October 15, 2024

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

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

The American Academy of Pediatrics, American Cancer Society Cancer Action Network, American Heart Association, American Lung Association, Campaign for Tobacco-Free Kids, and Truth Initiative submit these comments in response to the proposed rule for Submission of Food and Drug Administration Import Data in the Automated Commercial Environment for Certain Tobacco Products, 89 Fed. Reg. 66,647 (Aug. 16, 2024). This proposed rule would require that the Submission Tracking Number (STN) for electronic nicotine delivery system products (ENDS products or e-cigarettes) be submitted into the Automated Commercial Environment (ACE) or another U.S. Customs and Border Protection authorized electronic data interchange at the time the products enter the U.S. We support this proposed rule and FDA's efforts to improve detection of and, enforcement against, unauthorized imported ENDS products, many of which are flavored disposables with great youth appeal. However, as detailed below, we urge FDA to clarify that, consistent with the Family Smoking Prevention and Tobacco Control Act (TCA), it and its enforcement partners will limit entry to only those new tobacco products that have received marketing authorization. We also urge FDA to expand the rule to apply to all tobacco products, as defined in the TCA and 21 CFR 1114.3. Finally, we urge FDA and its enforcement partners to swiftly take several additional actions to clear the market of unauthorized ENDS products.

I. Clarify that FDA and Its Enforcement Partners Will Limit Entry to Only Those New Tobacco Products with FDA Marketing Authorization

Under the proposed rule, if a complete STN for an ENDS product is submitted into ACE at the time of entry and that STN matches the information in FDA's databases, "the entry of that ENDS product may be eligible for a 'May Proceed' using an automated admissibility review by FDA." 89 Fed. Reg. at 66,651. According to the proposed rule, this "will help to expedite FDA's import review process and increase the likelihood of an entry of an ENDS product with a currently effective marketing authorization receiving an automated 'May Proceed.'" *Id.* at 66,650.

It is critical that FDA and Customs and Border Protection (CBP) prohibit the entry of all new tobacco products lacking FDA authorization.[1] Requiring importers of ENDS products (and as detailed below, other new tobacco products) to submit STNs at time of entry is an important first step. However, given that FDA assigns STNs to all new tobacco products that have applied for FDA marketing authorization, *id.* at 66,649, many unauthorized products, including those that have received denial orders and those with unresolved pending applications, have STNs. FDA should clarify – and act to ensure – that it and its enforcement partners (e.g., CBP) will only allow a new tobacco product to enter the country if that product has an STN associated with an FDA marketing order (e.g., marketing granted order, substantial equivalence order, found exempt order).

While FDA has stated that "[t]o legally market a new tobacco product in the United States, a company must receive a written marketing order from FDA,"[2] and FDA Center for Tobacco Products' (CTP) Director Dr. Brian King recently testified that "there's no safe harbor for simply submitting an application . . . [,]"[3] the undersigned are aware of no enforcement actions that have been taken against products with pending applications. This policy, which allows unauthorized e-cigarettes, many of them flavored, to remain on the market illegally, is contrary to the statute and harmful to public health. Rejecting entry for all unauthorized new tobacco products would be an important step toward remedying this situation and enforcing the TCA premarket order requirement.

II. Apply the Rule to All New Tobacco Products

Under the proposed rule, submission of an STN is only required for ENDS products, but not other types of new tobacco products. According to FDA, the scope of the rule is limited in this way because:

> Currently, due to FDA's import program's limited resources, the automated look up validation process (the part of FDA's import systems that matches the STN with information in our databases) is only programmed for STNs for ENDS products. Thus, this proposed rule is limited to ENDS products because, at this time, the FDA automated look up validation process can only perform electronic verification of the STN for ENDS products.

---

[1] The TCA defines a "new tobacco product" as any tobacco product that was introduced or modified after February 15, 2007. 21 USC § 387j(a)(1). Before they can be legally marketed, all new tobacco products must receive an authorization order under one of three pathways: Premarket Tobacco Product Application, Substantial Equivalence, or Exemption from Substantial Equivalence. *Id.* § 387j; *see also* 89 Fed. Reg. at 66,650.

[2] FDA, *Tobacco Products Marketing Orders*, https://www.fda.gov/tobacco-products/market-and-distribute-tobacco-product/tobacco-products-marketing-orders#:~:text=on%20Metrics%20%26%20Reporting.-,Marketing%20a%20New%20Tobacco%20Product,does%20not%20apply%20to%20tobacco.

[3] Hearing at 42:24, *Evaluating FDA's Human Foods and Tobacco Program Before the Subcomm. on Health of the H. Comm. on Energy and Commerce*, 118th Cong. (Sept. 10, 2024), https://www.youtube.com/watch?v=yK8y5bO-2ik.

89 Fed. Reg. at 66,651.

It is important that the Final Rule require submission at the time of entry of STNs for all new tobacco products, not just ENDS products. While the problem of unauthorized products is particularly acute and massive in the ENDS marketplace, the failure to properly enforce the TCA's premarket review requirements is unfortunately not limited to e-cigarettes. As public health groups have repeatedly reported to FDA, there are many examples of cigarettes, smokeless tobacco, and cigars that have been promoted as new to the market after the February 15, 2007 statutory cut-off date and yet appear to have no marketing orders of any kind.[4] This includes youth-appealing flavored products like Newport Boost menthol cigarettes and White Owl Chocolate & Vanilla Swirl cigars.[5] Newer types of tobacco products, such as nicotine pouches, are also being introduced to the market without the required FDA authorization.[6] To improve enforcement against all unauthorized tobacco products, FDA should make the necessary updates to its automated look up validation process and require submission of STNs at the time of entry for all new tobacco products.

III. Additional Actions Are Needed to Clear the Market of Unauthorized ENDS Products

To date, FDA has authorized only 34 ENDS products and has made it clear that "[t]hese are the only e-cigarette products that currently may be lawfully sold in the U.S."[7] This means that virtually the entire e-cigarette market consists of unauthorized, illegal products, including a wide variety of flavored products (largely disposables) that FDA has found to be highly appealing to youth. This is an unacceptable failure to enforce the TCA that is putting youth at risk. As detailed in a recent letter from 78 public health, medical, education, and community

---

[4] *See, e.g.*, Letter from Action on Smoking & Health et al. to Mr. Mitchell Zeller, Dir., FDA, CTP (Feb. 26, 2016), https://assets.tobaccofreekids.org/content/what_we_do/federal_issues/fda/Coalition%20Letter%20re%20New%20Tobacco%20Products%202.26.16.pdf.

[5] Letter from Action on Smoking & Health et al. to Mr. Mitchel Zeller, Dir., FDA, CTP, on Continued introduction of new menthol cigarettes and flavored cigars without FDA marketing authorization (Aug. 9, 2021), https://assets.tobaccofreekids.org/content/what_we_do/federal_issues/fda/2021_08_10_FDA_Letter_Newport.pdf.

[6] *See, e.g.*, Anuja Majmundar et al., *Nicotine Pouch Sales Trends in the US by Volume and Nicotine Concentration Levels From 2019 to 2022*, 5 JAMA Network e2242235 (2022), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9667333/; FDA, *Searchable Tobacco Products Database*, https://www.accessdata.fda.gov/scripts/searchtobacco/ (last visited Oct. 10, 2024) (showing that no nicotine pouch product has received FDA marketing authorization).

[7] FDA, *Advisory and Enforcement Actions Against Industry for Unauthorized Tobacco Products*, https://www.fda.gov/tobacco-products/compliance-enforcement-training/advisory-and-enforcement-actions-against-industry-unauthorized-tobacco-products.

organizations to FDA, the U.S. Department of Justice (DOJ), and CBP,[8] there must be an intense and coordinated multi-agency federal effort to enforce the law against these illegal products in an effective and equitable manner. The letter details several concrete changes in tobacco enforcement policies and activities to bring this problem under control, including that:

- FDA should move beyond warning letters and make more frequent use of the full range of available enforcement tools, including civil monetary penalties (CMPs), no-tobacco-sale orders, product seizures, import restrictions, injunctive actions, and criminal prosecutions.
- FDA should seek greater penalties in CMP actions, and abandon its apparent current policy of charging companies with only a single violation even where the company may be marketing hundreds or thousands of unauthorized products.
- DOJ must prioritize tobacco product enforcement and streamline the process for bringing injunctive actions.
- CBP and FDA must prioritize detection of unauthorized products, including those that are not declared to be e-cigarettes, an important issue that this proposed rule does not appear to address. As FDA itself has pointed out, many unauthorized e-cigarettes are routinely intentionally mis-declared as various non-tobacco related items such as toys, shoes, battery chargers, and flashlights.[9]
- Enforcement actions must be brought against all parties in the supply chain, including manufacturers, distributors, importers, and retailers.
- FDA must end its broad exercise of enforcement discretion against ENDS products with pending applications.

On June 10, 2024, DOJ and FDA announced the creation of a multi-agency task force to address the illegal distribution and sale of e-cigarettes.[10] While a comprehensive, multi-agency effort is certainly needed to address this issue, it is not clear what, if any, actions the task force has taken to improve enforcement against unauthorized illegal ENDS products, or even that the

---

[8] Letter from Acad. Pediatric Ass'n et al. to Dr. Robert Califf, Commn'r, FDA et al. on Need for Stronger Enforcement Against Unauthorized E-Cigarettes (May 22, 2024), https://assets.tobaccofreekids.org/content/press_office/2024/2024_05_22_coalition-letter-e-cig-enforcement.pdf.

[9] FDA News Release, *Joint Federal Operation Results in Seizure of More than $18 Million in Illegal E-Cigarettes* (Dec. 14, 2023), https://www.fda.gov/news-events/press-announcements/joint-federal-operation-results-seizure-more-18-million-illegal-e-cigarettes?utm_campaign=ctp-compliance&utm_content=pressrelease&utm_medium=email&utm_source=govdelivery&utm_term=stratcomms.

[10] FDA News Release, *Justice Department and FDA Announce Federal Multi-Agency Task Force to Curb the Distribution and Sale of Illegal E-Cigarettes* (June 10, 2024), https://www.fda.gov/news-events/press-announcements/justice-department-and-fda-announce-federal-multi-agency-task-force-curb-distribution-and-sale.

task force is a priority for the participating agencies. For example, in a recent hearing before the House Energy and Commerce Subcommittee on Health, CTP Director King testified that he himself is not on the task force and has not personally attended any of its meetings.[11] Director King was also unable to identify the individual(s) leading the task force.[12]

IV. Conclusion

We support this proposed rule to require the submission of STNs for ENDS products at the time of entry. However, we urge FDA to apply this rule to all new tobacco products and to clarify that it and its enforcement partners will only allow entry to new tobacco products that have FDA marketing authorization. Finally, while this rule is important, additional actions (detailed above) are needed to clear the market of all unauthorized ENDS products.

Sincerely,

American Academy of Pediatrics

American Cancer Society Cancer Action Network

American Heart Association

American Lung Association

Campaign for Tobacco-Free Kids

Truth Initiative

[11] Hearing, *supra* note 3, at 1:48:50

[12] *Id.* at 54:52.