October 15, 2024

Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Docket No. FDA-2024-N-1111 for "Submission of Food and Drug Administration Import Data in the Automated Commercial Environment for Certain Tobacco Products

Dear FDA Staff:

The Energy Marketers of America (EMA) respectfully file these comments supporting FDA's proposed rule requiring that Submission Tracking Numbers ("STNs") be submitted in the Automated Commercial Environment ("ACE") at the time of entry for Electronic Nicotine Delivery Systems ("ENDS") being imported or offered for import into the U.S.

Introduction
EMA is a federation of 49 state and regional trade associations representing energy marketers throughout the United States. EMA member companies supply 80 percent of all finished motor and heating fuel products sold nationwide including gasoline, diesel fuel, heating fuels and biofuels such as renewable diesel and biodiesel. EMA members also own and operate the majority of gas stations nationwide, which are mostly small family-owned and operated businesses. The retail motor fuels market is the most competitive marketplace in the country. Retailers post their prices on big signs where a one-penny difference can decide where customers choose to fill up. Because gasoline retailers operate in such a competitive environment, the higher prices climb, the further margins are squeezed. Gas station retailers are also hurt by high fuel prices.

In addition, the majority of the major integrated oil companies have removed themselves from the retail gasoline business. Of the 150,000 U.S. retail gasoline locations, the vast majority are owned by independent motor fuel marketing businesses. While those small businesses may sell a particular brand of gasoline, they do not share in any of the profits (or losses) generated by refiners and oil companies. As such, EMA represents many of the tens of thousands of small businesses nationwide that, in addition to providing fuel, include convenience store outlets that derive a substantial percentage of their revenues from tobacco products.

Unfortunately, FDA's efforts to cut down on the illicit tobacco/nicotine market have not succeeded. Limited enforcement actions have allowed illicit market actors to expand beyond ENDS to other tobacco and nicotine categories. EMA urges the FDA to finalize a Foreign Manufacturer Registration rule; increase the scope of import alerts for detention without physical examination; increase the number of field examinations at ports of entry with high ENDS import volume; and increase the number of random joint inspections with Customs and Border Protection ("CBP").

Create a "Green List" of all Tobacco/Nicotine Products
Specifically, EMA urges the FDA to ensure that the ACE system correctly identifies and allow legal ENDS to be imported by using a "green list" to automatically verify which products are allowed entry into the U.S. marketplace. A "green list" of all tobacco products would serve as an automated verification tool, checking incoming tobacco products against a list of compliant ENDS products that have MGOs or were on the market by 8/8/16 with timely filed PMTAs awaiting a final determination. All other products, aside from those with exemption, should be refused entry. The "green list" should also be published to help Custom Border Patrol know which legal products can be distributed and sold.

Prevent Unscrupulous Manufacturers from Evading Enforcement
Importantly, the FDA and CBP should work together to stop unscrupulous manufacturers who have managed to evade enforcement by mis-labeling shipments, changing brand names, and using other, similar strategies. Currently, the proposed rule only includes "finished ENDS products" and not other tobacco/nicotine products which unscrupulous manufacturers will likely use to evade detection by creating loopholes to sell illegal products in the U.S. For instance, manufacturers and importers may attempt to use ENDS products as a loophole by identifying shipments as being "for further manufacture" when, in reality, they contain illicit finished products to be sold in the U.S. Therefore, the federal government should use all resources necessary such as Civil Monetary Penalties ("CMPs"), customs broker license revocations, liquidated damages to stop illicit actors from using loopholes to evade enforcement. Finally, the FDA should publish enforcement actions on its website to ensure transparency with the public.

Conclusion
The energy marketers represented by EMA's member associations stand ready to assist FDA and state and local officials in doubling down on enforcement efforts to reduce the amount of illicit ENDS from hitting the U.S. market. Transparency, compliance and enforcement efforts are crucial to ensure Americans are protected from illegal ENDS.

Sincerely,

Rob Underwood
President
Energy Marketers of America