NATO

The ABCs of FDA Tobacco Product Pre-Market Applications

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Introduction

In 2009, the Family Smoking Prevention and Tobacco Control Act (TCA) authorized the U.S. Food and Drug Administration to regulate cigarettes, smokeless tobacco and roll-your-own tobacco. This federal law required cigarettes, smokeless and RYO tobacco introduced into the marketplace after February 15, 2007 to receive marketing authorization from the FDA prior to being offered for sale.

Then, this same marketing authorization requirement was later extended by the FDA to cigars, pipe tobacco, electronic cigarettes, vapor products, hookah, and alternative nicotine products – referred to as "deemed" products - effective August 8, 2016.

As described below, in the coming months FDA will be requiring manufacturers of deemed tobacco products (that is, all products other than cigarettes, smokeless tobacco and roll-your-own) to file marketing authorization requests by September 9, 2020 or be subject to FDA enforcement. Note that the original filing deadline was May 12, 2020, but the FDA obtained court permission to extend the deadline by 120 days due to the impact of the Coronavirus.

The FDA is very limited in what information it can disclose regarding application status. Some manufacturers have already sent out communications to their retail and wholesale customers indicating that they are complying with the market authorization filing requirements for their particular family of products. These communications can serve as confirmation that those products may remain on the market during the FDA review process. In the absence of a communication from a manufacturer, retailers and wholesalers should consider contacting manufacturers directly and inquiring whether market applications have been or will be filed for the company's products.

FDA's requirements for market authorization applications depends on various factors, including date of product availability in the marketplace. This article is an in-depth review of the FDA's marketing authorization process that will affect a significant number of tobacco products currently on the market.

Marketing Authorization Submissions

All tobacco products introduced into the market after February 15, 2007 must receive FDA authorization. Manufacturers satisfy the marketing authorization requirement primarily through one of two product authorization pathways.

- The first type of marketing authorization pathway is known as a Substantial Equivalence report or "SE." In this pathway, a manufacturer must demonstrate that a new product has the same characteristics as a "predicate" product (either a grandfathered product that was already on the market as of February 15, 2007, or a product that has previously received an SE marketing authorization), or that the new product does not raise different questions of public health.

  This approach is most common with changes to existing combustible or moist smokeless tobacco products.

- The second kind of marketing authorization submission is called a Pre-Market Tobacco Application or "PMTA." The FDA's PMTA review, among other things, evaluates the product's risk to the individual user and possible impact to the population, considering both tobacco users and non-users. A product will be granted a PMTA marketing authorization order by the FDA if the agency finds that marketing of the new product is "appropriate for the protection of the public health."

  A PMTA will be most common among new product categories such as electronic cigarettes, e-vapor, hookah, nicotine gels and novel oral alternative nicotine tobacco products.

PMTA Content and Review Process

A PMTA is an extensive submission that the FDA subjects to a thorough review process. To be complete, a PMTA needs to include, among other things, the following information and documentation:

- A full statement of the ingredients, additives and properties of the tobacco product;

- Published reports from studies and investigations that show the health risks of the tobacco product and whether the tobacco product presents less risk than other tobacco products;

- Clinical human study outcomes based on the use of the tobacco product; and

- A full description of the methods used in, and the facilities and controls used for, the manufacturing, processing, and packing of the tobacco product.

In general, the FDA follows a three-step PMTA review process. At each juncture, the agency can reject a PMTA.

- First, upon submission of a PMTA, the FDA conducts an administrative review to verify that the tobacco product falls under the FDA's jurisdiction and confirms that the required information accompanies the application. At this point, the FDA may issue either a letter to accept a PMTA or a letter to "refuse to accept" an application.

- Second, the agency conducts a preliminary scientific review to ensure the application contains the required documentation, research, and reports to qualify for a substantive review. If the required documentation is submitted, the FDA issues a Letter of Filing to the manufacturer. At this point, the FDA may also "refuse to file" an application.

- Third, the FDA conducts a substantive review of the application and scientific research. Following this, the FDA issues a PMTA Marketing Approval Order authorizing the sale of the tobacco product or a No Marketing Order denying the sale of the product. If the FDA issues a No Marketing Order for a tobacco product, the product is "misbranded" and must be removed from the market.

Market Authorization Enforcement

FDA enforcement of the marketing authorization requirement varies based on product type and date of availability in the market. In general:

- *All* tobacco products on the market on or before February 15, 2007 are "grandfathered" and exempt from the premarket authorization requirement. This means that manufacturers are not required to submit SE or PMTA applications for grandfathered products to remain on the market, but the products must comply with all other FDA tobacco regulations.

- New cigarettes, smokeless and RYO products introduced between February 15, 2007 and March 22, 2011 were required to file marketing authorization submissions by March 22, 2011. Products which did so are referred to as "provisional" and may continue to be marketed unless FDA issues an order otherwise.

- New cigarette, smokeless and RYO products introduced *after* March 22, 2011 must receive a marketing order from the FDA *prior* to being offered for sale.

- The FDA previously extended timelines to submit tobacco product review applications for "deemed" products, including cigars, pipe tobacco, electronic cigarettes, vapor products, hookah, alternative nicotine products, and heated tobacco products introduced between February 15, 2007 and August 8, 2016.

  Based on a recent court order, manufacturers of these products must now file SE or PMTA marketing authorization requests by September 9, 2020. FDA may allow these products to remain on the market for up to one year, or potentially even longer, during the application review period.

  To be clear: The September 9, 2020 deadline applies to *all* new (non-grandfathered) deemed tobacco products introduced after February 15, 2007 including cigars, pipe

tobacco, electronic cigarettes, vapor products, hookah products, nicotine gels and alternative nicotine products.

This can be achieved through *either* the SE or PMTA pathway. In fact, many brands of cigars, pipe tobacco and some of the other deemed tobacco products are likely to be substantially similar to a tobacco product that was already on the market as of February 15, 2007. In those cases, manufacturers can file SEs with the FDA by September 9, 2020. At the same time, there were no electronic cigarette, vapor, or alternative nicotine products on the market as of February 15, 2007, which means that there is no substantially similar product to rely on to file a SE. For all of those products, manufacturers are required to file PMTAs with the FDA by the September 9th deadline.

It is important to know that one SE or PMTA application is required per product SKU or per brand family, which is the reason why such a high number of pre-market applications will likely be filed.

- "Deemed" products including cigars, pipe tobacco, electronic cigarettes, vapor products, hookah, alternative nicotine products, and heated tobacco products introduced to the market *after* August 8, 2016 must receive a marketing order from the FDA *prior* to being offered for sale.

While the FDA also regulates what are known as tobacco product "components" such as cigarette rolling papers, rolling tubes, and traditional tobacco pipes, these products are not "made or derived from tobacco" and are not subject to the pre-market application filing requirements.

Understanding the Status of Product Applications

As you can see, some products currently on the market may not be authorized to be sold post September 9th if the manufacturers of those new, deemed products do not submit a market authorization application.

The process will also continue to unfold. As outlined above, some products for which an application is submitted may receive "Refuse to Accept", "Refuse to File", or "No Marketing Order" determinations. If at any point the applicant receives one of these negative determinations, the FDA considers the product "misbranded" and it cannot be legally sold. Manufacturers will need to work with the agency to comply with the law and remove the products from the market.

Under federal law, the FDA is, in general, prohibited from disclosing information about pending market authorization applications or even disclosing for which products applications have been submitted. Indeed, the FDA has already indicated that it will not publish a list of those SE or PMTA applications that have been accepted for review by the agency or status updates on a product's review progress.

This means that retailers and wholesalers will need to rely on manufacturers to inform them of whether they have submitted timely applications or have received a negative decision at any point in the process.