

Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993-0002, 301-796-2855, email: [AADPAC@fda.hhs.gov](mailto:AADPAC@fda.hhs.gov), or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). A notice in the **Federal Register** about last-minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check FDA's website at <https://www.fda.gov/AdvisoryCommittees/default.htm> and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before the meeting.

**SUPPLEMENTARY INFORMATION:**

*Agenda:* The meeting presentations will be heard, viewed, captioned, and recorded through an online teleconferencing and/or video conferencing platform. The Committee will discuss BLA 761393, condoliase injection submitted by Seikagaku Corp., for the proposed indication of the treatment of radicular leg pain associated with lumbar disc herniation in adults.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available on FDA's website at the time of the advisory committee meeting. Background material and the link to the online teleconference and/or video conference meeting will be available at the location of the advisory committee meeting and at <https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee meeting link. The online presentation of materials will include slide presentations with audio and video components to allow the presentation of materials in a manner that most closely resembles an in-person advisory committee meeting.

*Procedure:* Interested persons may present data, information, or views, orally or in writing, on issues pending before the Committee. All electronic and written submissions to the Docket (see **ADDRESSES**) on or before December 26, 2024, will be provided to the Committee. Oral presentations from the public will be scheduled between approximately 1:15 p.m. and 2:15 p.m. Eastern Time. Those individuals

interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, whether they would like to present online or in-person, and an indication of the approximate time requested to make their presentation on or before December 17, 2024. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. Similarly, room for interested persons to participate in-person may be limited. If the number of registrants requesting to speak in-person during the open public hearing is greater than can be reasonably accommodated in the venue for the in-person portion of the advisory committee meeting, FDA may conduct a lottery to determine the speakers who will be invited to participate in-person. The contact person will notify interested persons regarding their request to speak by December 18, 2024. Persons attending FDA's advisory committee meetings are advised that FDA is not responsible for providing access to electrical outlets.

For press inquiries, please contact the Office of Media Affairs at [fdaoma@fda.hhs.gov](mailto:fdaoma@fda.hhs.gov) or 301-796-4540.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact LaToya Bonner (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at <https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. 1001 *et seq.*). This meeting notice also serves as notice that, pursuant to 21 CFR 10.19, the requirements in 21 CFR 14.22(b), (f), and (g) relating to the location of advisory committee meetings are hereby waived to allow for this meeting to take place using an online meeting platform in conjunction with the physical meeting room (see location). This waiver is in the interest of allowing greater transparency and

opportunities for public participation, in addition to convenience for advisory committee members, speakers, and guest speakers. The conditions for issuance of a waiver under 21 CFR 10.19 are met.

Dated: November 25, 2024.

**P. Ritu Nalubola,**

*Associate Commissioner for Policy.*

[FR Doc. 2024-28210 Filed 11-29-24; 8:45 am]

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**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 11-29-24; 8:45 am]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### Recharter for the National Advisory Council on Nurse Education and Practice

**AGENCY:** Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

**ACTION:** Notice.

**SUMMARY:** In accordance with the Federal Advisory Committee Act, HHS is hereby giving notice that the National Advisory Council on Nurse Education and Practice (NACNEP or Council) is rechartered.

**DATES:** The effective date of the recharter is November 30, 2024.

**FOR FURTHER INFORMATION CONTACT:** Justin Bala-Hampton, Bureau of Health Workforce, HRSA, 5600 Fishers Lane, Rockville, Maryland 20857; 301-443-2765 or [BHWNAACNEP@hrsa.gov](mailto:BHWNAACNEP@hrsa.gov).

**SUPPLEMENTARY INFORMATION:** NACNEP provides advice and recommendations to the Secretary of HHS and Congress on policy matters and the preparation of general regulations concerning activities under title VIII of the Public Health Service Act, including the range of issues relating to the nurse workforce, education, and practice improvement. NACNEP also prepares and submits an annual report to the Secretary of HHS and Congress describing its activities, including NACNEP's findings and recommendations concerning activities under title VIII, as required by the Public Health Service Act. The recharter of NACNEP was approved on October 31, 2024. The filing date for the NACNEP recharter is November 30, 2024. The recharter of NACNEP gives authorization for the Council to operate until November 30, 2026.

A copy of the NACNEP charter is available on the NACNEP website at <https://www.hrsa.gov/advisorycommittees/nursing/about.html>. A copy of the charter can also be obtained by accessing the FACA database that is