

September 10, 2021

Janet Woodcock, M.D.
Acting Commissioner of Food and Drugs
U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Mitchell Zeller, JD
Director of the Center for Tobacco Products
U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

RE: Publicly Available Information and Clarity for Retailers

Dear Acting Commissioner Woodcock and Director Zeller:

Following your statement yesterday on the progress of the premarket tobacco application (PMTA) review process, the undersigned national retail associations urge the Center for Tobacco Products (CTP) to swiftly publish a public list of electronic nicotine delivery system (ENDS) products for which the Agency has issued marketing denial orders (MDOs). Without this list, our retail members, who make every effort to comply with the law, do not know which products must be removed from shelves.

Last August, our associations sent a letter¹ asking CTP to publish a list of products for which PMTAs had been submitted to know which products could legally be sold in stores during the FDA's review process. In May, CTP published this list providing needed clarity for retailers, distributors and wholesalers. As the Agency takes action on PMTAs, it is imperative that there is continued transparency in the process and that stakeholders across the tobacco trade know all of the products that have had PMTAs rejected as well as all of the products that have had marketing orders granted.

Our retail members who sell ENDS products take the responsibility of compliance and operating in accordance with the law seriously. Publicly available information noting the status of individual products is the only way retailers can ensure compliance. Until such information is available, we respectfully ask CTP to focus enforcement on manufacturers who know the legal status of their own products and exercise enforcement discretion with respect to retailers selling ENDS products for which the status of their PMTAs has not been made publicly available.

Our associations understand the enormous task of reviewing more than 6.5 million applications in a year's time. In order for the Agency's retail partners to be in compliance with the law, we ask that the Agency as expeditiously as possible provide retailers with the information they need to comply with the law.

Respectfully,

Energy Marketers of America
FMI, The Food Industry Association
National Association of Convenience Stores
National Association of Truckstop Operators
Society of Independent Gasoline Marketers of America

¹ See Letter from Industry to Matthew Holman (Aug. 25, 2020) available at [https://www.convenience.org/Media/Daily/2020/Aug/28/2-NACS-Urges-FDA-Publish-PMTA-List-ENDS_NACS/Industry-Letter-re-PMTA-List-\(8-25-20\).pdf](https://www.convenience.org/Media/Daily/2020/Aug/28/2-NACS-Urges-FDA-Publish-PMTA-List-ENDS_NACS/Industry-Letter-re-PMTA-List-(8-25-20).pdf).