meeting and obtain the webcast information, please visit the following website: *https://events.gcc.teams.microsoft.com/event/7727cea2-45bc-45b4-844a-1f86f2772529@7d2fdb41-339c-4257-87f2-a665730b31fc.*

Transcripts: Please be advised that as soon as a transcript of the public meeting is available, it will be accessible at *https://www.regulations.gov.* It may also be viewed at the Dockets Management Staff (see **ADDRESSES**).

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–07248 Filed 4–14–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–D–1255]

Safety Assessment of Genome Editing in Human Gene Therapy Products Using Next-Generation Sequencing; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft document entitled ''Safety Assessment of Genome Editing in Human Gene Therapy Products Using Next-Generation Sequencing; Draft Guidance for Industry.'' The draft document provides recommendations for next-generation sequencing (NGS)-based methods used in nonclinical studies that will likely be needed to support initiation of clinical trials of investigational human genome editing (GE) products.

DATES: Submit either electronic or written comments on the draft guidance by July 14, 2026 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.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–1255 for ''Safety Assessment of Genome Editing in Human Gene Therapy Products Using Next-Generation Sequencing; 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 the draft guidance to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, by emailing *industry@biologics@fda.hhs.gov.* The draft guidance may also be obtained by mail by calling CBER at 800–835–4709 or 240–402–8010. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Andrew C. Harvan, Center for Biologics Evaluation and Research, Food and Drug Administration, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft document entitled ''Safety Assessment of Genome Editing in Human Gene Therapy Products Using Next-Generation Sequencing; Draft Guidance for Industry.''

This draft guidance is intended for sponsors developing human gene therapy products involving GE technologies. Clinical development programs of human GE products should address both the risks associated with the gene therapy product itself as well as the additional risks associated with GE, including off-target editing and

unintended consequences. The recommendations in this draft guidance may guide stakeholders on designing nonclinical studies that uses NGS methods and bioinformatics to evaluate the potential safety risks associated with off-target editing and loss of genome integrity in human GE products submitted in support of Investigational New Drug applications and Biologics License Applications.

The recommendations provided in this draft guidance are in addition to the nonclinical, clinical, and CMC considerations discussed in the ''Guidance for Industry: Human Gene Therapy Products Incorporating Human Gene Editing'' dated January 2024.

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 ''Safety Assessment of Genome Editing in Human Gene Therapy Products Using Next-Generation Sequencing.'' 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 part 312 relating to the submission of Investigational New Drug Applications, including clinical trials, have been approved under OMB control number 0910–0014. The collections of information contained in 21 CFR part 601 relating to the submission of biologics license applications have been approved under OMB control number 0910–0338. The collections of information in 21 CFR part 1271 relating to human gene therapy products have been approved under OMB control number 0910–0543.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov*.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–07285 Filed 4–14–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

HHS OMH Call for Nominations for Center for Indigenous Innovation and Health

AGENCY: Office on Minority Health (OMH), Office of the Assistant Secretary for Health, Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The U.S. Department of Health and Human Services (HHS) Office of Minority Health (OMH) hereby gives notice that OMH is accepting nominations of candidates to serve as primary and alternate delegates for the Center for Indigenous Innovation and Health Tribal Advisory Committee (CIIH TAC). OMH established the CIIH TAC to provide Tribal leaders a forum to exchange views, share information, and provide feedback to OMH on the development of activities addressing the four CIIH priority areas. The CIIH TAC shall support, but not supplant, government-to-government consultation activities that OMH undertakes.

DATES: Tribal leaders are encouraged to submit their nomination letters for CIIH TAC delegates by May 18, 2026, at the address listed below. OMH will continue to receive nominations until all CIIH TAC primary and alternate delegate positions are filled.

ADDRESSES: All nominations should be emailed to *minorityhealth@hhs.gov.* Please use the subject line ''CIIH TAC Nomination.''

FOR FURTHER INFORMATION CONTACT: For information and guidance about the nomination process for CIIH TAC delegates, please contact CDR Matthew Johns, OMH Tribal Affairs and Strategic Partnerships Lead, at Phone: (202) 365–0639 or *Matthew.Johns@hhs.gov.* Once approved, sample CIIH TAC nomination letters will be made available on the OMH website: *https://minorityhealth.hhs.gov/.*

SUPPLEMENTARY INFORMATION:

Background: Authorized under Section 1707 of the Public Health Service Act, *42 U.S.C. 300u–6,* as amended, the mission of OMH is to provide national leadership, resources, and coordination to improve the health of racial and ethnic minority populations and American Indians and Alaska Natives (AI/AN) and eliminate health disparities.

Through the Joint Explanatory Statement (JES) accompanying Public Law 116–260 (2021 Consolidated Appropriations Act), Congress directed OMH to create the CIIH to advance Indigenous solutions that ultimately address health disparities in AI/AN and Native Hawaiian and Pacific Islander populations.Congress identified four CIIH priority areas: research, education, service, and policy development. The JES accompanying the subsequent annual appropriations acts has included language for OMH to continue funding the CIIH.

TAC Membership: The CIIH TAC will consist of three delegate positions from any of the geographic areas served by the Indian Health Service (IHS) and three National At-Large Member positions.

The CIIH TAC charter establishes a two (2) year term length for each delegate. There are vacancies for all IHS areas due to the ending of the CIIH TAC members' 2-year terms.

Eligibility: The CIIH TAC delegates must be: (1) Elected Tribal officials from a federally recognized Tribe acting in their official capacity as elected officials of their Tribe, with authority to act on behalf of the Tribe; or (2) individuals designated by an elected Tribal official. Designees must have the authority to act on behalf of the Tribal official and the Tribe and be qualified to represent the views of the American Indians and Alaska Natives (AI/AN) Tribes in the area from which they are nominated. No delegate of the CIIH TAC may be an employee of the federal government.

Nomination Procedures: CIIH TAC candidates must be nominated by an elected Tribal leader. The nomination letter must be on Tribal letterhead and signed by an elected Tribal leader, and must include the following information:

- Name of the nominee
- Nomination Type (*Primary Delegate, National At-large Delegate. Alternate Delegate*)
- Nominee's official title
- Name of the nominee's tribe
- Date of nominee's election to official Tribal position and term length
- Nominee's contact information (mailing address, phone, and email)
- Nominee's expertise that is relevant to the CIIH TAC
- Name of Tribal leader submitting the nomination
- Official title of Tribal leader submitting the nomination