NATO

Questions and Answers Regarding "FDA Regulation of Tobacco Products" Webinar

Question: What do manufacturers need to include in a PMTA application?

Answer: 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.

Question: What tobacco products does the September 9, 2020 pre-market application deadline apply to?

Answer: FDA enforcement of the SE or PMTA 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 Substantial Equivalency (SE) or Pre-Market Tobacco Applications (PMTA) 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 SE or PMTA marketing order from the FDA *prior* to being offered for sale on the market.

- 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 agency's 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.

  The deadline can be complied with 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.

Question: What is the status of a tobacco product that is subject to SE or PMTA filing requirements, but the manufacturer does not file a SE or PMTA by September 9, 2020?

Answer: A tobacco product for which a SE or PMTA needs to be filed, but the application is not filed, is then considered to be "misbranded" and/or "adulterated" by the FDA. This means that this tobacco product cannot be legally sold on the market.

Question: How does the agency plan to remove products from the market if a SE or PMTA is not filed?

Answer: The FDA has stated that it will prioritize the agency's enforcement efforts against electronic nicotine products for which PMTAs are not filed. The agency has various enforcement powers and mechanisms including warning letters, civil penalties (fines), and seizure of misbranded and/or adulterated products. It is up to the FDA to determine what enforcement actions are warranted in any given case.

Question: Is there a sell-through period for those products which are required to have a SE or PMTA filed by September 9, 2020, but the manufacturer does not file an application?

Answer: Neither the Family Smoking Prevention and Tobacco Control Act nor the FDA has provided a sell-through period to sell off inventory of those tobacco products which do not have a SE or PMTA filed with the FDA. These tobacco products would need to be removed from the market and stores shelves.

Question: If a SE or PMTA is approved or denied, how will retailers know?

Answer: Generally, the FDA issues a press release on its website (www.fda.gov) if a SE or PMTA application is denied or accepted.