October 14, 2024

U.S. Food and Drug Administration
Regulations Comments Desk (SP)
Suite 4100, Strategy Division
Office of Strategy and Communication
National Archives and Records Administration
8601 Adelphi Road
College Park, MD 20740-6001

Dear Sir or Madam:

The National Association of Convenience Stores (NACS) appreciates this opportunity to provide comments on the proposed rule regarding the requirement of submission tracking numbers (STNs) for the import of electronic nicotine delivery systems (ENDS) (the Proposed Rule).

Requiring STNs is an important and necessary step toward ensuring that illicit products do not reach the U.S. market. NACS appreciates the Food and Drug Administration (FDA) taking this important step. Given the scope of the problems of illicit products coming into the United States, as set forth below, NACS recommends that the proposed rule be expanded to cover additional products and that additional actions be taken to stem the tide of these illicit products.

Background on the Convenience and Fuel Retailing Industry

NACS is an international trade association representing the convenience store industry with more than 1,500 retail and 1,600 supplier companies as members, the majority of whom are based in the United States.[1]

The convenience and retail fuels industry employed approximately 2.74 million workers and generated more than $859.8 billion in total sales in 2023, representing 3.1 percent of U.S. gross domestic product. Of those sales, approximately $532.2 billion came from fuel sales alone.

The industry, however, is truly an industry of small business. More than 60 percent of convenience stores are single-store operators. Less than 0.2% of convenience stores that sell gas are owned by a major oil company and about 4% are owned by a refining company. More than 95% of the industry, then, are independent businesses.

Members of the industry process more than 165 million transactions every single day. That means about half the U.S. population visits one of the industry's locations on a daily basis. In fact, 93% percent of Americans live within 10 minutes of one of our industry's locations. These businesses are particularly important in urban and rural areas of the country that might not have as many large businesses. In these locations, the convenience store not only serves as the place to get fuel but is often the grocery store and

[1] Data on the industry comes from the NACS, State of the Industry Annual Report of 2023 Data *available at* *NACS State of the Industry Report® of 2023 Data - Digital License | NACS (convenience.org)*.

center of a community.

Expand the Proposed Rule to Cover Additional Products

The Proposed Rule would require importers of ENDS products to provide STNs which would allow Customs and Border Protection in conjunction with FDA to ensure that the manufacturers of those products have followed the rules requiring timely submission of premarket approval applications (PMTAs) for their products. Large numbers of ENDS products are flowing into the country today even though manufacturers of many of those products have not followed FDA's rules requiring timely applications.

The Proposed Rule, however, does not address the risk of other deemed products entering the market (such as, but not limited to, nicotine pouches) that are not in compliance with FDA rules. FDA should do what it can to preempt this risk. The history of deemed products shows that many manufacturers are willing to take advantage of any loopholes they can find in the relevant regulatory and enforcement regime. Doing so has proved lucrative for those businesses. It would be far easier and less costly for FDA to act before such risks manifest themselves in large numbers rather than waiting for an illicit market to develop which may prove difficult to unravel.

Ensure the Efficiency of the Proposed Rule

Today, efforts to interdict illicit ENDS products are hampered by a lack of clear information. FDA should provide CBP and the industry with a clear database or list at the product level (not just manufacturers) showing every product for which a timely premarket approval application was submitted and that has not been the subject of a final marketing denial order that is no longer being challenged. A clear list of products that may be imported without incident will facilitate the import of products that do not present enforcement issues and allow FDA and CBP to focus on products that should be interdicted.

In addition to having a list of timely applications, FDA should provide a list or database at the product level of those ENDS products that have received a marketing denial order that is no longer being challenged. This list must include actual product names and not just manufacturer names to ensure that the right products are identified at the time of import. FDA should also develop a listing of known ENDS products for which no timely application was filed. As with the list of products that can be imported because timely applications were submitted, this tool would help to quickly identify problem imports that should not be allowed into the United States.

Require Foreign Manufacturers to Register

As part of the Proposed Rule, FDA should require all foreign manufacturers of deemed tobacco products to register with the agency. Legitimate manufacturers that comply with FDA's rules should not have concerns about registering – those that are skirting the rules likely will have concerns. With the manufacturers properly registered, FDA and CBP will more easily be able to identify imports that may be in violation of the rules. For example, imports with misleading or inaccurate information regarding the product being imported might be identified by the manufacturer. Having fuller data about the manufacturers that have submitted timely applications (and perhaps those who haven't as well) will provide additional helpful data points to enhance enforcement efforts.

Provide More Detailed Rules

The Proposed Rule sets an important baseline and will make progress toward cleaning up the illicit market, but more can be done. For example, the Proposed Rule should not be limited to finished ENDS

products. Manufacturers and importers may attempt to evade the Proposed Rule by mislabeling finished products as requiring further manufacturing. One part of dealing with this type of problem would be requiring that importers provide a letter from a domestic manufacturer indicating that they are going to use any unfinished products in their manufacturing processes and the STN of the finished products that they plan to produce from those imports. Such a requirement could provide the information necessary to ensure that labeling products as unfinished does not provide a loophole for importers of illicit products. FDA should anticipate this and similar evasion efforts and ensure they are addressed in the Proposed Rule.

Similarly, FDA should specify how it will identify and block other attempts to mislabel products to avoid detection. Close collaboration with CBP may be an effective way to identify the best methods for addressing these situations.

The Proposed Rule also does not identify the extent of enforcement that will occur in this area. The extent of fines, who will receive such fines, the fine schedule, and whether enforcement actions will be made public should be laid out with clarity before the Proposed Rule is finalized. These actions can make a large difference in the degree of deterrence that this new policy will engender.

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We appreciate this opportunity to comment on the Proposed Rule and urge the FDA to modify and finalize a rule that is as effective as possible.

Sincerely,

Doug Kantor
NACS General Counsel