EXTENSION & AN E-CIGARETTE EPIDEMIC

The FDA's Gatekeeping Authority for E-Cigarettes

The premarket review process for commercial tobacco products determines whether 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 FDA'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

The FDA's overarching mission in its regulation of all products is to minimize harms and maximize benefits. Until 2009, when the FDA acquired regulatory authority over tobacco products, its premarket review authority was limited to products that have intended benefits. For example, prescription drugs and devices that help alleviate certain diseases or symptoms required the agency to strike a balance between protecting the public from unnecessary harm and ensuring continued access to new beneficial products. In this context, the FDA's mission and that of the regulated industry often overlap — both the FDA and the industry have a goal of ensuring that a product's benefits to the public outweigh its harms.

Regarding commercial tobacco products, however, the FDA's role is fundamentally different from all other FDA-regulated products, because commercial tobacco products have no beneficial use. In tobacco regulation, the FDA's mission of protecting consumers from unnecessary harm and the industry's goal of introducing new tobacco products are entirely at

odds. Thus, the agency's relationship with the tobacco industry should be different from its relationship with manufacturers of products with beneficial or therapeutic uses. The FDA has no interest in ensuring the continued availability of dangerous commercial tobacco products, and in fact, enabling the introduction of new harmful products is entirely inconsistent with the FDA's greater mandate to ensure that new products with greater public health harms never reach the market. The agency's role should be to stringently enforce premarket review to ensure that products comply with the statutory requirements. Despite complaints from manufacturers, any delay of the introduction of new, harmful products as a result of federal oversight protects public health.

The Three Premarket Review Pathways

There are three separate processes, or marketing application pathways, by which tobacco products can be introduced into the marketplace: Premarket Tobacco Product Application (**PMTA**), Substantial Equivalence (**SE**), or Substantial Equivalence Exemption (**SE Exemption**). The following chart explains the premarket review process that applies to each of these pathways.

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 (**PMTA**, **SE**, or **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.

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.

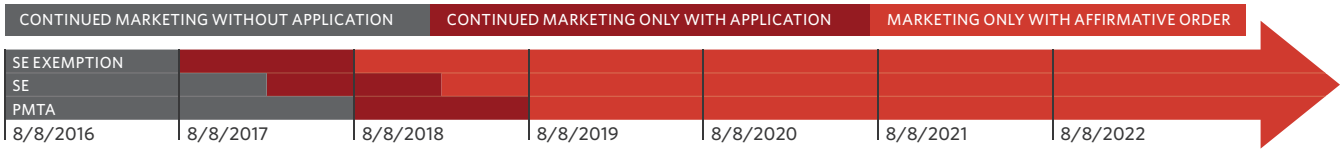
Premarket Review Under the Deeming Rule

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," which extended the agency's jurisdiction over all existing and future products made or derived from tobacco. Notably, this new authority included e-cigarettes, cigars, and waterpipe tobacco. Premarket review of these commercial tobacco products provides one of the most significant opportunities for FDA regulation to benefit public health.

The Final Deeming Rule

The final deeming rule went into effect on August 8, 2016. After that date, new products subject to the rule were no longer allowed to be marketed without first receiving authorization from the FDA. For newly deemed 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 is illustrated on the timeline below. Furthermore, 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. Though extension of the deadlines on a case-by-case basis was possible under the rule, the potential removal from the market would almost certainly have incentivized manufacturers to timely submit complete and accurate applications. While FDA did ultimately delay all application deadlines by three months, it was nonetheless a timeline that likely would have resulted in effective regulation of this previously unregulated portion of the commercial tobacco market.

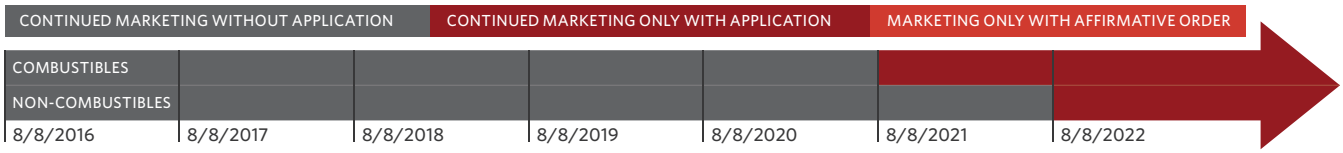
2016 Final Deeming Rule



The FDA's 2017 Regulatory Plan

On July 28, 2017, FDA Commissioner Scott Gottlieb announced a new regulatory plan for the agency's Center for Tobacco Products. That new regulatory plan continued to prohibit new products from entering the market without an affirmative marketing order after August 8, 2016, but it significantly weakened premarket review for newly deemed products. As seen in the graphic below, the application deadline for products already on the market was extended to August 8, 2021, for combustible products like cigars, and August 8, 2022, for non-combustible products like e-cigarettes. These extensions allowed products to remain on the market significantly longer without requiring manufacturers to file a marketing application. Perhaps most importantly, this new policy abandoned the possibility of eventually removing products from the market that had not yet received a marketing order, instead allowing them to remain on the market indefinitely.

2017 Regulatory Plan



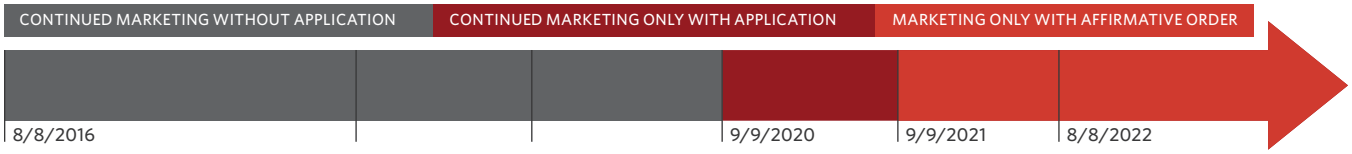
Court-Imposed Deadlines

Given the concerning implications of the revised deadlines in the 2017 regulatory plan, several public health groups and physician sued the FDA in U.S. District Court for the District of Maryland in 2018. The groups argued that the new revised timeline was beyond the scope of the FDA's authority under the Tobacco Control Act, and therefore unlawful.

On May 15, 2019, U.S. District Judge Paul Grimm ruled in favor of the public health groups, finding that the FDA had abdicated its statutory responsibilities under the Tobacco Control Act by failing to ensure that new tobacco products underwent the statutorily mandated premarket review process. On July 12, 2019, Judge Grimm issued an order requiring that new products on the market as of August 8, 2016, file marketing applications by May 12, 2020. The order further provides that products for which marketing applications have been filed by that date may remain on the market for an additional one-year period. Those products for which marketing applications have not been received by the May 12, 2020, deadline would be subject to FDA enforcement action under the order. As of January 2020, the FDA had planned to comply with the May 12, 2020, deadlines, having issued its own guidance that imposed the same deadlines for submitting applications as those outlined by the court.

Of course, in March 2020, priorities and resources all over the world shifted in the face of the global COVID-19 pandemic. On March 30, 2020, the FDA filed a request for a 120-day extension of the May deadline set by Judge Grimm's order. The public health plaintiffs expressed their concern with the extension, given that it will result in products remaining on the market for several more months. However, considering the extraordinary circumstances posed by the pandemic, they did not oppose the FDA's request. Therefore, the deadline to submit applications is now September 9, 2020. The graphic below reflects the new timeline. The case went up on appeal to the Fourth Circuit Court of Appeals, which upheld Judge Grimm's in a decision issued on May 4, 2020.

2019 Ruling (with 2020 extension)



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. Litigation initiated by public health groups has been immensely important to the continued forward progress of improving the premarket review process for new tobacco products. Premarket review is one of the most powerful tools at the FDA's disposal, giving it the power to ensure that potentially harmful tobacco products are removed from the marketplace. Of course, the application deadlines are only as effective as the agency is in enforcing them. Although the COVID-19 pandemic has resulted in additional extensions, the deadline to submit applications is still on the horizon. Once those applications are submitted, it is incumbent upon federal regulators to (1) vigorously execute their enforcement authority and remove unlawfully marketed products from the market; and (2) ensure that public health remains the guidepost in issuing marketing orders for new products.

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

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