August 25, 2020

By Email

Matthew Holman, Ph.D.
Director, Office of Science
Center for Tobacco Products
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Re: Public List of Currently Marketed ENDS Products Subject to PMTA Submission by the September 9, 2020 Deadline

Dear Dr. Holman:

The undersigned national retail associations respectfully urge the Food and Drug Administration (FDA or the Agency) to publish a public list of currently marketed electronic nicotine delivery system (ENDS) products for which the Agency has received a premarket tobacco product application (PMTA) by the September 9, 2020 deadline (hereinafter, PMTA List).[1]

As the September deadline approaches, the PMTA List will be critical to support compliance across the tobacco trade channel, helping inform distributors, wholesalers, and retailers which ENDS products are being marketed legally in accordance with FDA's compliance policy. Relatedly, such a list also would facilitate enforcement against those manufacturers that continue to introduce illegally marketed products without premarket authorization or, in the case of deemed, currently marketed products, without a PMTA submitted by the deadline.

To facilitate the publishing of the PMTA List, we offer support on how and why FDA can disclose a list of currently marketed products for which manufacturers have submitted a PMTA by the September deadline. In short, unlike the confidentiality provisions that are afforded to applicants of premarket filings for tobacco products generally, such restrictions are not applicable when the premarket filing applies to a currently marketed product. If, however, the Agency maintains that consent from the manufacturer is still needed before disclosure, we also provide recommendations on a streamlined process for obtaining such consent quickly upon receipt of the PMTA for currently marketed products.

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[1] *See FDA, Guidance for Industry, Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on the Market Without Premarket Authorization (Revised)*,* 3 (Apr. 2020) ("Enforcement Priorities Guidance").

I. INTRODUCTION

Under its Deeming Rule, FDA allowed ENDS and other deemed products on the market as of the rule's effective date (i.e., August 8, 2016) to remain on market, pending the submission of premarket filings under staggered compliance dates.[2] In doing so, FDA aimed to balance public health concerns and "allow the Agency to more efficiently manage the flow of incoming applications, and encourage high-quality premarket submissions from applicants."[3] In April 2020, FDA announced a revised compliance date of September 9, 2020, for PMTAs for such marketed ENDS products.[4]

A rigorous, science-based premarket-review process is foundational to FDA's regulatory framework for tobacco products. Congress's passage of the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) ensures robust FDA oversight of tobacco products, while shepherding the entry of innovative, alternative forms of nicotine delivery for adult smokers that are determined to be appropriate for the protection of public health. We fully support the PMTA process as a necessary regulatory control for public health and mechanism to bring new, potentially less harmful products to the market for current adult users.

Publication of the PMTA List will advance the goals of the premarket-review process and FDA's efforts to clear the market of illegally marketed ENDS products during this transitionary period of currently marketed products subject to premarket review. Without the PMTA List, distributors, wholesalers, retailers, and adult consumers will have no centralized and credible way of determining which ENDS products are being marketed in compliance with FDA policy. As discussed in more detail below, the Agency has adequate authority to publish such a list, consistent with applicable law and long-standing policy. For these reasons, we urge FDA to promptly publish the PMTA List on its website or other appropriate public venues following the September 9, 2020 deadline.

II. FDA HAS FULL AUTHORITY TO PUBLISH THE PMTA LIST

No provision of the Federal Food, Drug, and Cosmetic Act (FDCA) or any other applicable law prohibits FDA from publishing the PMTA List. The FDCA prohibits public disclosure of "information reported to or otherwise obtained by" FDA in a PMTA if the information is trade secret or confidential commercial information (CCI), exempt from disclosure under Exemption 4 of the Freedom of Information Act.[5]

The PMTA List would contain no such information. As FDA has explained, it considers the existence of a PMTA to be CCI when public disclosure would prematurely reveal the

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[2] *See* 81 Fed. Reg. 28973 (May 10, 2016).

[3] *Id.* at 29010.

[4] Enforcement Priorities Guidance at 3.

[5] 21 U.S.C. § 387f(c); 5 U.S.C. § 552(b)(4).

manufacturer's "intent to market a tobacco product" and, as a result, "could result in a competitive advantage to competitors."[6]

While FDA typically does not disclose the existence of a premarket product application (unless the applicant has publicly disclosed or acknowledged the existence of the application), the underlying rationale for non-disclosure does not apply in this situation. Unlike PMTAs for products that have not yet been marketed, disclosing the existence of PMTAs submitted for ENDS products that have been on the market since at least August 8, 2016, through publication of the PMTA List, would not reveal any trade secret or CCI.

For these ENDS products, the manufacturer's intent to market the product already is public and well known. Moreover, for such products to be marketed after September 9, 2020, they must be the subject of a submitted PMTA. Because the PMTA List would provide only the name, brand, and manufacturer of the marketed product that is the subject of the PMTA — all of which are publicly available information already — it would not reveal any information that is confidential.

FDA has long recognized this important distinction between premarket submissions for marketed products and those that have not yet been marketed. For example, for medical devices subject to premarket notification, FDA determines whether to disclose the existence of a premarket notification submission based on, in relevant part, whether the device is on market.[7] If the device is marketed (i.e., introduced or delivered for introduction into interstate commerce for commercial distribution), FDA "will disclose publicly whether there exists a premarket notification submission" for the product.[8] In contrast, if the "device is not on market and the intent to market the device has not been so disclosed," FDA "will not disclose publicly the existence of a premarket notification submission for the device" pursuant to the applicable statutory deadline, so long as the manufacturer treats its intent to market the device as CCI and certifies this to FDA.[9]

Similarly, FDA did not treat a manufacturer's intent to market a "provisional" tobacco product (i.e., tobacco products commercially marketed after February 15, 2007, but before March 22, 2011, subject to an SE Report submitted by March 22, 2011) as confidential within the context of not substantially equivalent (NSE) determinations. When FDA first began issuing NSE orders for such products, the Agency posted a list of marketed NSE products on its website and directed manufacturers, retailers, and distributors to that list.[10]

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[6] *See* 84 Fed. Reg. 50566, 50624 (Sept. 25, 2019).

[7] 21 C.F.R. § 807.95(a).

[8] *Id.* § 807.95(a)(1).

[9] *Id.* § 807.95(b).

[10] FDA, Letter to Industry on Certain Tobacco Products Found to be Not Substantially Equivalent 1 (Feb. 21, 2014) ("Letter to Industry"). That list continues to be available on FDA's website. *See* FDA, "Misbranded and Adulterated NSE Tobacco Products," https://www.fda.gov/tobacco-products/market-and-distribute-tobacco-product/misbranded-and-adulterated-nse-tobacco-products.

The same logic applies here. A manufacturer's intent to market an already marketed ENDS product — especially those that have been on the market for at least four years — hardly can be considered confidential. The Agency therefore has full authority to publish the PMTA List, consistent with applicable law and longstanding precedent.

III. IMPORTANCE OF THE PMTA LIST TO ENSURE COMPLIANCE ACROSS THE TOBACCO TRADE CHANNEL DURING THIS TRANSITIONARY PERIOD

As noted above, the premarket-review process is a critical component of the Tobacco Control Act's public health paradigm for tobacco regulation and will help ensure that new products are appropriate for the protection of public health. The PMTA List would enable distributors, wholesalers, and retailers, particularly those with smaller operations, to better comply with the Tobacco Control Act. Relatedly, this also would advance the law's important public health mission by identifying which products are the subject of timely submitted PMTAs and, therefore, can continue to be marketed across the trade channel for adult consumers.

In addition to manufacturers, distributors, wholesalers, and retailers may face liability for the "introduction or delivery for introduction into interstate commerce," "receipt in interstate commerce," or "delivery, or proffered delivery" of ENDS products that are misbranded or adulterated because they lack a timely-filed premarket submission.[11] While ENDS manufacturers have an obligation to be transparent with firms in the supply chain about the regulatory status of their products, it is imperative that FDA take action to better enable compliance among retailers, distributors, and wholesalers during this critical transitionary period. Without access to the PMTA List, these and other stakeholders would have no centralized and credible mechanism to determine which ENDS products may be marketed in accordance with FDA policy. This is particularly the case for smaller operators, which may not have resources or abilities to ensure that each and every ENDS product in inventory has complied with the September deadline.

The approach we suggest here parallels FDA's actions when it first issued NSE orders for provisional products. At that time, FDA issued a letter to retailers, manufacturers, importers, and distributors to remind them of their responsibility to comply with the requirements of the FDCA.[12] This "Letter to Industry" directed stakeholders to a list of NSE products posted on FDA's website.[13] It also stated that "FDA is making this information available so that everyone will know which tobacco products can no longer be sold or distributed in interstate commerce or imported into the United States."[14]

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[11] 21 U.S.C. §§ 331(a), (c); 387b(6)(A)-(B); § 387c(6). *See also* 61 Fed. Reg. 44396, 44432 (Aug. 28, 1996) (stating that, under FDA's 1996 final rule, "each manufacturer, distributor, and retailer is responsible for ensuring that *its* products (whether it manufactures, labels, advertises, packages, distributes, sells, or otherwise holds them for sale) comply with all requirements applicable to it and its products") (emphasis in original).

[12] Letter to Industry at 1.

[13] *Id.*; *see* FDA, "Misbranded and Adulterated NSE Tobacco Products," https://www.fda.gov/tobacco-products/market-and-distribute-tobacco-product/misbranded-and-adulterated-nse-tobacco-products.

[14] Letter to Industry at 1. FDA later clarified that it would not take action against retailers and distributors for marketing products that were the subject of an NSE order for 30 days after the NSE order was posted on FDA's

FDA likewise should publish the PMTA List to provide notice to key stakeholders of which ENDS products can continue to be marketed and, thereby, help clear the market of noncompliant ENDS and further advance the objectives of the Tobacco Control Act.

IV. POTENTIAL ALTERNATIVE APPROACHES

If, for some reason, FDA believes it cannot publish the PMTA List without the express consent of applicants, the Agency should adopt a streamlined approach to obtaining such consent upon the receipt of PMTAs for currently marketed products. For example, FDA could ask for an applicant's consent at the time of submission. To do so, FDA could add a field in its submission portal notifying the applicant of the option to permit the Agency to disclose the existence of its PMTA in a public list. Alternatively, in its initial acknowledgement letter, which provides the submission tracking number (STN) to applicants, FDA could ask for such consent. In both cases, the applicant would have the opportunity to provide affirmative consent.

Under either approach, FDA would provide a clear and direct mechanism for applicants to provide consent. In addition, if applicable, FDA could add a disclaimer indicating the incomplete nature of the PMTA List, similar to the Agency's disclaimer on its public database for grandfathered determinations for tobacco products that are based upon voluntary submissions.[15] The PMTA List thus could include a disclaimer stating: "This list identifies deemed ENDS products on the market as of August 8, 2016 for which a PMTA was submitted on or before the September 9, 2020 compliance date. This database contains information that was voluntarily submitted for disclosure by ENDS product manufacturers. This database does not list all products for which PMTAs were submitted by the compliance date."

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The undersigned appreciate the opportunity to provide recommendations to ensure the robust enforcement of FDA's September 9, 2020 submission deadline for deemed, currently marketed products. We support FDA's efforts to ensure that novel tobacco products in the marketplace are subject to a rigorous, science-based premarket review process. We stress that manufacturers must be transparent about their compliance with the September deadline, and expect many companies to notify distributors, wholesalers, retailers, and other stakeholders about their submitted PMTAs and the currently marketed products covered by those applications.

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website. *FDA, Draft Guidance for Industry, Enforcement Policy for Certain Marketed Tobacco Products** 2 (Feb. 2019); *FDA, Guidance for Industry and Tobacco Retailers, Enforcement Policy for Certain (Provisional) Tobacco Products that FDA Finds Not Substantially Equivalent* 1-2 (Sept. 2015).

[15] *See generally FDA, Guidance for Industry, Establishing That a Tobacco Product Was Commercially Marketed in the United States as of February 15, 2007* (Sept. 2014); FDA, "Grandfathered Tobacco Products," https://www.fda.gov/tobacco-products/market-and-distribute-tobacco-product/grandfathered-tobacco-products#voluntary. The disclaimer on the database for grandfathered product determinations states: "This database contains grandfathered determination information from standalone Grandfathered Submissions that were voluntarily submitted to CTP. This database does not list all grandfathered tobacco products." *See* FDA, "Standalone Grandfathered Determinations," https://www.accessdata.fda.gov/scripts/ctpGnd/.

Nonetheless, the PMTA List will be a necessary element of FDA enforcement of the premarket-review requirements of the Tobacco Control Act, particularly beyond September 9, 2020. We urge FDA to use its authority to disclose which ENDS products are the subject of timely submitted PMTAs to better facilitate implementation and enforcement of the premarket requirements as well as the public health goals of the Tobacco Control Act.

Respectfully submitted,

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