Tony Abboud

From: AskCTP <AskCTP@fda.hhs.gov>
Sent: Friday, August 28, 2020 4:39 PM
To: Tony Abboud
Subject: PMTA EXTENSION REQUEST

Vapor Technology Association
Via abboud@vaportechnology.org

Dear Mr. Abbound:

Thank you for contacting the U.S. Food and Drug Administration's (FDA's or the Agency) Center for Tobacco Products (CTP) to request an additional extension of the premarket application deadline on behalf of your members with deemed new tobacco products.

FDA is aware that tobacco manufacturers and importers are dealing with unexpected circumstances due to the COVID-19 pandemic. On July 12, 2019, the United States District Court for the District of Maryland issued an order directing FDA to require that premarket authorization applications for all new deemed tobacco products be submitted to the Agency within 10 months, by May 12, 2020, and providing for a one-year period during which products with timely filed applications might remain on the market pending FDA review (*Am. Acad. of Pediatrics v. FDA*, 399 F. Supp. 3d 479, 487 (D. Md. 2019). The order stated that "FDA shall have the ability to exempt [new tobacco products] from filing requirements for good cause on a case-by-case basis." In March, the Agency asked the court for a 120-day extension of its original premarket application submission deadline for deemed new tobacco products on the market as of August 8, 2016. That timeframe reflected a balance between the critical public health priority in promptly requiring submission of premarket tobacco product applications and the difficulties posed by the COVID-19 pandemic. The court agreed with the Agency's request, extending the premarket application deadline for such deemed new tobacco products to September 9, 2020. As required by the court's order, deemed new tobacco products on the market as of August 8, 2016, for which premarket authorization applications are not filed by September 9, 2020, are subject to FDA enforcement actions, in the Agency's discretion.

FDA has received many individual requests for a further extension of the September 9, 2020, premarket application deadline. After considering your request, FDA has determined that it will not grant a further extension of the September 9, 2020, premarket application deadline set by the Court for members' products. Any additional delay would impede FDA's critical public health priority to promptly require submission of premarket tobacco applications.

As FDA's Enforcement Priorities for Electronic Nicotine Delivery System (ENDS) and Other Deemed Products on the Market Without Premarket Authorization guidance explains, manufacturers of deemed new tobacco products will be required to submit marketing applications for those products by September 9, 2020, consistent with the U.S. District Court for the District of Maryland's order. To make the most efficient use of its resources, FDA intends to prioritize enforcement decisions on a case-by-case basis such as prioritizing enforcement based on the likelihood of youth use or initiation.

However, FDA intends to take individual circumstances into account as it considers your members' premarket tobacco product applications that are submitted by the September 9, 2020, deadline. During review of an application, FDA will determine whether it meets the applicable statutory and regulatory requirements under sections 905 and 910 of the Federal Food, Drug, and Cosmetic Act, including final regulations at 21 C.F.R. Parts 1105 and 1107, for applications to be accepted and filed and proceed to scientific review. FDA encourages your members to explicitly identify any content that may be missing from an application and clearly explain how COVID-19, a recent natural disaster, or other unforeseen circumstance has affected ability to provide such information. If an application is sufficient to be accepted,

filed, and proceed to scientific review and, during such review, your member would subsequently provide the needed information and make substantial progress toward addressing deficiencies in an application, we intend to take that into account in deciding whether to initiate enforcement action against products for being on the market without premarket authorization, even where FDA is reviewing applications after September 9, 2021. The decision as to whether to enforce after the one-year review period may take into account responsiveness to our requests, the particular nature and extent of scientific evidence that is lacking, and evidence of demonstrated hardship due to the COVID-19 pandemic, recent natural disasters, or other unforeseen circumstance in obtaining such evidence.

Should you have further questions regarding this specific inquiry, please reference the incident ID: IM2014233 and contact CTP at SmallBiz.Tobacco@fda.hhs.gov.

FDA also encourages you to subscribe to FDA's "CTP News" and "CTP Connect" newsletters. By subscribing, you'll receive updates about regulatory activities, retailer notices, upcoming events, and public education campaigns.

Thank you,

FDA Center for Tobacco Products