



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2026-D-5083]

Enforcement Priorities for Certain New Tobacco Products Marketed Without Premarket Authorization; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing the availability of a final guidance for industry entitled “Enforcement Priorities for Certain New Tobacco Products Marketed Without Premarket Authorization.” 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.

DATES: The announcement of the guidance is published in the *Federal Register* on [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else’s Social Security number, or confidential business information, such as a manufacturing process. Please note that if

you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA-2026-D-5083 for “Enforcement Priorities for Certain New Tobacco Products Marketed Without Premarket Authorization.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out,

will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at:

<https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this guidance to the Center for Tobacco Products, Food and Drug Administration, 10903 New Hampshire Ave., Document Control Center, Bldg. 71, Rm. G335, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the guidance may be sent. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: Samantha Rivera, Food and Drug Administration, 10903 New Hampshire Ave., Document Control Center, Bldg. 71, Rm. G335, Silver Spring, MD 20993-0002, 877-287-1373, CTPRegulations@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a final guidance for industry entitled “Enforcement Priorities for Certain New Tobacco Products Marketed Without Premarket Authorization; Guidance for Industry.” We are issuing this guidance consistent with our good guidance practices (GGP) regulation (§ 10.115 (21 CFR 10.115)). We are implementing this guidance without prior public comment because we have determined that prior public participation is not feasible or appropriate (§ 10.115(g)(2)). We made this determination because this guidance is necessary to promote transparency, and to assist FDA in efficiently allocating enforcement resources by focusing regulatory oversight on products that are more likely to meet the applicable public health standard. FDA’s approach is intended to facilitate an orderly shift toward a regulated market in which compliant products, supported by appropriate evidence and subject to meaningful oversight, can replace unauthorized offerings. FDA expects this approach to encourage the development of applications for potentially less harmful tobacco products and support more timely evaluation and marketing authorization decisions for products that may benefit public health. Although this guidance document is immediately in effect, it remains subject to comment in accordance with FDA’s GGP regulation.

The Federal Food, Drug, and Cosmetic Act (FD&C Act) provides that new tobacco products¹ may not legally be marketed without premarket authorization. Accordingly, all new tobacco products, including those that are ENDS and nicotine pouch products, on the market without authorization are illegally marketed products. This guidance document describes certain enforcement policies with regard to the marketing of certain electronic nicotine delivery systems and nicotine pouch products that do not have premarket authorization.

The guidance represents the current thinking of FDA on “Enforcement Priorities for Certain New Tobacco Products Marketed Without Premarket Authorization; Guidance for

¹ Section 910 of the Federal Food, Drug, and Cosmetic Act defines the term “new tobacco product” to mean “(A) any tobacco product (including those products in test markets) that was not commercially marketed in the United States as of February 15, 2007; or (B) any modification (including a change in design, any component, any part, or any constituent, including a smoke constituent, or in the content, delivery or form of nicotine, or any other additive or ingredient) of a tobacco product where the modified product was commercially marketed in the United States after February 15, 2007.” 21 U.S.C. 387j(a)(1).

Industry.” 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.

II. Paperwork Reduction Act of 1995

This guidance refers to previously approved FDA collections of information. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3521). The collections of information in 21 CFR 1107.1(b) and (c) have been approved under OMB control number 0910-0684; the collections of information under section 910 of the FD&C Act have been approved under OMB control number 0910-0879. The collections of information in section 905(j) of the FD&C Act (21 U.S.C. 387e(j)) have been approved under OMB control number 0910-0673.

III. Electronic Access

Persons with access to the internet may obtain an electronic version of the guidance at <https://www.fda.gov/tobacco-products/rules-regulations-and-guidance-related-tobacco-products/guidance-related-tobacco-products>, <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>, or <https://www.regulations.gov>.

Lowell M. Zeta,

Deputy Commissioner for Strategic Initiatives.

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