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American
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June 3, 2022

Michele Mital
Acting Director, Center for Tobacco Products
U.S. Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993-0002

RE: Disclosure of Synthetic Nicotine Tobacco Products for Which Premarket Applications were Timely Submitted to FDA

Dear Director Mital:

On March 15, 2022, Congress enacted H.R. 2471, the Consolidated Appropriations Act, 2022, which amended the Food, Drug and Cosmetic Act (FD&C Act) to subject synthetic nicotine products to the same regulation by the U.S. Food and Drug Administration (FDA) as tobacco-derived nicotine products. One critically important aspect of this new legislation is that synthetic nicotine products must now undergo FDA review and obtain premarket authorization to remain on or enter the market. Products already on the market had until May 14, 2022, to submit premarket applications or be subject to FDA enforcement.¹

The undersigned organizations write to urge the FDA to disclose the information necessary for the public to know the synthetic nicotine products for which premarket applications have been timely submitted and are undergoing the premarket review. At a minimum, FDA should promptly disclose to the public a list of synthetic nicotine products, and their manufacturers, for which applications for marketing orders were timely submitted.²

¹ Synthetic nicotine products for which timely and complete applications were submitted may remain on the market until July 13, 2022 unless FDA previously issued a marketing denial order, refused to file an application because it was not complete, or withdrew a marketing order for a previous version of the product that used nicotine derived from tobacco.

² This should include disclosure of all products (and their manufacturers) for which Premarket Tobacco Product Applications (PMTAs), Substantial Equivalence (SE) Reports and Requests for an Exemption from SE (EX REQ) were submitted on or before May 14, 2022. A Freedom of Information Act (FOIA) request was submitted to FDA on May 31, 2022 and received by the Center for Tobacco Products on June 1, 2022. This FOIA request was assigned reference number FDA22083888.

The disclosure of this information is necessary to allow the public to determine the extent of industry compliance with the Congressionally-mandated application deadline, as well as to monitor the FDA's enforcement of the marketing transition period ending July 13, 2022 going forward. Unless FDA publicly identifies the products and manufacturers that met the application deadline, the public cannot know whether products that remain on the market following May 14 have complied with the law. Such disclosure is also necessary for the public to adequately assess whether FDA is enforcing the H.R. 2471 deadlines and the statutory requirement that all synthetic nicotine products be subject to premarket review.

Because the disclosures we seek involve synthetic nicotine products that were already on the market, releasing this information to the public would not result in disclosure of trade secrets or confidential commercial information. The fact that a product already on the market is the subject of a legally required PMTA, SE Report or EX REQ should not be regarded as a trade secret or confidential commercial information.³ Rather, the requested disclosures are the minimum necessary for the public to determine the extent of industry compliance with the H.R. 2471 application deadline and FDA enforcement of that deadline, the end of the transition period, and the statutory requirement of premarket review.

Thank you for your consideration,

American Academy of Pediatrics
American Cancer Society Cancer Action Network
American Heart Association
American Lung Association
Campaign for Tobacco-Free Kids
Parents Against Vaping e-cigarettes (PAVe)
Truth Initiative

Cc: The Honorable Dr. Robert M. Califf, M.D., FDA Commissioner

³ Indeed, in the closely analogous circumstances of premarket notifications for certain medical devices, FDA will disclose publicly whether there exists a premarket notification submission for a device that is already on the market. 21 C.F.R. §807.95(a)(1).