

With respect to Microgrids, allowable activities will be further described in the NOFO.

Application Preparation

Comment: In regard to EAGLE, one commenter requested clarification regarding whether applicants would be required to submit separate applications for specific project areas or a single application that could later be aligned to a project area during review.

Response: For EAGLE, applicants will be required to submit a separate application for each project area under which they choose to apply. Additional information regarding the application process will be provided in the NOFO.

Training and Technical Assistance Consolidation

Comment: While ANA received multiple comments supporting Training and Technical Assistance (TTA) consolidation, other comments raised concerns about the risks to institutional knowledge and operational effectiveness.

Response: The consolidation of ANA's four TTA contracts into a single cooperative agreement will streamline operations and strengthen program support. This new model will:

- Provide specialized subject matter expertise for specific regions
- Improve operational integration
- Allow for stronger federal involvement in program direction
- Increase responsiveness to agency priorities

By shifting to one cooperative agreement, ANA will deliver more cohesive and consistent TTA services that improve grantee capacity, performance, and long-term sustainability. This transition also enhances ANA's overall efficiency in project management and supports recent changes in administrative strategy and oversight.

This approach is both practical and aligned with the Native American Programs Act (NAPA), the foundation of ANA's mission. NAPA emphasizes promoting self-sufficiency and economic development in Native communities, principles that remain central to ANA's work. As a complement to direct grant funding, this structure ensures ANA's active involvement in shaping TTA services so they remain responsive to community priorities and aligned with the long-term objectives of NAPA and the Administration.

Comment: ANA received comments regarding concerns about losing regional expertise through the implementation of the TTA Cooperative Agreement.

Response: The consolidation of ANA's four TTA contracts into a single cooperative agreement will streamline operations and strengthen program support. This new model will continue to serve ANA grant recipients in specific regions through specialized subject matter experts. This option creates a unified, more agile framework for managing TTA services. The cooperative agreement structure is ideal when federal guidance and collaboration are essential to ensure effective implementation.

Comment: One commenter stated that the proposed ceiling level of \$3.1M over three years for a single NCNTTA cooperative agreement represents a substantial consolidation of resources and equates to a reduction of more than 70 percent in regional staffing capacity. This significant reduction in geographically distributed staff risks undermining the culturally responsive, community informed technical assistance that has been foundational to ANA's success.

Response: The funding level, which is 3.1 million per fiscal year, is intended to support a coordinated national technical assistance approach that would include serving ANA grant recipients in specific regions through specialized subject-matter experts. ANA will monitor performance under the cooperative agreement to ensure alignment with program and statutory requirements.

For Profit Entities

Comment: ANA received comments regarding eligibility of for-profit entities.

Response: Eligibility is determined by the authorizing statute for each program. Under 42 U.S.C. 2991b, which governs EAGLE and the AI3 Action Institute grants, eligible entities do not include for-profit organizations. In contrast, 42 U.S.C. 2991c, which governs NCNTTA, allows for-profit entities to apply. Therefore, for-profit eligibility differs between these three opportunities based on their respective statutory requirements. ANA recognizes that for-profit organizations play an important role in economic development, including creating jobs, attracting private investment, and supporting innovation in communities. ANA does not allocate funding based on organizational type. All applications will be evaluated in accordance with the published merit review criteria. ANA will monitor awards to ensure consistency with program requirements and statutory requirements.

Program Income

Comment: One commenter requested clarification regarding the treatment of program income generated through community subscription services, including whether such revenue would reduce the federal award and how it should be addressed in sustainability planning.

Response: Program income earned from award-supported project activities must be used for the purposes of the award and in accordance with the terms and conditions of the award and applicable federal requirements, including 2 CFR 200.307. The NOFO and award terms, as applicable, will govern how program income must be treated for funded projects.

Proposed Program Areas for Eagle

Comment: One commenter recommended the addition of an explicit EAGLE priority area focused on Indigenous data sovereignty and community communications infrastructure and requested clearer recognition of sovereign digital communications activities and related operational costs within the EAGLE framework.

Response: ANA will maintain the EAGLE project area structure as proposed; however, the IDEAS project area is intended to remain broad enough to accommodate innovative and emerging community-designed concepts, including concepts that may align with the themes identified in this comment. Applicants should review the NOFO carefully to determine whether proposed activities fall within the scope of the IDEAS project area or any other applicable project area.

Statutory Authority: Sections 803, 804, and 814 of NAPA, as amended (42 U.S.C. 2991b, 2991c, 2992b–1).

Hope MacDonald LoneTree,

Deputy Commissioner, Administration for Native Americans, Administration for Children and Families.

[FR Doc. 2026–15150 Filed 7–23–26; 4:15 pm]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–N–7514]

Pediatric Advisory Committee (PAC); Notice of Meeting; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of a public docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA or the Agency) announces a forthcoming public advisory committee meeting of the Pediatric Advisory Committee (PAC). The general function of the committee is to provide advice and recommendations to FDA on pediatric regulatory issues. The meeting will be open to the public. FDA is establishing a docket for public comment on this document.

DATES: The meeting will be held virtually on September 16, 2026, from 10:00 a.m. to 4:00 p.m. Eastern Time (ET).

ADDRESSES: All meeting participants will be heard, viewed, captioned, and recorded for this advisory committee meeting via an online teleconferencing and/or video conferencing platform. Answers to commonly asked questions about FDA advisory committee meetings may be accessed at: <https://www.fda.gov/advisory-committees/about-advisory-committees/common-questions-and-answers-about-fda-advisory-committee-meetings>.

FDA is establishing a docket for public comment on this meeting. The docket number is FDA-2026-N-7514. The docket will close on September 15, 2026. Submit either electronic or written comments on this public meeting on or before September 15, 2026. 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 September 15, 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.

Comments received on or before September 9, 2026, will be provided to the committee. Comments received after that date will be taken into consideration by FDA. In the event that the meeting is cancelled, FDA will continue to evaluate any relevant applications or information, and consider any comments submitted to the docket, as appropriate.

You may submit comments 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-N-7514 for "Pediatric Advisory Committee (PAC); Notice of Meeting; Establishment of a Public Docket; Request for Comments." 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. ET, 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." FDA 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 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 the 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: Shivana Srivastava, Office of Pediatric Therapeutics, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5157, Silver Spring, MD 20993-0002, 301-796-8695, shivana.srivastava@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 related to the meeting.

SUPPLEMENTARY INFORMATION: The meeting presentations will be heard, viewed, captioned, and recorded through an online teleconferencing and/or video conferencing platform.

Agenda: On September 16, 2026, the PAC will meet to discuss post-marketing pediatric-focused safety reviews of the following products:

1. Center for Biologics Evaluation and Research
 - a. Epicel (cultured epidermal

- autografts) Humanitarian Device Exemption (HDE)
- b. Quelimmune (HDE)
2. Center for Devices and Radiological Health
 - a. Enterra Therapy System (HDE)
 - b. Liposorber LA-15 System (HDE)
 - c. Medtronic Activa Neurostimulator for Dystonia Treatment (HDE)
 - d. Medtronic Contegra Pulmonary Valved Conduit (HDE)
 - e. Minimally Invasive Deformity Correction (MID-C) System (HDE)
 - f. nAbCyte Anti-AAVRh74var HB-FE Assay (HDE)
 - g. Pleximmune (HDE)
 - h. Reflect Scoliosis Correction System (HDE)
 - i. Sonalleve MR-HIFU (HDE)
 - j. The Tether—Vertebral Body Tethering System (HDE)
 3. Center for Drug Evaluation and Research
 - a. Aranesp (darbepoetin alfa)
 - b. Dalvance (dalbavancin)
 - c. Fragmin (dalteparin sodium)
 - d. Isopto Atropine (atropine sulfate)
 - e. Kloxado nasal spray, Zimhi injection, Naloxone Hydrochloride Autoinjector, Naloxone hydrochloride nasal spray, RiVive nasal spray, Rezenopy nasal spray (naloxone hydrochloride)
 - f. Lymphoseek (technetium Tc 99m tilmanocept)
 - g. Nextstellis (drospirenone/estetrol)
 - h. Sprycel (dasatinib)
 - i. Suprep Bowel Prep Kit (sodium sulfate, potassium sulfate, magnesium sulfate)
 - j. Tecentriq (atezolizumab)
 - k. Veklury (remdesivir)
 - l. Vemlidy (tenofovir alafenamide)
 - m. Zelsuvmi (berdazimer)
 - n. Zevtera (ceftobiprole medocartil sodium)
 - o. Zinplava (bezlotoxumab)

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 <https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee meeting link.

The meeting 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 submitted to the Docket (see **ADDRESSES**) on or before September 9, 2026, will be provided to the committee. Oral presentations from the public will be scheduled between approximately 10:30 a.m. to 11:30 a.m. ET on September 16, 2026. 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 comments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before September 1, 2026. 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. The contact person will notify interested persons regarding their request to speak by September 2, 2026.

For press inquiries, please contact the FDA Newsroom at <https://www.fda.gov/news-events/fda-newsroom>.

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 Shivana Srivastava (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. 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.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2024-D-1402]

Cancer Clinical Trial Eligibility Criteria: Laboratory Values; Guidance for Industry, Institutional Review Boards, and Clinical Investigators; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the availability of a final guidance for industry, institutional review boards (IRBs), and clinical investigators entitled “Cancer Clinical Trial Eligibility Criteria: Laboratory Values.” This guidance is one in a series of guidances that provide recommendations regarding eligibility criteria for clinical trials of investigational drugs regulated by the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation Research (CBER) for the treatment of cancer. Specifically, this guidance includes recommendations for selecting appropriate laboratory values as trial eligibility criteria to avoid unjustified exclusions of trial participants. This guidance finalizes the draft guidance of the same title issued on April 26, 2024.

DATES: The announcement of the guidance is published in the **Federal Register** on July 28, 2026.

ADDRESSES: You may submit either electronic or written comments on Agency guidances 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