June 1, 2023

VIA ELECTRONIC SUBMISSION ON REGULATIONS.GOV

Mr. Xavier Becerra, Secretary
Department of Health & Human Services
200 Independence Avenue, S.W.
Washington, DC 20201
Xavier.Becerra@hhs.gov

Robert Califf, M.D., Commissioner
United States Food and Drug Administration
10903 New Hampshire Avenue, HF-1
Silver Spring, MD 20993
Robert.Califf@fda.hhs.gov

Divisions of Dockets Management
Food and Drug Division
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Citizen Petition

The Energy Marketers of America (EMA) submits this citizen petition under 21 C.F.R. § 10.30 and the Family Smoking Prevention and Tobacco Control Act ("Tobacco Control Act"). EMA respectfully requests that the Food and Drug Administration ("FDA" or "agency") publish a list of electronic nicotine delivery systems (ENDS) and other deemed tobacco products (containing nicotine derived from any source) as described below, which would help to eliminate confusion and uncertainty in the marketplace.

EMA is a federation of 47 state and regional trade associations representing family-owned and operated small business energy marketers including 60,000 convenience stores throughout the United States. Energy marketers represent a vital link in the motor and heating fuels distribution chain. EMA members supply 80 percent of all finished motor and heating fuel products sold nationwide, including renewable hydrocarbon biofuels, gasoline, diesel fuels, biofuels, heating fuel, jet fuel, kerosene, racing fuel, and lubricating oils. EMA member companies also market large volumes of cigarettes and other tobacco products at convenience stores throughout the Nation and at kiosks located adjacent to the pumps at their gasoline service stations. The sale of tobacco products is an important component of their businesses, and their interests align with those of FDA in promoting protective measures aimed at eliminating unlawful sales to minors. The vast majority of these energy marketers qualify as small businesses under U.S. Small Business Administration size categories for both wholesale and retail entities.

A. Action Requested

Specifically, EMA requests that FDA publish a list by brand and category of (i) ENDS and other deemed tobacco products with tobacco-derived nicotine that were on the market as of August 8, 2016, and (ii) ENDS and other deemed tobacco products with nicotine not derived from tobacco that were on the market as of April 14, 2022, that indicates whether each of those products:

- Has received a marketing granted order;

- Has received an MDO that has been stayed by a court or FDA, rescinded by FDA, or vacated by a court; and/or

- Has a timely filed premarket tobacco product application ("PMTA") pending and is not subject to one of FDA's enforcement priorities identified in FDA's *Enforcement Priorities for Electronic Nicotine Delivery System (ENDS) and Other Deemed Products on the Market Without Premarket Authorization* (rev. Apr. 2020).

Publishing a list as outlined above will better protect the public health by diminishing the availability of illicit products in the marketplace. Retailers will be better able to manage inventory and business operations by checking the published list and readily identifying that those products on the list are not enforcement priorities. The published list will also assist in FDA's efforts to curtail youth vaping, as those products that are enforcement priorities for FDA – often tobacco products in kid-friendly flavors – would not appear on the list and therefore be readily discernible by retailers who would be able to promptly remove them from shelves.

B. Statement of Grounds

The Tobacco Control Act granted FDA authority to regulate the manufacture, marketing, and distribution of cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco products to protect the public health and reduce the use of tobacco products by minors. Pub. L. No. 111-31, 123 Stat. 1776 (2009). The Act also gave FDA authority to issue regulations deeming other products that meet the statutory definition of a tobacco product to be subject to FDA authority. *Id.* On May 5, 2016, FDA finalized its "deeming" rule, extending FDA's regulatory authority to additional tobacco products, including ENDS products. 81 Fed. Reg. 28,973, 28,976 (May 10, 2016). After the rule's effective date, *new* deemed tobacco products (those not commercially marketed in the United States as of February 15, 2007) were required to obtain marketing authorization under Section 910 of the Food, Drug, and Cosmetic Act.

Pursuant to its enforcement discretion, FDA provided that any such products with tobacco-derived nicotine that were already on the market as of August 8, 2016, could remain on the market for designated periods provided they met the agency's deadline for submission of a request for marketing authorization. After repeated adjustments of the deadline for PMTAs for ENDS products and ensuing litigation, FDA gave manufacturers of newly deemed products until September 9, 2020, to file applications.[1] Deemed new tobacco products on the market as of August 8, 2016, for which premarket authorization applications were *not* filed by September 9, 2020, are subject to FDA enforcement actions. Between promulgation of the deeming rule and the PMTA deadline, FDA saw an uptick in youth use of ENDS products. In response, the agency

[1] FDA, *Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on the Market Without Premarket Authorization (Revised): Guidance for Industry* (Apr. 2020), https://tinyurl.com/76erxxka ("2020 ENDS Guidance").

first conducted a nationwide undercover enforcement effort targeting brick-and-mortar retail establishments that were illegally selling ENDS products to minors. By 2018, the agency announced it had issued more than 1,300 warning letters and fines to retailers as part of its nationwide "blitz" to crack down on retailers illegally selling ENDS products to minors.[2]

But the blitz was not enough. In 2019, the National Youth Tobacco Survey ("NYTS")—the school-based survey that collects information on tobacco use from middle-school and high-school students—found that youth ENDS use hit higher levels than previously recorded. Findings from the NYTS also indicated that, at that time, youth preferred cartridge-based products with flavors other than tobacco and menthol. As a result, FDA issued a guidance document, stating that the agency would prioritize enforcement of the Tobacco Control Act's premarket review requirements against (i) flavored cartridge-based ENDS products (other than tobacco- and menthol-flavored products), (ii) ENDS products for which the manufacturer failed to take adequate measures to prevent minors' access, and (iii) ENDS products targeted to minors.[3] In that same guidance document, FDA also stated that it intended to prioritize enforcement of ENDS products for which a premarket application had *not* been submitted by September 9, 2020, noting, among other things, "the potential public health benefit of noncombusted options." *Id.*[4]

Accordingly, for the last several years, FDA's exercise of enforcement discretion has allowed certain tobacco-derived nicotine ENDS products that were on the market as of August 8, 2016, and that met the agency's deadline for submission of a request for marketing authorization to remain on the market. FDA, however, has failed to transparently communicate which products meet these requirements and which remain enforcement priorities. Since the PMTA process has commenced, the lack of clarity and communication about the products that are enforcement priorities has created uncertainty in the marketplace that impedes EMA's member companies' ability to conduct business. The result is not only marketplace confusion but also a proliferation of illegal ENDS products on store shelves as retailers struggle to understand which products they should sell.

Application of the PMTA process to ENDS products has also presented considerable administrative challenges given the agency's limited resources. FDA has struggled to administer the volume of applications in an expedient manner. Commissioner Robert Califf recently testified before the House Appropriations Committee that the FDA received applications for 27 million ENDS products, some of which still have not been reviewed. The Commissioner said the agency did not anticipate the volume of applications and explained that he once believed the task

---

[2] FDA News Release, *FDA takes new steps to address epidemic of youth e-cigarette use, including a historic action against more than 1,300 retailers and 5 major manufacturers for their roles perpetuating youth access* (Sept. 11, 2018), https://tinyurl.com/2p8ffj8e.

[3] 2020 ENDS Guidance.

[4] *See also Am. Acad. of Pediatrics v. FDA*, No. 8:18-cv-883, Dkt. 120-1, at ¶ 15 (D. Md. June 12, 2019) (Decl. of Director of FDA's Center for Tobacco Products, Mitchell Zeller) (stating that FDA "is concerned by the potential that adult former smokers who switched to ENDS could be at risk of migrating back to combustible products if there were an abrupt market exit of ENDS").

of reviewing all applications was "hopeless."[5] The delays and uncertainty have a very real impact on the daily lives of American entrepreneurs like EMA's member companies that require predictability and transparency to operate. EMA's member companies and other retailers are well positioned to aid in the fight against illegal and dangerous products by keeping them off their shelves, but the ability to do so requires a clear and rational regulatory framework, with changes communicated consistently and transparently.

Although the FDA has provided a list of products with marketing granted orders and a list of companies that received MDOs, those lists have not proven useful to EMA's member companies as they seek to comply with the law. Thus, FDA should make public a list of (i) all ENDS and other deemed tobacco products with tobacco-derived nicotine that were on the market as of August 8, 2016, and (ii) all ENDS and other deemed tobacco products with nicotine not derived from tobacco that were on the market as of April 14, 2022, that indicates whether each such product:

- Has received a marketing granted order;
- Has received an MDO that has been stayed by a court or FDA, rescinded by FDA, or vacated by a court; and/or
- Has a timely filed premarket tobacco product application ("PMTA") pending and is not subject to one of FDA's enforcement priorities identified in FDA's *Enforcement Priorities for Electronic Nicotine Delivery System (ENDS) and Other Deemed Products on the Market Without Premarket Authorization*. (rev. Apr. 2020).

This list should be updated monthly and use consumer-facing brand names to identify the products on the list. Doing so would help EMA's member companies, as well as other retailers, distributors, Customs and Border Protection, state and local officials, and the public to identify whether a particular product is not an enforcement priority for FDA simply by checking whether that product is on the list. EMA and its member companies regard such measures as important tools in their already diligent efforts to comply with FDA mandates, and to assist FDA in its mission to strengthen the protections aimed at minors.

C. Environmental Impact

The Energy Marketers of America (EMA) claims a categorical exclusion under 21 C.F.R. § 25.30.

[5] Budget Hearing – Fiscal Year 2024, *Request for the Food and Drug Administration: Hearing Before the House Appropriations Committee*, 118 Cong. (2023) (Statement of Robert M. Califf M.D., MACC) ("2023 Califf Statement").

D. Economic Impact

This information will be provided upon the request of the Commissioner.

E. Certification

The undersigned certifies that, to the best knowledge and belief of the undersigned, this petition includes all relevant information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

Respectfully submitted,

Rob Underwood
President
Energy Marketers of America (EMA)

Energy Marketers of America
Petroleum & Convenience Marketers of Alabama
Arizona Petroleum Marketers Association
Arkansas Oil Marketers Association, Inc.
Colorado Petroleum Marketers and Convenience Store Association
Connecticut Energy Marketers Association
Florida Petroleum Marketers Association, Inc.
Georgia Oilmen's Association
Hawaii Energy Marketers Association
Idaho Petroleum Marketers & Convenience Store Association
Illinois Fuel & Retail Association
Indiana Food & Fuel Association
FUELIowa
Fuel True: Independent Energy and Convenience of Kansas
Kentucky Petroleum Marketers Association
Louisiana Oil Marketers and Convenience Store Association
Maine Energy Marketers Association
Michigan Petroleum Association / Michigan Association of Convenience Stores
Mid-Atlantic Petroleum Distributors Association
Minnesota Petroleum Marketers Association
Mississippi Petroleum Marketers and Convenience Stores Association
Montana Petroleum Marketers & Convenience Store Association
Nebraska Petroleum Marketers & Convenience Store Association
Nevada Petroleum Marketers & Convenience Store Association

New England Convenience Store & Energy Marketers Association
Fuel Merchants Association of New Jersey
New Mexico Petroleum Marketers Association
Empire State Energy Association, Inc.
North Carolina Petroleum & Convenience Marketers
North Dakota Petroleum Marketers Association
Ohio Energy & Convenience Association
Oklahoma Petroleum Marketers & Convenience Store Association
Oregon Fuels Association
Pennsylvania Petroleum Association
South Carolina Convenience & Petroleum Marketers Association
Tennessee Fuel & Convenience Store Association
Texas Food & Fuel Association
Utah Petroleum Marketers & Retailers Association
Vermont Fuel Dealers Association
Virginia Petroleum & Convenience Marketers Association
Washington Independent Energy Distributors
West Virginia Oil Marketers & Grocers Association
Western Petroleum Marketers Association
Wisconsin Petroleum Marketers & Convenience Store Association
Wyoming Petroleum Marketers and Convenience Store Association