burden estimate. FDA appreciates this feedback. Reports submitted through the form help FDA identify potential regulatory misconduct, assess risks to patients, and determine whether further investigation or action is warranted. CDRH prioritizes its review based on potential risks to patients. Depending on the assessment, FDA may take regulatory action, request additional information, or continue monitoring the allegation.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Electronic submission of voluntary allegations to CDRH ..	2,800	1	2,800	0.25 (15 minutes) ..	700

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Our estimated burden for the information collection reflects an overall increase of 75 hours and a corresponding increase of 300 responses. We attribute this adjustment to an increase in the number of submissions we received over the last few years.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–24046 Filed 11–25–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–D–11783]

Individualized Human Genome Editing Products: Considerations for BLA Submission and Postapproval Management; Draft Guidance for Industry; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is extending the comment period for the draft guidance for industry titled ''Individualized Human Genome Editing Products: Considerations for BLA Submission and Postapproval Management'' that appeared in the **Federal Register** of October 28, 2026. In the notice of availability for the draft guidance, FDA requested comments on the draft guidance. The Agency is taking this action in response to requests for an extension to allow interested persons additional time to submit comments.

DATES: FDA is extending the comment period on the draft guidance for industry published October 28, 2026 (91 FR 67838). Either electronic or written comments must be submitted by December 28, 2026.

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 28, 2026. 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–2026–D–11783 for ''Individualized Human Genome Editing Products: Considerations for BLA Submission and Postapproval Management.'' 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: Phillip Kurs, Center for Biologics Evaluation and Research, Food and Drug Administration, 240–402–7911.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of October 28, 2026, FDA published a notice with a 30-day comment period to request comments on the draft guidance for industry titled ''Individualized Human Genome Editing Products: Considerations for BLA Submission and Postapproval Management.'' The Agency has received two requests for a 30-day extension of the comment period. The requests conveyed concern that the current 30-day comment period does not allow sufficient time to develop a meaningful or thoughtful response to the draft guidance.

FDA has considered the request and is extending the comment period for 30 days, until December 28, 2026. The Agency believes that a 30-day extension allows adequate time for interested persons to submit comments on this draft guidance.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–24021 Filed 11–25–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Environmental Health Sciences; Notice of Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Advisory Environmental Health Sciences Council.

The meeting will be partially open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend as well as those who need special assistance, such as sign language interpretation or other reasonable accommodation, must notify the Contact Person listed below in advance of the meeting. The open session will be videocast and can be accessed from the NIH Videocasting and Podcasting website (*https://www.niehs.nih.gov/news/webcasts*).

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Advisory Environmental Health Sciences Council (NAEHSC).

Date: February 19, 2027.

Open: 9:00 a.m. to 12:00 p.m.

Agenda: Discussion of Program Policies and Issues/Council Discussion.

Address: NIEHS/National Institutes of Health, Building 4401, East Campus, 79 T.W. Alexander Drive, Research Triangle Park, NC 27709.

Meeting Format: Virtual.

Closed: 12:45 p.m. to 3:00 p.m.

Agenda: To review and evaluate review and Evaluate Grant Applications.

Address: NIEHS/National Institutes of Health, Building 4401, East Campus, 79 T.W. Alexander Drive, Research Triangle Park, NC 27709.

Meeting Format: Virtual.

Contact Person: David M. Balshaw, BA, Ph.D., Director and Acting Chief, Scientific Review Branch, Division of Extramural Research and Training, National Institute of Environmental Health Sciences, P.O. Box 12233; MD EC–27, Research Triangle Park, NC 27709–2233, 984–287–3234, *balshaw@niehs.nih.gov.*

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person. In the interest of security, NIH has procedures at *https://security.nih.gov/visitors/Pages/visitor-campus-access.aspx* for entrance into on-campus and off-campus facilities. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors attending a meeting on campus or at an off-campus federal facility will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

Information is also available on the Institute's/Center's home page: *www.niehs.nih.gov/dert/c-agenda.htm,* where an agenda and any additional information for the meeting will be posted when available.

Dated: November 23, 2026.

Margaret Vardanian,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2026–24152 Filed 11–25–26; 8:45 am]

BILLING CODE 4167–05–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Center for Scientific Review Special Emphasis Panel, Training and Career Development: Neurosciences, Development, and Aging, December 17, 2026, 12:30 p.m. to December 17, 2026, 03:00 p.m., National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 which was published in the **Federal Register** on November 20, 2026, FR Doc. 2026–23621, 91 FR 75336.

This meeting is being amended to change the meeting times from 12:30 p.m.–3:00 p.m. to 9:00 a.m.–6 p.m., December 17, 2026. The meeting is closed to the public.

Dated: November 23, 2026.

Margaret Vardanian,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2026–24134 Filed 11–25–26; 8:45 am]

BILLING CODE 4167–05–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Human Genome Research Institute; Notice of Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the Board of Scientific Counselors, National Human Genome Research Institute.

The meeting will be closed to the public as indicated below in accordance with the provisions set forth in sections 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.