FDA Deeming Regulations:

Will Premarket Review Crush New Products?

The reality of introducing new cigars, pipe tobaccos, and vaping products—and keeping certain currently available ones on the market—has completely changed. It's a tough road ahead and could render the market unrecognizable. **>BY BRYAN M. HAYNES**

On May 5, the U.S. Food & Drug Administration (FDA) released the long-awaited deeming regulations, which now subject e-cigarettes, pipe tobacco, cigars, and all other tobacco products to the FDA's tobacco regulatory authority. Manufacturers, distributors, and retailers of these products will now be subject to a host of regulatory requirements and prohibitions, from mandatory testing, registration, and product listing to a ban on free samples. For many companies, these requirements—while onerous—are tolerable.

The FDA's premarket review requirements, however, are a different story. These requirements will, at a minimum, impose substantial additional costs on the regulated businesses. The worst case scenario is that a company may no longer be permitted to market all or certain of its products.

PREMARKET REVIEW OF CURRENTLY-REGULATED PRODUCTS

The FDA has been conducting premarket review of cigarettes, cigarette tobacco, and roll-your own tobacco for a little over five years, since March 22, 2011. That is because the Tobacco Control Act established a limited "provisional" window—between February 15, 2007 and March 22, 2011—for companies to provisionally introduce new products. These provisional products could continue to be sold pending the FDA's review as long as the manufacturer submitted a "substantial equivalence" report by March 22, 2011. Products that were introduced before February 15, 2007 (and unchanged since then) are "grandfathered" and not subject to premarket review.

Under this premarket review regime, many products—and perhaps most cigarettes sold in the United States—are grandfathered and therefore exempt from scrutiny. The provisional window also saw many products introduced prior to March 22, 2011, with the vast majority of substantial equivalence reports submitted shortly before the deadline. Manufacturers seeking to introduce new products after March 22, 2011 must obtain FDA pre-approval before the products can be sold.

As a result of this provisional window, substantial equivalence remains by far the preferred pathway. The vast majority of submitted and approved applications have been pursued under this pathway. By way of comparison, the FDA has approved only *one* application under the "exemption from substantial equivalence" pathway. The FDA has approved only *eight* products under the premarket tobacco application (PMTA) pathway and those were similar snus products manufactured by the same company.

The legal burden for a PMTA is also higher. In contrast to the substantial equivalence pathway—where the applicant must show that the differences between a new and grandfathered product do not "raise different questions of public health"—the PMTA applicant must show that the introduction of the product is "appropriate for the protection of the public health." The exemption from substantial

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equivalence pathway is limited because it only applies to additive changes.

PREMARKET REVIEW AS APPLIED TO THE NEWLY DEEMED PRODUCTS

The premarket review process is certain to be more burdensome for the newly-deemed products. Significantly, the Tobacco Control Act's February 15, 2007 "grandfather" date will apply to the newly deemed products. As a result, the e-cigarette industry may be foreclosed from using the substantial equivalence or exemption from substantial equivalence pathways because e-cigarettes were not widely available in 2007 and today's products are markedly different from products sold in 2007. Although the FDA did not foreclose the possibility of "cross-category" comparisons—for example comparisons between e-cigarettes and grandfathered cigarettes—the FDA's commentary in the deeming regulations certainly discouraged such comparisons.

Moreover, there will be no "provisional" window for the newly deemed products. Upon the regulations' August 8, 2016 effective date, every product must undergo premarket review by the FDA before it is introduced. Only those products that have been introduced before August 8 can continue to be marketed, and only so long as the manufacturer submits an exemption from substantial equivalence report by August 8, 2017, a substantial equivalence report by February 8, 2018, or a PMTA by August 8, 2018.

Finally, and perhaps most significantly, the manufacturer now bears the burden of the FDA's regulatory inertia. That is because unless the FDA acts on the manufacturer's application within a year, the manufacturer's products are subject to enforcement action. This stands in stark contrast to the current process, whereby the manufacturer's provisional products can continue to be sold unless and until the FDA acts. The FDA has been notoriously slow to rule on premarket review submissions; the FDA has not ruled on the vast majority of applications more than five years after they were filed. In light of this track record, it is hard to imagine the FDA ruling on most submissions within a year.

> Unless the FDA acts on a manufacturer's premarket tobacco application within a year, the manufacturer's products are subject to enforcement action.

The premarket review process will also have a unique impact on certain businesses that manufacture the newly deemed products. Manufacturers that provide bespoke products, for example the vape shops that prepare custom e-liquids, the cigar manufacturers that produce limited and special edition releases, and the pipe tobacco retailers that prepare blends on-site, will likely have to cease these practices because each and every custom product would need to undergo premarket review. The premarket review costs—which generally exceed several thousand dollars and could be in the millions for a PMTA—likely would not be justified for limited releases or custom products.

The industry has learned a great deal about the FDA's tobacco product premarket review process during the last five years. This experience should somewhat shorten the learning curve as the industry prepares to engage in this process for the newly deemed products. Unfortunately, in light of the way the FDA has decided to apply the premarket review requirements to the newly deemed products, manufacturers of these products are likely to have a much more difficult time navigating that process. S

Premarket Tobacco Application: *What's Required?*

FDA's Center for Tobacco Products estimates that conducting the necessary scientific investigations and preparing a premarket tobacco application would take 5,000 hours. This estimate includes the time to conduct a chemical analysis and any necessary nonclinical or clinical studies, though it is possible that based on existing studies, an applicant may not need to conduct any new nonclinical or clinical studies. Required information includes, but isn't limited to:

- Full reports of all information, published or known to (or which should reasonably be known to) the applicant, concerning investigations which have been made to show the health risks of such tobacco product and whether such tobacco product presents less risk than other tobacco products; (Applications must provide scientific data to demonstrate that the new tobacco product is beneficial to the population as a whole including users and non-users. This demonstration shall take into account the increased or decreased likelihood that existing tobacco users will stop using such products, and the increased or decreased likelihood that those who do not use tobacco products will start using them);
- A full statement of the tobacco product's components, ingredients, additives, properties, an principle(s) of operation;
- A full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, such tobacco product;
- An identifying reference to any tobacco product standard, under Section 910(b)(1) of the FD&C Act, which would be applicable to any aspect of such tobacco product, and either adequate information to show that such aspect of such tobacco product fully meets such tobacco product standard or adequate information to justify any deviation from such standard;
- Samples of the product and its components, as the Secretary may reasonably require;
- Samples of the product's proposed labeling;

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