April 23, 2020

Dr. Stephen Hahn, M.D.
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993-0002

RE: Disclosure of Tobacco Products for Which Premarket Applications Filed by the Court-Ordered Deadline

Dear Dr. Hahn:

In light of the skyrocketing youth e-cigarette epidemic, and concerns that smoking and vaping may increase the risk of severe complications from COVID-19,[1] it is more critical than ever that new tobacco products be subject to statutorily-required public health review by the Food and Drug Administration (FDA) and that products for which timely and complete applications are not filed be removed from the marketplace as quickly as possible.

The undersigned organizations write to urge the FDA to disclose the information necessary for the public to know the products for which premarket applications have been filed and are undergoing the premarket review mandated by the Family Smoking Prevention and

[1] Dr. Nora, Vokow, Director of the National Institute on Drug Abuse, has observed that "[b]ecause it attacks the lungs, the coronavirus that causes COVID-19 could be an especially serious threat to those who smoke tobacco or marijuana or who vape." https://www.drugabuse.gov/about-nida/noras-blog/2020/03/covid-19-potential-implications-individuals-substance-use-disorders

Tobacco Control Act, as well as to identify those products still being marketed in violation of that statute.

As you are aware, on July 12, 2019, the U.S. District Court for the District of Maryland, in *American Academy of Pediatrics, et al. v. FDA*,[2] entered a Remedial Order directing the FDA to require that, for new tobacco products subject to FDA jurisdiction by virtue of the Deeming Rule, including e-cigarettes and cigars, that were on the market as of the August 8, 2016 effective date of that Rule, applications for marketing orders must be filed within the next 10 months, i.e., by May 12, 2020. The Remedial Order also provided that those new products for which applications are not filed by that date shall be subject to FDA enforcement actions.[3] Recently, the District Court, on an unopposed motion by the FDA, revised its Remedial Order to extend the application deadline by 120 days to September 9, 2020, due to the extraordinary exigencies of the COVID-19 pandemic.

We write to urge the FDA, following September 9, to promptly disclose to the public the new tobacco products, and their manufacturers, for which applications for marketing orders were timely filed by that date.[4] We also urge the FDA to disclose a list of all products that FDA exempts from the premarket application requirement for "good cause," if any, as provided for in the Remedial Order, with a statement of the basis for FDA's finding of "good cause". Finally, we urge disclosure of any FDA list of all new and deemed tobacco products, including e-cigarettes and cigars, currently on the market for which applications must be filed by September 9 to remain on the market and not be subject to FDA enforcement actions. If this list does not exist, please disclose that fact and provide an explanation of why such a list has not been compiled by the agency.

The disclosure of this information is necessary to allow the public to determine the extent of industry compliance with the court-ordered deadline for filing premarket applications, as well as to monitor the FDA's enforcement of the September 9 deadline going forward. Unless the FDA publicly identifies the products and manufacturers that met the filing deadline, the public cannot know whether products that remain on the market following September 9 have complied with the condition set by the federal court to allow products to continue on the market without being subject to FDA enforcement actions. Such disclosure also is necessary for the public to adequately assess whether the FDA is enforcing the September 9 deadline and the statutory

[2] 399 F.Supp. 3d. 479 (D. Md. 2019), *appeal docketed*, Oct. 30, 2019 (4th Cir).

[3] FDA's January 2, 2020 Guidance for Industry also indicated that FDA was adopting the May 12, 2020 deadline as a matter of FDA enforcement policy for e-cigarettes, independent of the court's Remedial Order. FDA Guidance for Industry: Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on the Market Without Premarket Authorization (January 2, 2020), at 27 https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-priorities-electronic-nicotine-delivery-system-ends-and-other-deemed-products-market.

[4] This should include disclosure of all products (and their manufacturers) for which Premarket Tobacco Product Applications (PMTAs), Substantial Equivalence (SE) Reports and requests for SE Exemption were filed on or before September 9, 2020. It would not include such applications, reports and requests for which FDA issued "refused to accept" and "refused to file" determinations, nor such submissions that were withdrawn.

requirement that all new tobacco products be subject to premarket review, consistent with the court's Remedial Order.

The disclosure by the FDA of a list of new and deemed products for which a September 9 filing was necessary to continue on the market free of possible FDA enforcement actions also would materially assist the public in knowing whether new tobacco products continue to be marketed even though their manufacturers did not meet the September 9 deadline.

Because the disclosures we seek involve new tobacco products that are already on the market, releasing this information to the public could not possibly 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 SE exemption request should not be regarded as a trade secret or confidential commercial information.[5] Rather, the requested disclosures are the minimum necessary for the public to determine the extent of industry compliance with the September 9 deadline and FDA enforcement of that deadline and the statutory requirement of premarket review.

We urge the FDA to affirmatively respond to this request promptly and to announce that it plans to disclose the requested information shortly after September 9.

Thank you for your consideration,

Action on Smoking & Health (ASH)
African American Tobacco Control Leadership Council
Allergy & Asthma Network
American Academy of Family Physicians
American Academy of Oral and Maxillofacial Pathology
American Academy of Oral and Maxillofacial Radiology
American Academy of Oral Medicine
American Academy of Pediatrics
American Association for Cancer Research
American Association for Dental Research
American Association for Respiratory Care
American Cancer Society Cancer Action Network
American College Health Association
American College of Cardiology
American Dental Education Association
American Federation of School Administrators
American Heart Association
American Lung Association

[5] 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).

American Public Health Association
American School Health Association
American Society of Addiction Medicine (ASAM)
Association for Clinical Oncology
Association of Schools and Programs of Public Health
Association of State and Territorial Health Officials
Asthma and Allergy Foundation of America
Big Cities Health Coalition
Campaign for Tobacco-Free Kids
Catholic Health Association of the United States
Children's Hospital Association
ClearWay Minnesota
Community Anti-Drug Coalitions of America (CADCA)
Counter Tools
Eta Sigma Gamma – National Health Education Honorary
GO2 Foundation for Lung Cancer
March of Dimes
National African American Tobacco Prevention Network
National Association of County and City Health Officials (NACCHO)
National Association of Pediatric Nurse Practitioners
National Association of School Nurses
National Association of Secondary School Principals
National Association of Social Workers
National Center for Health Research
National Education Association
National Network of Public Health Institutes
North American Quitline Consortium
Oncology Nursing Society
Parents Against Vaping e-cigarettes (PAVe)
Prevent Cancer Foundation
Public Health Solutions
Society for Cardiovascular Angiography and Interventions
Students Against Destructive Decisions (SADD)
The Society of State Leaders of Health and Physical Education
Truth Initiative

CC: Mitch Zeller, Director, FDA Center for Tobacco Products