United States Senate
WASHINGTON, DC 20510

May 28, 2020

Stephen Hahn, MD
Commissioner
Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993-0002

Dear Commissioner Hahn:

We write to urge you to disclose to Congress and make available to the public a list of marketed e-cigarettes and other deemed tobacco products for which the Food and Drug Administration (FDA) receives premarket applications by September 9, 2020. Such a list would inform consumers and policymakers about the unauthorized e-cigarettes and other deemed tobacco products that FDA is permitting for distribution and sale after that date. It would also aid enforcement efforts to remove those unauthorized products that are not permitted for distribution and sale after that date. To fight the surging epidemic of youth tobacco use effectively and to hold tobacco companies accountable to following the law, we need transparency from the FDA.

The Family Smoking Prevention and Tobacco Control Act requires new tobacco products to undergo a scientific review by FDA before they can be marketed. Manufacturers are required to submit applications to FDA that demonstrate the new product is "appropriate for the protection of the public health" or is substantially equivalent to a product that was on the market as of February 15, 2007. This premarket review requirement was intended to put an end to a dangerous legacy of tobacco companies introducing new products to the market that were more addictive, more appealing to youth, and more harmful than what was previously available.

Many of us have strongly criticized FDA's decision to use its enforcement discretion to delay review of tobacco products, allowing e-cigarettes and many other new tobacco products to remain on the market without undergoing the premarket review required under the Tobacco Control Act. This delay is responsible for what the FDA and the Surgeon General have called an "epidemic" of youth tobacco use. More than five million youth currently use e-cigarettes, and use of e-cigarettes by high school students soared from 11.7 percent in 2017 to 27.5 percent in 2019. As a result of the delay, an array of cheap, flavored cigars and other tobacco products harmful to public health also have remained on the market without FDA review.

As a result of a federal court order, the delay is approaching its end. The court originally set a deadline of May 12, 2020 for manufacturers of e-cigarettes and other deemed tobacco products to submit product applications to FDA, although at FDA's request, the court extended that deadline to September 9, 2020. After the deadline, the agency can allow for a one-year grace period for products that are the subject of timely applications, unless a negative action is taken by the FDA on an application during that time. All e-cigarettes and other deemed tobacco products that are not the subject of an application submitted by September 9, 2020 will no longer

be subject to a grace period; those products will be subject to enforcement action for lacking the premarket authorization required by law.

While the further delay is regrettable, the approaching deadline creates an important opportunity for FDA finally to remove from the market products that are harmful to kids and public health. A critical first step in FDA's implementation of the premarket review requirement is to ensure that products for which FDA does not receive applications by September 9, 2020 are quickly removed from the market. We have concerns about FDA's past efforts to police the marketplace, particularly its inadequate efforts to remove certain e-cigarettes and other deemed tobacco products from the market that were never subject to the grace period and lacked the required premarket review. FDA must do better in enforcing the September 9 deadline.

We request FDA develop a list of marketed tobacco products for which it receives a premarket application by September 9, 2020, share that list with Congress, and make that list available to the public. Specifically, we request this list include all marketed deemed tobacco products for which a manufacturer has filed a premarket application – including Premarket Tobacco Product Applications (PMTAs), Substantial Equivalence (SE) reports, and SE exemption requests – as well as any products FDA exempts from the premarket application requirement for "good cause," as provided for in the federal court order.

Without such a publicly disclosed list, only FDA will know if a manufacturer has filed an application for a particular product by September 9, 2020. Meanwhile, consumers, public health and medical groups, policymakers, and others will be left in the dark as to whether a product available for sale after that date is subject to the grace period or subject to enforcement action. If FDA published a list of marketed products for which FDA has received applications, policymakers will be able to assess industry compliance with the premarket review requirement and FDA enforcement of that requirement; consumers will be able to make better-informed decisions about purchasing e-cigarettes and other deemed tobacco products; and the public will be able to aid enforcement efforts by alerting FDA to marketed products that are no longer subject to the grace period.

Publicly disclosing a list of marketed products for which FDA has received applications would not reveal any trade secrets or confidential commercial information. The receipt of an application here is not like FDA's customary receipt of an application for a product that is not yet on the market. The applications here are for products that have been on the market since at least August 8, 2016, continue to be on the market, and will remain on the market pending FDA review. FDA need only list enough information to identify the existence of an application, the name of the marketed product that is the subject of the application, and the name of the manufacturer, packer, or distributor declared on the product label currently available for retail sale.

Although limited, such information is critical for the public health. The public health benefits of the premarket review requirement in the Tobacco Control Act will be further eroded if FDA does not quickly remove from the market products for which manufacturers fail to file applications by September 9, 2020. Publicly disclosing information on which marketed products have filed

applications with FDA will help hold manufacturers accountable and facilitate enforcement of the law by FDA. This information should not be withheld from Congress or the public.

Sincerely,

Patty Murray
United States Senator

Sherrod Brown
United States Senator

Richard J. Durbin
United States Senator

Sheldon Whitehouse
United States Senator

/s/ Jack Reed

Jack Reed
United States Senator

Edward J. Markey
United States Senator

Jeffrey A. Merkley
United States Senator

Margaret Wood Hassan
United States Senator

Richard Blumenthal
United States Senator

Elizabeth Warren
United States Senator