October 14, 2021

Janet Woodcock, M.D.
Acting Commissioner of Food and Drugs
U.S. Food & Drug Administration
10903 New Hampshire Avenue
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Mitchell Zeller, JD
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RE: Publicly Available Product Information for Retailers

Dear Acting Commissioner Woodcock and Director Zeller:

The undersigned national retail associations asked the Food and Drug Administration (FDA) and the Center for Tobacco Products (CTP) to provide a list of electronic nicotine delivery system (ENDS) products for which the Agency has issued marketing denial orders (MDOs) in a letter[1] on September 10. This list is critical for our retail members who strive to comply with the law and need to know which products are legal to market and which products are not.

Yesterday, the FDA announced it had authorized products of the R.J. Reynolds (RJR) Vapor Company: the Vuse Solo closed electronic nicotine delivery system (ENDS) device, and tobacco-flavored e-liquid pods. Specifically, these products were identified by FDA as the Vuse Solo Power Unit, Vuse Replacement Cartridge Original 4.8% G1, and Vuse Replacement Cartridge Original 4.8% G2. Additionally, the Agency announced that 10 marketing denial orders (MDOs) had been issued for flavored ENDS products submitted under RJR's Vuse Solo brand, and that menthol-related products under the brand were still under evaluation.

Addressing whether it would identify the products that received MDOs, the Agency stated, "Due to potential confidential commercial information issues, the FDA is not publicly disclosing the specific flavored products. These products subject to an MDO for a premarket application may not be introduced or delivered for introduction into interstate commerce. Should any of them already be on the market, they must be removed from the market or risk enforcement. Retailers should contact RJR with any questions about products in their inventory."[2]

While the agency claims that it cannot identify the products that received MDOs, in the same release it discloses the three products that received authorization and that menthol products are still under review. Our members do not need any confidential or detailed information about the products, they simply need to know the names of the products so that they can be identified and ensure that they are off the market. If the names of products on PMTA applications were confidential, then the FDA could not have provided that information for the product that was approved or one of the

[1] *See* Letter from Associations (Sept. 10, 2021) *available at* https://www.convenience.org/Media/Daily/2021/Sept/13/3-NACS-Requests-List-FDA-denied-ENDS-Products_GR/Retail-Association-Letter-PMTA-Status-List.

[2] Food & Drug Administration. (Oct. 12, 2021). *FDA Permits Marketing of E-Cigarette Products, Marking First Authorization of Its Kind by Agency* [Press release]. https://www.fda.gov/news-events/press-announcements/fda-permits-marketing-e-cigarette-products-marking-first-authorization-its-kind-agency?utm_medium=email&utm_source=govdelivery.

products that remains under review. Asking the hundreds of thousands of tobacco retailers to verify the PMTA status of ENDS products with each manufacturer does not fulfill the agency's responsibility to inform regulated businesses of its decisions. There is no guarantee that manufacturers will provide such information in a timely, complete, or accurate manner.

Just as the Agency provided a list of products for which PMTAs were submitted earlier this year (adding support to the idea that identifying the products does not reveal confidential information), we respectfully ask the Agency to publish a list of the products for which MDOs have been issued. This level of transparency is vital for our retail members 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
SIGMA: America's Leading Fuel Marketers

September 10, 2021

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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 letter[1] 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.