EXHIBIT 8

Perspective: FDA's Progress on Review of Tobacco Product Applications Submitted by the Sept. 9, 2020 Deadline

By Mitch Zeller, Director of the FDA's Center for Tobacco Products (CTP)
February 16, 2021

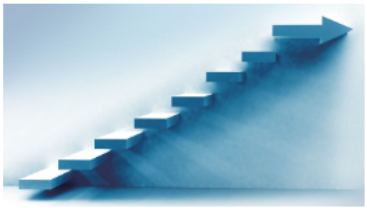
Per a court order, premarket applications for many new tobacco products, including e-cigarettes, certain cigars, and hookah products, currently on the market were due to FDA by Sept. 9, 2020. Also consistent with a court order, products for which applications were submitted by the Sept. 9 deadline may remain on the market for up to a year pending FDA review, although they remain subject to FDA enforcement. This piece is a follow-up to our August perspective piece and aims to provide an update on the progress we have made on the processing and review of these applications. [1]

Content current as of:
02/22/2021

Regulated Product(s)
Tobacco

Background

Following the Sept. 9 premarket application deadline for certain deemed new tobacco products on the market as of Aug. 8, 2016, FDA's job is to process, review, and take action on a massive number of applications for products that are currently on the market. Premarket review of new tobacco products is a critical part of how we carry out our mission to protect the public—especially kids—from the harms associated with tobacco use.



This undertaking represents a major milestone for tobacco product regulation and for public health as a whole. By implementing the premarket review requirement for new electronic nicotine delivery systems (ENDS) and other "deemed" new tobacco products, such as hookah and pipe tobacco, we are taking steps to transform the marketplace toward one where deemed new tobacco products available for sale will have undergone careful, science-based review and oversight by the FDA. [2]

We have worked for several years to prepare for premarket review of a large number of deemed products. These efforts included improving information technology systems, engaging with stakeholders, significantly increasing hiring, streamlining review procedures, and providing and promoting guidance and resources to inform industry.

As anticipated, we received thousands of tobacco product submissions covering millions of tobacco products, the majority of which came in very close to the Sept. 9 deadline. Furthermore, the submissions varied substantially in number of tobacco products contained in each submission, size, format and organization. However, despite these

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In an August perspective piece, I pledged that the agency would keep interested stakeholders updated on the agency's progress. We are now at a point in the review of these applications where we can share some updates on our progress.

Processing and Reviewing Applications

Receipt and Processing of Submissions

After a firm submits their application(s) to the FDA, the agency goes through a number of Processing steps to properly receive and prepare it for the review process (e.g., acceptance review, filing review, substantive review). This includes physical or electronic "intake" of the submission and determining the type and number of applications contained in the submission. For example, this is when we determine if a submission is a Premarket Tobacco Product Application (PMTA) or Substantial Equivalence (SE) Report and how many individual applications for tobacco products are included within the submission. This is also when FDA ensures that the files are safely viewable by conducting virus scans on hard drive submissions and unzipping any zipped files. Lastly, FDA uploads all the files into internal review systems to prepare them for the next step in the review process.

We have seen significant variety in the number of tobacco products included in each submission, so each and every submission package is being carefully assessed. For example, some applicants provided information on one product per submission while other applicants provided information for all of the company's products within one submission. In addition, the submissions arrived in many different formats, including electronic submissions, paper submissions, and mixed media (flash drives, hard drives or CDs, sometimes combined with paper), and varied widely in their organization and presentation of information. We also received several duplicate submissions; for example, companies submitted an electronic version and a paper version of the same application. Lastly, while some firms used a spreadsheet made available by FDA to enable faster processing, most firms used other means to present the information. This impacted our ability to more quickly process the information provided, as it required our staff to manually enter the product information into our systems.

Recently, we completed the Processing step of ALL Exemption from Substantial Equivalence Requests (EX REQ) and ALL Substantial Equivalence (SE) Reports submitted by the Sept. 9 deadline. For the EX REQ pathway, we received applications for about 350 products from about 15 companies. For the SE pathway, we received applications for about 6,800 products from about 100 companies.

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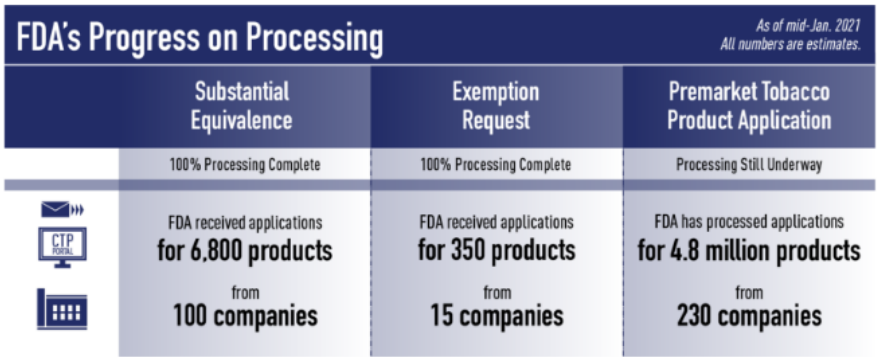

For PMTAs, as of mid-January 2021, the agency has completed the Processing step of applications for more than 4.8 million products from over 230 companies. During Processing, FDA found that the PMTAs posed additional challenges due to the size, complexity and diversity of the submissions; for example, some firms provided separate submissions for each section of the tobacco product application, such as submitting the clinical information separately from product identification and manufacturing information, while others included up to tens of thousands of products within a submission. One firm submitted information on more than 4 million tobacco products within a single submission. The amount of content in each submission also greatly varied, with some applications including up to 2,000,000 files where each file contains multiple pages of content for FDA to review.

Given the high level of public interest in these submissions, we'd hoped to be able to share a list of products submitted under all three pathways at once. However, we have not completed Processing all of the applications submitted through the PMTA pathway. Because we want to provide as much of an update as possible, we are therefore sharing the SE and EX REQ list and providing a PMTA update at this time.

While processing PMTA submissions, the Agency continues to enforce the law. As previously stated in FDA's enforcement priorities, after Sept. 9, 2020, FDA is prioritizing enforcement against any ENDS product that continues to be sold and for which the agency did not receive a product application. Additionally, for deemed tobacco products—other than ENDS or "premium cigars"—that do not have premarket authorization, FDA will make enforcement decisions on a case-by-case basis and intends to prioritize enforcement based on the likelihood of youth use or initiation to make the most efficient use of its resources (FDA is currently enjoined from enforcing the premarket requirements for products that meet the definition of "premium cigar" in the court's order).

In January 2021, FDA issued the first set of warning letters to firms who have not submitted premarket applications to FDA and are continuing to sell or distribute unauthorized ENDS after Sept. 9, 2020. To date, FDA has sent warning letters to 30 firms

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In January 2021, FDA issued the first set of warning letters to firms who have not submitted premarket applications to FDA and are continuing to sell or distribute unauthorized ENDS after Sept. 9, 2020. To date, FDA has sent warning letters to 30 firms who manufacture and operate websites selling electronic nicotine delivery system (ENDS) products, specifically e-liquids, which lack premarket authorization.

We are continuing to process packages submitted by the Sept. 9 deadline and aim to share the final PMTA numbers as soon as possible.

Acceptance and Filing

Once a submission package is processed, the individual product applications within the submission proceed to the review process.

Phase 1 in the review process is to conduct an application's Acceptance review. This review ensures the product falls under CTP's jurisdiction and confirms that basic requirements of an application are met. If an application is Accepted, it will move on to the Notification or Filing stage (based on which pathway it was submitted through). During the Acceptance review, FDA may also Refuse to Accept (RTA) a premarket application if it contains certain deficiencies. Examples of deficiencies that lead to an RTA include: if the submission does not pertain to a tobacco product, if it is not in English or does not contain complete English translations, if it is in an electronic format FDA cannot process, read, review, and archive, or if the submission does not include an environmental assessment or valid claim of categorical exclusion. If a product that is currently on the market is part of an application that receives an RTA, that product must be removed from the market or risk FDA enforcement action.

As of mid-January 2021, of the applications submitted by Sept. 9, we have accepted applications for about 5,200 products and refused to accept applications for about 1,600 products submitted through the SE pathway, and we have accepted applications for about 250 products and refused to accept applications for about 100 products submitted through the EX REQ pathway. Finally, we have accepted applications for about 84,000 products and refused to accept applications for about 3,100 products submitted through the PMTA pathway.

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