September 14, 2026

Submitted via regulations.gov

RE: Comments in Docket No. FDA-2025-N-7130, "Establishment Registration and Product Listing for Tobacco Products" Proposed Rule, 91 Fed. Reg. 39,168 (June 29, 2026)

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 to the U.S. Food and Drug Administration ("FDA") in response to the Proposed Rule on Establishment Registration and Product Listing for Tobacco Products ("Rule").

As detailed below, our organizations urge FDA to finalize the Rule. We believe the Rule will close a gap in agency information and enable greater FDA oversight of foreign tobacco product manufacturers and their products, enhance FDA's efforts to identify and enforce against illegal e-cigarettes and other tobacco products, and improve implementation of FDA's manufacturing practice requirements for tobacco products. As noted in the Preamble to the Rule, such actions would advance public health by "enabling FDA to better pursue enforcement actions against non-compliant tobacco products," which directly advances the Administration's priorities, as outlined in Executive Order 14212. 91 Fed. Reg. at 39,169.

I. The Rule Would Close a Long-Time Gap in Agency Information and Enable Greater Oversight of Foreign Tobacco Product Manufacturers and Their Products.

The Family Smoking Prevention and Tobacco Control Act ("Tobacco Control Act") requires all manufacturers of tobacco products to register their establishments with FDA and to provide FDA with a list of the products they manufacture, which must be updated biannually. 21 U.S.C. § 387e(b), (i). The Tobacco Control Act also subjects all registered establishments to biennial FDA inspections. *Id.* § 387e(g). These requirements have been in place for domestic manufacturers since shortly after the Tobacco Control Act took effect in 2009, *id.* § 387e(b), but have never applied to foreign manufacturers. The Rule, if finalized, would address this discrepancy by extending the establishment registration and product listing requirements to foreign manufacturers.

Applying these requirements to foreign manufacturers would close "significant gaps in Agency information," 91 Fed. Reg. at 39,169, namely around foreign manufacturers and their

products, and help ensure FDA has foundational information about *all* tobacco products sold in the U.S. (and their manufacturers), regardless of where they are manufactured. *See id.* at 39,172 (The Rule would "improve FDA's understanding of the types of tobacco products being manufactured, the tobacco products sold in the United States, and the location of all establishments engaged in manufacturing them."). Requiring this information will enhance FDA's capacity to monitor foreign-made products' compliance with applicable laws and regulations across the entire supply chain, and allow FDA to take prompt enforcement actions when warranted. It is particularly important to extend these requirements to foreign manufacturers given the evolving tobacco product landscape, in which a greater proportion of newer tobacco product classes, such as e-cigarettes, are manufactured abroad as compared to conventional products, like cigarettes, that are primarily manufactured in the U.S. The Rule will enable FDA to keep pace and best capture the necessary information to optimally regulate these tobacco product classes. To that end, we support FDA's proposal to require the additional contact information for manufacturing establishments' direct accounts, importers, consignees, brand owners, specification developers, and distributors. *See id.* at 31,9178, 39,186. Such information would further increase FDA's knowledge of the industry and enhance the agency's monitoring and enforcement activities.

The Rule would also help ensure that FDA is collecting user fees for all tobacco products entering the U.S. market. By requiring the submission of identifying information about tobacco product manufacturers and their products, the Rule would allow FDA to cross-reference other data sources to verify that user fees have been paid on all tobacco products sold in the U.S. As the sole source of funding for FDA's tobacco activities, user fees are essential to FDA's tobacco regulatory efforts.

Finally, by requiring foreign manufacturers to register, the Rule would allow FDA to inspect foreign manufacturing facilities and to enforce against such noncompliant establishments. *See* 21 U.S.C. § 387e(g) (subjecting all registered establishments to biennial FDA inspections). Inspections serve an important public health function, allowing the agency to directly evaluate manufacturing facilities and document potential violations, such as unsanitary conditions, that may create additional risks beyond those normally associated with tobacco products.

By increasing FDA's visibility into the tobacco industry, particularly around foreign manufacturers and the products they make, the Rule would enable greater FDA oversight of such entities and products, which serves the public health.

II. The Rule Would Strengthen Efforts to Identify and Enforce Against Unauthorized E-cigarettes and Other Tobacco Products.

The most significant challenge the Rule, if finalized, would help address is the sale of illegal tobacco products, a problem that is particularly acute with respect to e-cigarettes. Under the Tobacco Control Act, all new tobacco products—defined as those introduced into the U.S.

after February 15, 2007—must receive FDA authorization prior to entering the market. 21 U.S.C. § 387j(a). Despite this requirement, there are an astounding number of unauthorized products on the market in the U.S., most notably e-cigarettes. One recent study estimated that as of December 2025, nearly 70% of the e-cigarettes sold in convenience and grocery stores in the U.S. were not authorized by the FDA and therefore illegal under federal law.[1] FDA, for its part, estimated in September 2025 that up to 54% of the e-cigarettes sold in the U.S. were illegal.[2] Many of these unauthorized products are manufactured outside of the U.S., particularly China.[3]

Finalizing the Rule would provide FDA with critical information that could facilitate more robust and efficient enforcement against unauthorized tobacco products made abroad. For example, the Rule would require that registrants submit, as part of their product listing, "a reference to the authority for the marketing of the tobacco products" as well as all Submission Tracking Numbers and Product Identification Numbers, which are numbers FDA assigns to identify, respectively, a submission and the particular products included in that submission, such as products identified in a premarket tobacco product application. *See* 91 Fed. Reg. at 39,200-01 (proposed 21 C.F.R. § 1108.24). These requirements would enhance the ability of FDA and its enforcement partners to efficiently verify the authorization status of a foreign-made tobacco product, and to keep such product off the U.S. market if it lacks the authorization order required by the Tobacco Control Act.

Enhanced enforcement efforts against unauthorized e-cigarettes would provide significant public health benefits, particularly to youth. E-cigarettes remain the most commonly used tobacco product among American youth. In 2025, over 1.4 million youth, including 7.1% of high schoolers, reported current e-cigarette use.[4] Many of the e-cigarettes used by youth are unauthorized and manufactured abroad. For example, the four most popular brands of e-

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[1] Varvara Schoute et al., *Sales of Unauthorized E-Cigarettes in the United States, December 2025*, 5 NEJM Evidence 1, 3 (Aug. 11, 2026), https://doi.org/10.1056/EVIDpha2600137.

[2] FDA Statement, *A Statement From FDA Commissioner Marty Makary, M.D., M.P.H.: Encouraging Retailers to Stop Selling Illegal Vapes* (Sept. 30, 2025), https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-marty-makary-md-mph-encouraging-retailers-stop-selling-illegal-vapes.

[3] *See, e.g.*, Chris Kirkham & David Kirkton, *China e-cigarette titan behind 'Elf Bar' floods the US with illegal vapes* (Dec. 6, 2023), https://www.reuters.com/world/china/china-e-cigarette-titan-behind-elf-bar-floods-us-with-illegal-vapes-2023-12-06/ ("More than 90% of the world's vaping devices are manufactured" in China.).

[4] Eunice Park-Lee et al., *Tobacco product use among middle and high school students in the United States: National Youth Tobacco Survey, 2025*, NICOTINE & TOBACCO RES. 1, 3 (2026), https://doi.org/10.1093/ntr/ntag116.

cigarettes among youth (Geek Bar, Elf Bar, Lost Mary, and Raz) have no FDA-authorized products and are owned by foreign companies.[5]

These products pose health risks, particularly to young people. Most e-cigarettes "contain high concentrations of nicotine,"[6] which is "among the most addictive substances used by humans." *Nicopure Labs, LLC v. FDA*, 944 F.3d 267, 270 (D.C. Cir. 2019). According to the U.S. Centers for Disease Control and Prevention, adolescent brains are particularly sensitive to nicotine, and exposure during this critical period can "harm the parts of an adolescent's brain that control attention, learning, mood, and impulse control."[7] Many e-cigarettes also contain other harmful chemicals. The Office of the Surgeon General recently noted that "[r]esearch has detected arsenic along with other toxic metals in vapes, e.g., chromium, antimony, nickel, lead, tin, and aluminum" and that "[i]norganic arsenic and antimony are classified as carcinogenic and can lead to an increased risk of cancer and disruption of hormones."[8] FDA also recently warned that illegal e-cigarettes "frequently contain chemicals such as formaldehyde, lead, and acrolein—materials more commonly found in industrial textiles and pesticides."[9] As former Acting Commissioner of U.S. Customs and Border Protection Pete Flores warned in 2025: "Consumers should understand these e-cigarette products… could be dangerous, produced and adulterated under unsafe conditions."[10]

Because the Rule would provide FDA with information that could strengthen its enforcement efforts against unauthorized tobacco products, particularly foreign-made e-cigarettes, we urge FDA to finalize it.

III. The Rule Would Improve the Implementation of Tobacco Product Manufacturing Practices Requirements.

The requirements imposed by this Rule would provide FDA with more complete data about foreign manufacturers, their facilities, and their tobacco products, which would assist FDA in more efficiently implementing and enforcing current and future tobacco product

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[5] *See id.* at Supplemental Table 3.

[6] Office of the Surgeon General, *Sound the Alarm: Youth Vaping Can Harm* 2 (2025), https://www.hhs.gov/sites/default/files/osg-youth-vaping-data-sheet.pdf.

[7] U.S. Centers for Disease Control and Prevention, *E-Cigarette Use Among Youth* (Oct. 17, 2024), https://www.cdc.gov/tobacco/e-cigarettes/youth.html.

[8] Office of the Surgeon General, *supra* note 6, at 3.

[9] FDA Statement, *supra* note 2.

[10] U.S. Customs and Border Protection, *CBP and FDA seize nearly $34 million of illegal E-Cigarettes during joint operation* (May 22, 2025), https://www.cbp.gov/newsroom/local-media-release/cbp-and-fda-seize-nearly-34-million-illegal-e-cigarettes-during-joint.

manufacturing practice requirements.[11] The information required to be submitted to FDA under the Rule would enable FDA to identify the facilities subject to manufacturing practices requirements, prioritize inspections of such facilities, and link manufacturing deficiencies to specific products. Therefore, the Rule would provide a strong foundation for FDA to impose tobacco product manufacturing practices requirements.

IV. Conclusion

For the reasons outlined above, we urge FDA to finalize the Rule.

Respectfully submitted,

American Academy of Pediatrics

American Cancer Society Cancer Action Network

American Heart Association

American Lung Association

Campaign for Tobacco-Free Kids

Truth Initiative

[11] FDA proposed a rule that would establish such requirements in March 2023, but has not yet finalized it. *See* Requirements for Tobacco Product Manufacturing Practice, 88 Fed. Reg. 15,174 (proposed Mar. 10, 2023). We urge FDA to finalize the Proposed Rule on Requirements for Tobacco Product Manufacturing Practice.