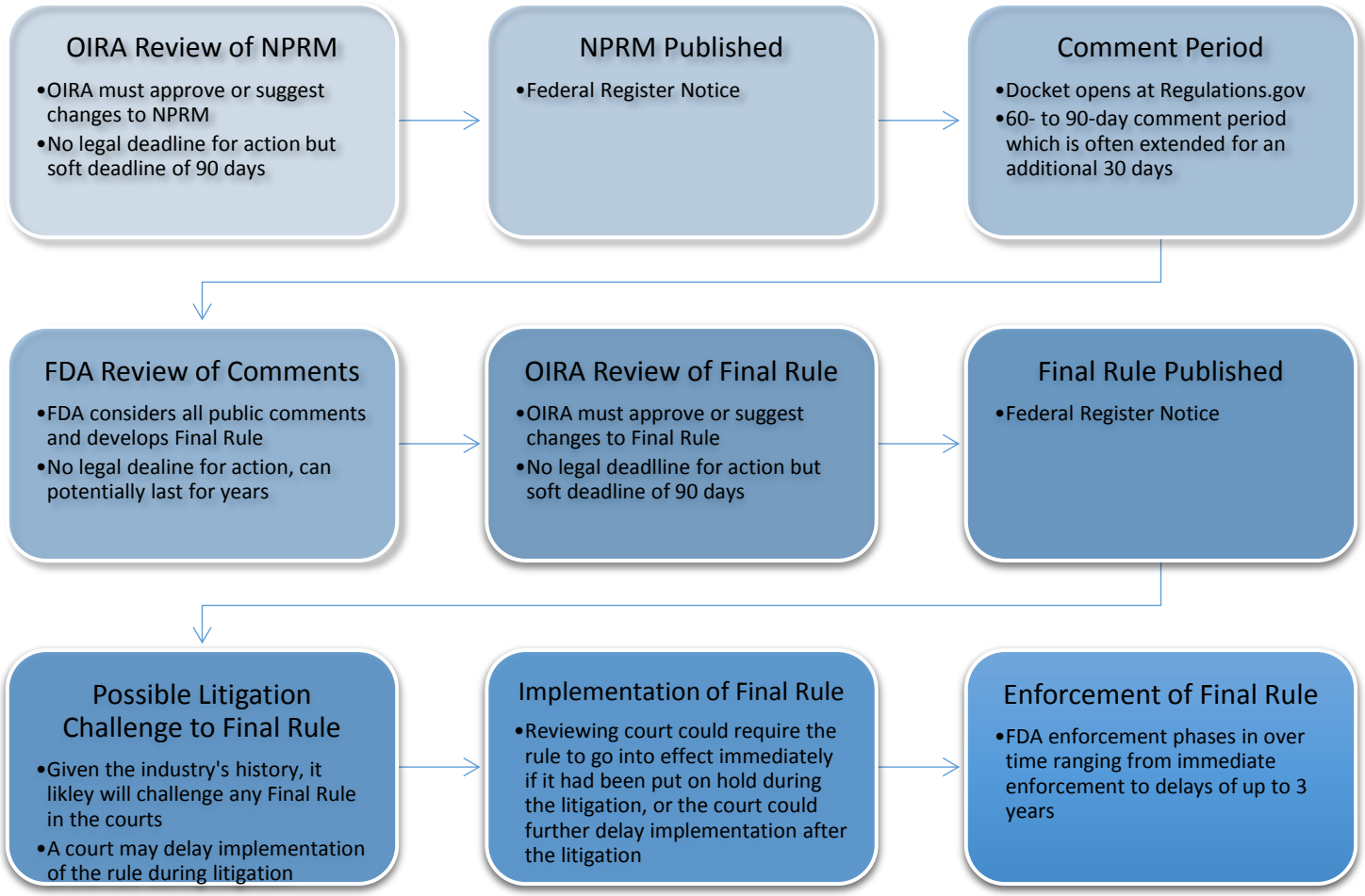
Premarket review will be mandatory; however, the FDA proposal would delay the enforcement of this requirement until twenty-four months after the rule would take effect. During that time period, manufacturers would be free to market new products so long as they submit an application to the FDA. After that time period ends, manufacturers could continue to market those products until the FDA issues an order prohibiting the marketing. A similar loophole was established during the passage of the Act to apply to cigarettes and smokeless products. The FDA received 3,517 applications but three years later has only issued an order removing 11 products from the market. After the withdrawal of 155 applications, the tobacco companies are still able to market the unapproved products represented by the 3,351 outstanding applications. See the Consortium's factsheet, A Dangerous Loophole in the Process for FDA Approval of New Tobacco Products, for more information on the FDA's authority and actions related to premarket review.

When will the Deeming Regulation take effect?

By the time the comment period for the Deeming Regulation ended on August 8, 2014, the FDA received over 80,000 comments from public health professionals, the tobacco industry, and consumers. The FDA must now review all of the comments before developing a final rule, a process which may take many months. Once that review is complete, there are several more steps remaining in the FDA's rulemaking process before the Deeming Regulation is fully

implemented and enforced. The chart below provides an outline of the FDA's rulemaking process.

The FDA Rulemaking Process

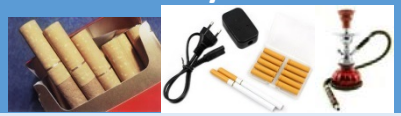


What other restrictions apply to each product and when will the restrictions take effect?

While many of the requirements in the Tobacco Control Act will apply to newly-covered products, some will not. In addition to the "automatic" requirements, the FDA has specifically extended some existing restrictions to the newly-covered products. However, some of these requirements won't go into effect immediately, as the FDA has established drawn-out implementation periods.

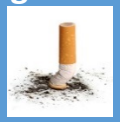
Table 1 lists some of the provisions in the Act that will apply to all products, and it identifies their extended implementation periods. Table 2 lists some of the provisions in the Act that will, and will not, apply to newly-covered products.

Table 1
Timeline for Implementation of Automatic Statutory Requirements

	E-Cigarettes and Other Newly-covered Tobacco Products 
Regulation of adulterated products	Immediate upon effective date of the Final Rule
Required disclosure of manufacturer information and statement of weight, measure or numerical count of contents	24 months after the issuance of the Final Rule
Prohibition on false or misleading advertising	Immediate upon effective date of Final Rule
Required disclosure of ingredients, substances, compounds and additives	6 months after the effective date of the Final Rule
Required disclosure of harmful and potentially harmful constituents	36 months after the effective date of the Final Rule
Required disclosure of health-related documents	6 months after the effective date of the Final Rule
Required registration of manufacturers	By the end of the calendar year in which the Final Rule is issued (if issued in the second half of the year, FDA will designate a date)
Required disclosure of product lists	Upon submission of new product applications
Prohibition of the use of “light,” “mild,” “low,” or similar descriptors	12 months after the effective date of the Final Rule

All of these requirements currently apply to cigarettes, cigarette tobacco, smokeless tobacco and roll-your-own tobacco.

Table 2
FDA Discretionary Regulation

	Cigarettes 	Smokeless Tobacco 	Cigars 	E-Cigarettes and Other Newly-covered Products 
Minimum age of 18 for purchase and age verification under 27	☑	☑	☑	☑
Prohibition on vending machine sales	Allowed in adults-only facilities	Allowed in adults-only facilities	Allowed in adults-only facilities	Allowed in adults-only facilities
Prohibition on self-service displays	Allowed in adults-only facilities	Allowed in adults-only facilities	☐	☐
Minimum package size requirements	☑	☐	☐	☐
Prohibition on breaking packages by retailers (e.g., sales of loosies)	☑	☑	☐	☐
Prohibition on free samples	☑	Allowed in adults-only facilities	☑	☑
Prohibition on characterizing flavors	Menthol and tobacco allowed	☐	☐	☐
Mandatory warning labels on packages and advertisements	9 Rotating warnings	4 Rotating warnings	5 Rotating warnings	1 Static warning
Prohibition on brand names on non-tobacco products and brand name sponsorship of sporting and cultural events	☑	☑	☐	☐
Required notice of advertising in any non-traditional medium	☑	☑	☐	☐

Other Resources

For additional information on the Deeming Regulation, the Consortium has created a factsheet that provides general information about the FDA's action, A Deeming Regulation: What is Possible Under the Law. The Consortium has also created two short videos that provide additional information on how the Deeming Regulation can work: Why Should I Care about a Deeming Regulation? and A Deeming Regulation: Expanding FDA Regulation of Tobacco Products.

For more information on the FDA's regulation of tobacco products, visit our FDA Tobacco Action Center. For public health advocates and professionals interested in regulating tobacco products at the state and local level, the Consortium has several publications that discuss the policy options for regulating e-cigarettes and other tobacco products.

Last updated: October 2014

Notes

[1] Family Smoking Prevention and Tobacco Control Act § 101(a), Pub. L. No. 111-31, 123 Stat. 1783 (2009) (codified at 21 U.S.C. § 321(rr)(1)) [hereinafter Tobacco Control Act].
[2] Tobacco Control Act, §901(b), 123 Stat. at 1786 (codified at 21 U.S.C. § 387a(b)).
[3] Tobacco Control Act, §101(a), 123 Stat. at 1783 (codified at 21 U.S.C. § 321(rr)(1)).
[4] 15 U.S.C. § 1335.
[5] 15 U.S.C. § 4402(c).
[6] Tobacco Control Act, § 906(d), 123 Stat. at 1796 (codified at 21 U.S.C. § 387f(d)).