



## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2024-N-4085]

### Advancing Smoking Cessation: Food and Drug Administration and National Institutes of Health Priorities; Public Meeting; Request for Comments; Reopening of Public Comment Period

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of public meeting; reopening of public comment period.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) published in the *Federal Register* of September 23, 2024, a notice of public meeting scheduled for October 21, 2024, and solicited comments from interested parties. FDA requested that all electronic and written comments be submitted by November 21, 2024. FDA is reopening the public comment period until December 20, 2024, in response to feedback received from interested parties. This action will allow for interested parties additional time to review the meeting transcript and recording to prepare information and comments.

**DATES:** The comment period for the notice of public meeting published on September 23, 2024, (89 FR 77521) is reopened. Either electronic or written comments must be received on or before December 20, 2024.

**ADDRESSES:** You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of December 20, 2024. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

#### *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-2024-N-4085 for "Advancing Smoking Cessation: Food and Drug Administration and National Institutes of Health Priorities." Received comments, those filed in a timely manner (see ADDRESSES), 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.

**FOR FURTHER INFORMATION CONTACT:** Laura Chilaka, Center for Tobacco Products, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 877-287-1373, [TobaccoCessation@fda.hhs.gov](mailto:TobaccoCessation@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** On September 23, 2024, FDA published in the *Federal Register* a notice announcing a public meeting entitled “Advancing Smoking Cessation: Food and Drug Administration and National Institutes of Health Priorities.” Jointly convened by FDA and the National Institutes of Health, this public meeting addressed the need for novel smoking cessation products to help individuals of all ages, including underserved and vulnerable populations, stop smoking.

Interested persons were originally given until November 21, 2024, to submit comments on the public meeting.

FDA has received requests for additional time in submitting comments. Due to the significant interest in the topic and to allow interested parties time to review the meeting transcript and recording, FDA has reopened the comment period until December 20, 2024.

Dated: November 25, 2024.

**P. Ritu Nalubola,**

*Associate Commissioner for Policy.*

[FR Doc. 2024-28205 Filed: 11/29/2024 8:45 am; Publication Date: 12/2/2024]