4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2026-D-1817]

Flavored Electronic Nicotine Delivery Systems (ENDS) Premarket Applications -- Considerations Related to Youth Risk; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability; request for comment.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft document entitled "Flavored Electronic Nicotine Delivery Systems (ENDS) Premarket Applications -- Considerations Related to Youth Risk; Draft Guidance for Industry." The draft document describes FDA's current thinking and provides recommendations regarding evidentiary considerations for premarket tobacco product applications (PMTAs) for flavored ENDS submitted under section 910 of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

DATES: Submit either electronic or written comments on the draft guidance by **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]** to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance 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-1817 for "Flavored Electronic Nicotine Delivery Systems (ENDS) Premarket Applications -- Considerations Related to Youth Risk; Draft Guidance for Industry." 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, Document Control Center, 10903 New Hampshire Ave., 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 document may be sent. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

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

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft document entitled "Flavored Electronic Nicotine Delivery Systems (ENDS) Premarket Applications -- Considerations Related to Youth Risk; Draft Guidance for Industry."

This draft guidance, when final, is intended to assist persons submitting premarket tobacco product applications (PMTAs) for electronic nicotine delivery systems (ENDS) under section 910 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 387j). The draft guidance, when final, will describe FDA's current thinking on evidentiary considerations relevant to determining whether the marketing of a flavored ENDS product would be "appropriate for the protection of the public health" (APPH), including how FDA generally evaluates the risks and benefits of flavored ENDS to the population as a whole, with particular attention to youth initiation and use.

The draft guidance reflects FDA's concerns regarding the known and substantial risk of youth initiation and use associated with certain flavored ENDS products, especially fruit and candy/dessert/other sweet flavored products, and it is intended to provide additional clarity regarding FDA's risk-proportionate, product-specific approach to assessing non-tobacco flavors. FDA recognizes that ENDS products with flavors other than tobacco may, in certain circumstances, provide benefits to adults who smoke combusted cigarettes, including by facilitating switching away from combusted tobacco products, increasing quit attempts, supporting sustained smoking abstinence, and reducing cigarette consumption among adults who would otherwise continue smoking. Emerging evidence indicates that many adult smokers who use ENDS products to transition away from combusted cigarettes report a preference for non-

tobacco flavors. The draft guidance discusses the scientific evidence FDA may consider regarding differential youth appeal and initiation risks across flavor categories and the types of evidence that may be relevant to demonstrating adult benefit (e.g., complete switching or substantial reduction in combusted cigarette use), including examples of study designs and methods that may help characterize youth appeal and adult orientation of flavors. As FDA gains experience that would be broadly applicable, FDA will consider issuing further guidance in this area, which may include generating scientifically valid evidence characterizing the relative appeal of non-tobacco flavors.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on "Flavored Electronic Nicotine Delivery Systems (ENDS) Premarket Applications -- Considerations Related to Youth Risk." 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.

As we develop any final guidance on this topic, FDA will consider comments on costs or cost savings the guidance may generate, relevant for Executive Order 14192.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3521). The collections of information in 21 CFR 1114 relating to the submission of Premarket Tobacco Product Applications have been approved under OMB control number 0910-0879.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at https://www.regulations.gov, https://www.fda.gov/tobacco-products/rules-regulations-and-

guidance/guidance, or https://www.fda.gov/regulatory-information/search-fda-guidance-documents.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.
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