



September 1, 2020

Dr. Stephen M. Hahn
 Commissioner of Food and Drugs
 Food and Drug Administration
 10903 New Hampshire Ave
 Silver Spring, MD 20993

Commissioner Hahn:

On behalf of taxpayers and consumers across the country, the undersigned 15 organizations strongly urge you to issue immediate guidance regarding the deferral of enforcement actions for Premarket Tobacco Authorization (PMTA) processes related to electronic nicotine delivery (ENDS) products under the Tobacco Control Act. Doing so will protect the thousands of businesses who sell ENDS, as well as the millions of adults whose lives have been improved and likely saved through the use of tobacco alternatives. Providing this guidance will provide significant public health benefits by giving smokers more options to quit their deadly habit. While we recognize that the August 31 statement by the FDA stating that the agency "may continue to defer enforcement of the premarket requirements for up to one year," is a positive development, it still falls far short of what is needed to provide certainty to manufacturers and retailers.

Set to come into effect on September 9th, ENDS-related PMTA requirements have the potential to bankrupt almost all small businesses engaged in the sale of these products. As a result, millions of former smokers who rely on these products are highly likely to return to deadly combustible cigarettes. These policies will pose significant hardships for more than 14,000 businesses [employing more than 160,000 persons across the United States](#) and generating more than \$25 billion in economic activity. PMTA requirements will also pose considerable consequences for public health, given that tobacco smoking is the leading cause of preventable premature disease and death in the U.S.

Under the present regulatory framework, the "deeming" rule classifies vaping products as tobacco products despite these ENDS containing no tobacco. As a result of this classification, the FDA mandates that all businesses who sell ENDS products must undertake the PMTA process for all products sold to the public. According to a conservative estimate by the Food and Drug Administration (FDA), the estimated cost of these regulations is ["around \\$117,000 to around \\$466,000"](#) per product. With an average manufacturing retailer selling dozens, if not hundreds, of different flavors (each at various concentrations), the cost for any small business could easily be in the tens of millions of

dollars. This is simply unaffordable for thousands of small sellers. This is simply unaffordable for thousands of small sellers. Despite promises from HHS to introduce a streamlined PMTA process for small manufacturers, which might address this dire situation, no such streamlined pathway has materialized.

Furthermore, regulations imposed by the FDA go significantly beyond statutory requirements. These regulations impose an impossible burden, which, despite promises by agency representatives to rectify the situation, has still not been addressed. The FDA retains discretion regarding enforcement of the PMTA process depending on “whether the particular enforcement action requested best fits the agency’s overall policies.” Consistent with this, the FDA has previously issued guidance exempting products such as premium cigars from endorsement of PMTA mandates. Additionally, manufacturers may request deferral of enforcement for products provided that the manufacturer’s marketing does not and will not target underage persons.

If the FDA continues to refuse to delay the September 9th PMTA implementation date or create streamlined processes for small businesses, discretion must be granted to protect small businesses and the former smokers who rely upon them. The FDA can and must issue guidance that eligible companies (e.g. those with sales of under \$10 million) who provide a good faith basic submission by the deadline should be excused from regulatory enforcement. Under this framework, companies would supply basic information including the listing and quantities of ingredients and materials, description of manufacturing process, and evidence of compliance with other relevant regulations. Furthermore, these companies could disclose youth prevention guidelines and *population level* studies, if available, on the impact of product ingredients.

This streamlined, modified approach would keep ENDS sellers in business and thus be beneficial to public health. The weight of the evidence overwhelmingly demonstrates that e-cigarettes are an effective safe way for people to quit smoking. ENDS products are “around [95 percent less harmful than smoking](#)” combustible tobacco, and [numerous studies](#) have shown that e-cigarettes are considerably more effective than traditional nicotine replacement therapies such as nicotine gums and patches. Similarly, open system ENDS products, such as those predominantly sold in vape stores, are overwhelmingly used by older, former smokers. As such, these policies would not contradict the priorities of the FDA in combatting the use of ENDS products by young Americans. Similarly, through exercising discretion on an individual manufacturer level, certainty could also be provided for those manufacturers who are able to provide levels of information that go above and beyond these minimum requirements.

As the United States continues to grapple with the effects of the Covid-19 pandemic, it is imperative that the FDA focuses its priorities on ensuring the best public health outcomes for the country. In doing so, the agency should make sure that regulatory enforcement does not take away resources from laboratories struggling under the workload of Covid-19 testing. The FDA should cease focusing on unnecessary individual product level testing

when aggregate or population level data may be available, or where evidence from identical products from other manufacturers may be substituted in.

In the interests of public health and the economic health of small businesses across the country, we strongly urge you to issue guidance to allow small ENDS manufacturers to request deferral of PTMA enforcement once basic requirements are met.

Sincerely,

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