EXTENSIONS & AN EPIDEMIC

The FDA's Gatekeeping Authority for E-Cigarettes

The premarket review process for commercial tobacco products determines whether or not a particular tobacco product can be legally sold in the U.S. The manner in which the process is implemented has a major impact on public health in communities across the country.

Premarket review is one of the U.S. Food and Drug Administration's most powerful regulatory tools, as it makes the agency the gatekeeper of the tobacco product marketplace.

While the focus of this factsheet is premarket review under the 2016 deeming regulation, the FDA's premarket review process for tobacco products has been rife with problems since the FDA began regulating these products in 2009. For a more detailed examination of the premarket review process and information on the problems associated with the process, see *The FDA's Premarket Review of Tobacco Products Fails to Fully Protect Public Health* and *FDA's Misplaced Priorities: Premarket Review Under the Family Smoking Prevention and Tobacco Control Act*.

The Purpose of Premarket Review of Tobacco Products

It is important to remember that tobacco products are fundamentally different from all other FDA-regulated products because commercial tobacco products have no beneficial uses. The FDA's overarching mission in its regulation of all products is to minimize harms and maximize benefits. Until 2009, the FDA had only ever had premarket review authority over products that have intended benefits. For these non-tobacco products, the agency's role is to strike a balance between protecting the public from unnecessary harm but also ensuring continued access to new beneficial products. In this context, the FDA's mission and that of the regulated industry often overlap.

In tobacco regulation, the FDA's mission of protecting consumers from unnecessary harm and the industry's goal of introducing new products that are harmful are entirely at odds. Thus, the agency's relationship with the regulated industry should be different from its relationship with manufacturers of products with beneficial or therapeutic uses. In tobacco regulation, ensuring the continued availability of dangerous commercial tobacco products and enabling the introduction of new harmful products is inconsistent with the FDA's greater mission and its statutory mandate to regulate tobacco products. The agency's role should be to stringently enforce premarket review to ensure that products comply with the statutory requirements and that new products do not create greater public health harms. Despite complaints from

manufacturers, any delay of the introduction of new harmful products as a result of federal oversight serves the public's interest.

There are three separate processes, or marketing application pathways, by which tobacco products can be introduced into the marketplace. The following chart explains the premarket review process.

Premarket Review Process Overview

A tobacco product manufacturer gathers and submits scientific data to establish that the marketing of a new tobacco product meets the statutory standards of one of three marketing application pathways: Premarket Tobacco Product Application (**PMTA**), Substantial Equivalence (**SE**), or Substantial Equivalence Exemption (**SE Exemption**).

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The FDA's scientific experts evaluate the merits of the data to determine if the manufacturer has provided sufficient evidence to meet the statutory standard for the identified marketing pathway.

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The FDA issues a marketing order allowing the product to be introduced to the market and sold indefinitely as long as the product meets future product and manufacturing standards established by the agency or circumstances change that cause the FDA to reevaluate the marketing of the product.

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The FDA denies the marketing application and the product cannot be introduced to the market. Manufacturers are free to resubmit the application with additional information.

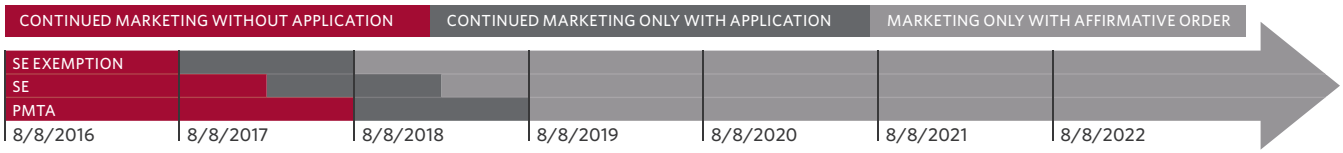
Premarket Review Under the Deeming Rule

When the Tobacco Control Act became law in 2009, the FDA's premarket review authority was limited to cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco. On May 10, 2016, the FDA issued the final deeming rule, extending the agency's jurisdiction over all existing and future products made or derived from tobacco. Premarket review of e-cigarettes, cigars, hookah, and other commercial tobacco products provides one of the most significant opportunities for FDA regulation to benefit public health.

2016 Final Deeming Rule

The final deeming rule went into effect on August 8, 2016. After that date, new products subject to the rule are no longer allowed to be marketed without first receiving authorization from the FDA. For newly covered products that were already on the market on August 8, 2016, the FDA established three deadlines for manufacturers to submit marketing applications based on the application pathway chosen by the manufacturer: August 8, 2018 for PMTAs, February 8, 2018 for SE, and August 8, 2017 for SE Exemption. This staggering of deadlines can be seen on the timeline below. If a manufacturer met the application deadline, a product would have been allowed to stay on the market for an additional 12 months without receiving a marketing order. At the end of that 12-month grace period, products that had not yet received a marketing order from the FDA would have been removed from the market entirely. The FDA stated that it would have examined extending that grace period on a case-by-case basis but the potential for removal from the market would almost certainly have incentivized the submission of complete and accurate applications as soon as manufacturers could have submitted them. In May 2017, the FDA delayed all of the application deadlines by three months, which public health advocates perceived as unnecessary and harmful, but still a functional timeline to regulate this previously unregulated portion of the commercial tobacco market.

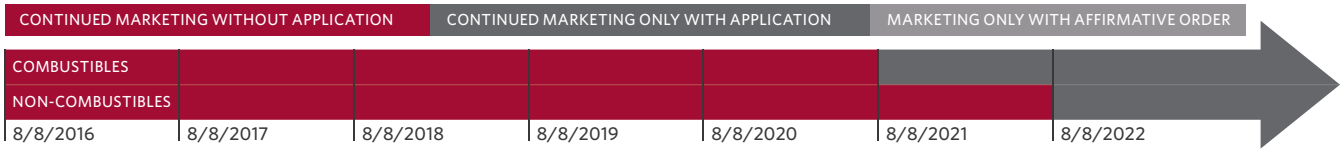
2016 Final Deeming Rule



2017 Regulatory Plan

Unfortunately, the timeline above was thrown out on July 28, 2017, when FDA Commissioner Dr. Scott Gottlieb announced a new regulatory plan for the agency's Center for Tobacco Products. While the new regulatory plan continues to prohibit new products from entering the market without an affirmative marketing order after August 8, 2016, other changes to the policy significantly weaken premarket review for newly deemed products. As seen below, the application deadlines for products already on the market were extended to August 8, 2021,

2017 Regulatory Plan



for combustible products like cigars, and August 8, 2022, for non-combustible products like e-cigarettes. These extensions allow products to remain on the market significantly longer without even filing a marketing application. This can be seen by comparing the two timelines. Perhaps most importantly, this new policy abandons the possibility of eventually removing products from the market that have not yet received a marketing order. Instead of removing products after 12 months from the application deadline, products are allowed to remain on the market indefinitely unless the FDA orders their removal. If the FDA treats these products like past products allowed to enter the market without an affirmative marketing order, these products might remain on the market for many years after the application deadlines in 2021 and 2022. The timeline shows that this new plan never reaches a phase where only products with a marketing order remain on the market. In addition, the FDA is currently defending regulatory and enforcement actions against several tobacco industry lawsuits that could potentially further weaken the implementation of premarket review.

Since Congress granted the FDA authority over tobacco products in 2009, many public health advocates have been bewildered and frustrated by the slow pace of federal rulemaking. There are many reasons for this, including the tobacco industry's relentless efforts to delay and undermine effective regulation. Because premarket review is a powerful tool that the FDA can employ without going through the cumbersome rulemaking process, it is critical that the agency act now to prevent potentially harmful tobacco products from remaining in the marketplace indefinitely.

For additional information on the FDA's premarket review of tobacco products and deeming rule implementation, visit the Public Health Law Center's FDA Tobacco Action Center.

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