The FDA's New Catch-22

The federal agency threatens early enforcement against new tobacco products as it stalls on long-awaited guidance.

>BY BRYAN M. HAYNES

The U.S. Food and Drug Administration (FDA) is threatening to step up enforcement of premarket review requirements for "new tobacco products." At the same time, the Agency is stalling on long-awaited regulations and guidance establishing the boundaries for industry submissions. This untenable situation leaves manufacturers and importers in a regulatory Catch-22, as they apparently are expected to expedite their premarket review submissions but without clear guidance from the FDA.

By way of background, the Family Smoking Prevention and Tobacco Control Act (the law giving the FDA authority over tobacco products), establishes premarket review requirements for "new tobacco products," which are products that were introduced or changed after February 15, 2007. Manufacturers seeking to sell "new tobacco products" must first obtain marketing authorization from the FDA. Manufacturers can obtain marketing authorization by: (1) showing that the sale of the product "is appropriate for the protection of public health" through a premarket tobacco application ("PMTA"), (2) showing that the product does not "raise different questions of public health" through a substantial equivalence ("SE") application, or (3) showing that the product involves a minor modification to a lawfully-marketed product through an exemption from substantial equivalence ("EXSE") application.

When FDA asserted jurisdiction over "deemed" tobacco products—electronic nicotine delivery systems ("ENDS"), pipe tobacco, cigars, and all other products made or derived from tobacco and intended for human consumption) in 2016, it recognized that newly-regulated companies would need some time to prepare premarket submissions for new products. This made sense because many of the newly-deemed tobacco products were also "new tobacco products." This is particularly true for ENDS, which were not widely sold in 2007.

The FDA also seemingly recognized that manufacturers of deemed products would need adequate guidance for their premarket review submissions. When the FDA issued the deeming regulations in 2016, it offered only a draft guidance for PMTAs for ENDS and supplied no guidance for other deemed products. Accordingly, the FDA established extended deadlines for premarket review submissions—until August 2017 for EXSE submissions, June 2019 for SE submissions, and August 2018 for PMTAs. In May 2017, the FDA extended these deadlines by three months.

A few months later, in August 2017, the FDA announced a significant extension of the premarket review deadlines for deemed tobacco products. Manufacturers of combustible products (like cigars) would have until August 2021 to make premarket review submissions and manufacturers of non-combustible products would have until August 2022. The FDA acknowledged that the additional compliance period was necessary for manufacturers to submit more thorough applications based on regulations and guidance to be issued by the Agency. The FDA stated that, during the compliance period, "the agency plans to issue regulations governing the information to be included in premarket applications, to develop standards that certain products must meet, and to publish additional guidance explaining what applications should contain and how they will be reviewed."

As of this writing, the FDA has done none of this. The only guidance or regulation specifically applicable to deemed tobacco products is the May 2016 draft guidance on PMTAs for ENDS. The FDA has recently published for notice and comment a proposed regulation on SE submissions. However, the proposed regulation offers scant guidance for suppliers of deemed tobacco products. For instance, the proposed regulation discusses testing for harmful and potentially harmful constituents ("HPHCs") to facilitate a review of whether new products raise "different questions of public health" versus grandfathered products. However, the FDA fails to

acknowledge that there is no consensus as to how HPHCs should be measured for deemed products, including premium cigars and hookah tobacco. Indeed, this lack of consensus prompted the FDA to recently defer the deadline for HPHC testing and reporting. How is industry supposed to report HPHCs in SE submissions when the FDA has not identified how the products should be tested?

In the meantime, the FDA recently indicated that it intends to significantly modify the premarket review deadlines for certain products. In March 2019, the FDA issued a draft guidance, entitled "Modifications to Compliance Policy for Certain Deemed Tobacco Products." Citing concerns regarding youth access to certain products, the FDA proposed to eliminate the compliance policy for flavored cigars. In other words, any non-grandfathered flavored cigar would be subject to immediate enforcement action unless it obtains FDA marketing authorization. Flavored ENDS (other than tobacco, mint, and menthol) would be subject to enforcement action unless the manufacturer submits a PMTA by August 8, 2021 (effectively moving the compliance date forward a year) and subject to immediate enforcement action unless sold in adult-only locations. As of this writing, the modified compliance policy remains only a draft, but it is reasonable to assume that it could be finalized by the summer of 2019.

In making these proposed modifications to the compliance policy, the FDA did not address the recognized need to provide more detailed guidance to applicants. It has been nearly two years since the FDA acknowledged that manufacturers of deemed products need more information to prepare applications. Yet, without having provided any additional information, the agency now apparently expects manufacturers of flavored cigars to immediately submit SE applications. Manufacturers of flavored ENDS (other than tobacco, mint, and menthol) are expected to submit PMTAs in two years or less, yet the FDA still has not finalized its draft guidance for these submissions. This places industry in the untenable position of having to rapidly prepare submissions while making educated guesses about the FDA's expectations for their contents.

Complicating matters further, a federal judge in Maryland has recently ruled that the FDA acted unlawfully when it extended the compliance deadlines in August 2017. The implications of this ruling are unclear at this time, as the court has ordered the parties to submit briefing on the appropriate remedy and the FDA may appeal. But the ruling could further shorten the timelines for manufacturers to file premarket submissions.

One thing is clear—the landscape for premarket review of deemed products is evolving rapidly. Stay tuned for updates (including from our blog—tobacccolawblog.com) as the FDA considers finalizing the modified compliance policy and the industry anxiously awaits more detailed guidance for submissions. S

Troutman Sanders Tobacco Team, Troutman Sanders LLP, *1001 Haxall Point, Richmond, Va. 23219, Tel: (804) 697-1420, Fax: (804) 697-6042, Web: www.troutmansanders.com, Email: bryan.haynes@troutmansanders.com.*