Enforcement Priorities for Certain New Tobacco Products Marketed Without Premarket Authorization

Guidance for Industry

Comments may be submitted at any time for Agency consideration. Electronic comments may be submitted to http://www.regulations.gov. Alternatively, submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD, 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this guidance, contact the Center for Tobacco Products at (Tel) 1-877-CTP-1373 (1-877-287-1373) Monday-Friday, 9 a.m. – 4 p.m. EDT.

Additional copies are available online at https://www.fda.gov/tobacco-products/rules-regulations-and-guidance-related-tobacco-products/guidance-related-tobacco-products. You may send an e-mail request to SmallBiz.Tobacco@fda.hhs.gov to receive an electronic copy of this guidance. You may send a request for hard copies to U.S. Food and Drug Administration, Center for Tobacco Products, Attn: Office of Small Business Assistance, Document Control Center, Bldg. 71, Rm. G335, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Tobacco Products

May 2026

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Guidance for Industry[1]

This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance as listed on the title page.

I. INTRODUCTION

This guidance document describes certain enforcement policies with regard to the marketing of certain electronic nicotine delivery systems and oral nicotine pouch products that do not have premarket authorization.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

II. ENFORCEMENT PRIORITIES POLICY

This guidance applies to the following categories of tobacco products: (1) Electronic nicotine delivery systems (ENDS)[2] that include e-liquids and products that deliver aerosolized e-liquid when inhaled, and (2) oral nicotine pouch products that include nicotine from any source.[3]

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[1] This guidance was prepared by the Office of Compliance and Enforcement, Office of Science, and Office of Regulations in the Center for Tobacco Products at FDA.

[2] FDA considers vapes or vape pens, personal vaporizers, e-cigarettes, cigalikes, e-pens, e-hookahs, e-cigars, and e-pipes that contain nicotine from any source to be ENDS. ENDS products fall within the definition of "tobacco product" under section 201(rr) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and are subject to the tobacco product authorities in chapter IX of the FD&C Act. Components and parts of ENDS products are also subject to FDA's tobacco products authorities.

[3] Nicotine pouch products are tobacco products that do not meet the definition of smokeless tobacco under 21 USC § 387(18) and contain nicotine which is either extracted from tobacco leaf or chemically synthesized. The pouches do not contain cut ground powdered or leaf tobacco. The pouches are placed between the gum and lip and are not

The Federal Food, Drug, and Cosmetic Act (FD&C Act) provides that new tobacco products[4] may not legally be marketed without premarket authorization.[5] Accordingly, all new tobacco products on the market without authorization are illegally marketed products.

For ENDS and nicotine pouch products marketed without FDA authorization, FDA generally does not intend to prioritize enforcement of the premarket authorization requirement,[6] where the product:

- is subject to an application that is pending, and the application has been accepted and filed[7] or is subject to a supplemental application (sPMTA)[8] that has been accepted and pending for more than 180 days; and

- for nontobacco-flavored ENDS products, if FDA has determined that the application also includes data necessary to evaluate whether such product is appropriate for the protection of the public health.

In FDA's experience thus far, many applications have been administratively incomplete to the extent that they received a refuse to accept (RTA) or refuse to file (RTF) determination and did not proceed to scientific review. Examples of inadequate information for filing include but are not limited to: lack of full tobacco product identification; lack of manufacturing information; lack of test method information and validation; lack of information on all ingredients, constituents, chemicals, and additives; lack of information regarding the health risks of the tobacco product such as the aerosol's level of harmful or potentially harmful constituents (HPHCs) and other constituents that can affect the user's health; and lack of information about the device including principles of operation such as maximum temperature and minimum temperature.

Applications that include the types of studies, data, and evidence identified above are more likely to be applications that have the information necessary for the Agency to determine if the tobacco products in such applications meet the required standards under the law for granting marketing authorization. In turn, by not prioritizing these tobacco products for enforcement, FDA will be able to better allocate its enforcement resources.

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intended to be swallowed. These products fall within the definition of "tobacco product" under section 201(rr) of the FD&C Act and are subject to the tobacco product authorities in chapter IX of the FD&C Act.

[4] 21 U.S.C. 387j(a)(1).

[5] FDA is authorized to require premarket review of new tobacco products under section 910 of the FD&C Act (21 U.S.C. 387j).

[6] For purposes of this guidance, the premarket authorization requirement refers to submitting premarket tobacco applications (PMTA) and supplemental premarket tobacco applications (sPMTA) under part 21 CFR part 1114.

[7] This means the application has successfully completed acceptance and filing review, threshold determinations indicating the application contains sufficient information to support scientific/substantive review, and the acceptance and filing reviews were for an application submitted on or after November 4, 2021, and subject to 21 CFR 1114.27(a) and (b).

[8] sPMTAs are subject to an already authorized PMTA, which has been evaluated under the appropriate for the protection of the public health (APPH) standard. Because it has already been evaluated for APPH, FDA will prioritize enforcement for new PMTAs.

FDA lacks the resources to pursue enforcement against every product that has not received authorization. Products not falling within the categories set forth above are subject to FDA prioritized enforcement. FDA does not intend to prioritize enforcement against products falling within the categories set forth above, unless they have certain presumptively underage-appealing elements such as depicting a cartoon-like fictional character, disguising its nature as a vaping product, or resembling a children's toy, phone, or gaming platform.

FDA will also consider whether a tobacco product presents a significant public health or safety concern that is greater than generally presented by ENDS or nicotine pouch products or other tobacco products, such as a product that has high nicotine content, has serious adverse experiences or a larger number of unexpected associated adverse experiences compared with authorized ENDS or nicotine pouch products, lacks child-resistant packaging (CRP) in accordance with Child Nicotine Poisoning Prevention Act of 2015, or that is a potential fire hazard. Any FDA compliance or enforcement actions would be informed by available information and relevant circumstances and could involve violations related to any ENDS or nicotine pouch product. This includes, but may not be limited to, products that are disposable,[9] cartridge-based,[10] and other ENDS.[11]

III. INFORMATION ON MARKETING STATUS

To promote transparency to consumers, retailers and other industry stakeholders and to assist FDA in efficiently allocating enforcement resources, FDA will create and maintain a public-facing webpage identifying manufacturers and their associated products that FDA generally does not intend to prioritize enforcement against as described above.

FDA recommends that manufacturers of ENDS and nicotine pouch products whose pending applications are in scientific review and who wish to be included on this list should reach out to the regulatory health project manager (RHPM) for such review indicating that the products that are the subject of such application may be made publicly available on such website.

FDA recognizes that much of the information requested by the RHPM will, in many cases, already be contained within the manufacturer's pending PMTA submission. To minimize administrative burden and promote consistency between the webpage listing and the underlying application, FDA requests that manufacturers cross-reference the specific section(s), module(s), or page(s) of their pending PMTA where the relevant information can be found, in lieu of or in addition to providing the information directly. FDA intends to update this webpage on a rolling

[9] For the purposes of this guidance, the term "disposable ENDS product" is defined as ENDS that are pre-filled with e-liquid and not designed to be refilled.

[10] This term is generally used to describe ENDS that use a replaceable cartridge or pod that holds the e-liquid.

[11] FDA's April 2020 guidance "Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on the Market Without Premarket Authorization (Revised)" prioritized enforcement against certain flavored, cartridge-based ENDS due to, for example, data from the 2019 National Youth Tobacco Survey that indicated that youth overwhelmingly preferred those products. The patterns of youth use have changed since then. For example, youth use of flavored disposable ENDS subsequently increased. Results from the 2025 National Youth Tobacco Survey showed that the device types used most often by middle and high school students reporting current e-cigarette use were disposables (66.3%), followed by prefilled or refillable pods or cartridges (12.0%) and tanks or mod systems (5.4%); 16.4% of students currently using e-cigarettes were unsure of the device type used.

basis to reflect changes in manufacturer status, including the addition of manufacturers and products, and, where applicable, the removal of manufacturers and products that no longer fall under this policy.

Providing this information does not guarantee that FDA will not pursue enforcement, on a case-by-case basis, against a particular product.

The fact that an ENDS or nicotine pouch product falls within this enforcement policy in this guidance in no way has a bearing on whether the tobacco product is likely to receive premarket authorization.

Other guidances that have enforcement policies related to ENDS products include Compliance Policy for Limited Modifications to Certain Marketed Tobacco Products, Nov. 2019, and Interpretation of and Compliance Policy for Certain Label Requirement; Applicability of Certain Federal Food, Drug, and Cosmetic Act Requirements to Vape Shops, March 2023.

In addition, with the issuance of the final guidance, FDA is withdrawing the April 2020 guidance titled "Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on the Market Without Premarket Authorization (Revised)." The Agency notes that the April 2020 guidance has information and discussions that continue to be relevant and helpful, such as about the history leading up to those enforcement policies, about ENDS products targeted to youth or whose marketing is likely to promote use of ENDS by youth, and about youth having continued access to ENDS products in the face of legal prohibitions and even after voluntary actions by some manufacturers. FDA is thus including the April 2020 guidance as a reference to this guidance.