Name of recipient that has IIJA funds to be returned for reallotment	Preliminary amount available for reallotment [1]
Northern Arapaho Nation	7,860.60
Total	484,019.07

[1] Reallotment amounts were calculated by subtracting the allowable 10 percent carryover from each grant recipient's IIJA fund balance in the Payment Management System (PMS). These figures include IIJA funds from both FY 2024 and FY 2025 and reflect amounts from 60 grant recipients. Karuk, Nanticoke, and Sac & Fox are the only grant recipients returning IIJA funds from both FY 2024 and FY 2025. Modoc Tribe of Oklahoma did not receive funding in FY 2026 and is not eligible for reallotment.

If funds are reallotted, then they will be allocated in accordance with 42 U.S.C. 8623 and must be treated by LIHEAP recipients that receive them as funds appropriated for FY26. As FY26 funds, they will be subject to all requirements of the LIHEAP statute, including 42 U.S.C. 8626(b)(2), which requires that a recipient obligate at least 90 percent of its total block grant allocation for a FY by the end of the FY for which the funds are appropriated; that is, by September 30, 2026. Furthermore, recipients who receive these funds may use them for any purpose authorized under LIHEAP and must add them to their total LIHEAP funds payable for FY26 to calculate statutory caps on administrative costs, carryover, Assurance 16 activities, and weatherization assistance.

Additionally, all recipients of these funds must (1) ensure that these funds are included in the amounts on Lines 1.1 of their FY26 CRRs; (2) reconcile these funds, to the extent that they received them, on their corresponding FFRs; and (3) record, on their FY26 Household Reports, households that receive benefits at least partly from these funds. State recipients must also ensure that these funds are included in the Grantee Survey sections of their FY26 LIHEAP Performance Data Forms.

Statutory Authority: 42 U.S.C. 8626(b).

Elizabeth Leo,

Grants Policy Branch Chief, Office of Grants Policy, Office of Administration.

[FR Doc. 2026–06130 Filed 3–30–26; 8:45 am]

BILLING CODE 4184–80–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–N–2476]

Advancing the Use of Digital Health Technologies in Clinical Investigations for Drugs and Biological Products; Request for Information and Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; Request for information and comments.

SUMMARY: Digital health technologies (DHTs) used for remote data acquisition are playing a growing role in health care and offer important opportunities in clinical research. As outlined in the sixth reauthorization of the Prescription Drug User Fee Act (PDUFA VII) included as part of the FDA User Fee Reauthorization Act of 2022, the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER) have committed to supporting the use of DHTs in drug and biological product development. To inform potential FDA activities in this area, CDER and CBER are requesting information to better understand the opportunities and challenges sponsors and other interested parties face in making innovative use of DHTs in clinical investigations of drugs and biological products.

DATES: Either electronic or written comments must be submitted by June 1, 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 June 1, 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–N–2476 for ''Advancing the Use of Digital Health Technologies in Clinical Investigations for Drugs and Biological Products; Request for Information and 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., 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: Elizabeth Kunkoski, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Avenue, Bldg. 51, Rm 3332, Silver Spring, MD 20993, 301–796–6439, *DHTsforDrugDevelopment@fda.hhs.gov;* or Mark Walderhaug, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 5270, Silver Spring, MD 20993–0002, 240–402–8812 *CBER-DHTRT@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

DHTs are systems that use computing platforms, connectivity, software, and/or sensors for health care and related uses. DHTs include technologies such as wearable, implantable, ingestible, and contactless sensors. To advance the use of DHTs in drug and biological product development and review, as part of PDUFA VII, FDA committed to establishing a framework to guide the use of DHT-derived data in regulatory decision-making for drugs and biological products.

CDER and CBER's *Framework for the Use of DHTs in Drug and Biological Product Development* (March 2023) describes plans for demonstration projects, public meetings, guidance development and establishment of the DHT steering committee. Additionally, FDA's December 2023 guidance entitled *Digital Health Technologies for Remote Data Acquisition in Clinical Investigations* (2023 DHT Guidance) outlines recommendations intended to facilitate the use of DHTs in clinical investigations, as appropriate, for the evaluation of medical products. These recommendations include selection of suitable DHTs, verification and validation of DHTs, and use of DHTs to collect data for clinical investigation endpoints.

Since the publication of the 2023 DHT Guidance, there have been considerable advances in technology that may be used in clinical investigations. The range of sensors and the clinical features they can measure has expanded. Many of these sensors are present in smartwatches and mobile phones and may be customized using mobile applications (apps) for clinical investigations. Apps and other DHTs are being designed to perform interactive clinical tests of patient function. Examples include dynamometers to measure strength, apps to measure coordination and fine motor skills, and accelerometers to measure balance during specified tasks. Besides mechanical tasks, screen-based technologies are being explored to test neuropsychiatric functions such as reaction time, cognition, vision, hearing and to evaluate conditions such as autism or post-traumatic stress disorder. CDER and CBER are looking for ways to encourage the use of digitally derived endpoints based on these novel technologies in clinical investigations.

In addition, DHTs are being designed specifically for pediatric use and may play a role in evaluating new drugs and biological products in children. Gamification is a promising strategy to engage children in interactive clinical tests. Machine learning is also playing an increased role in the development of algorithms for DHTs to measure clinical features. Further opportunities for the innovative use of DHTs in clinical investigations remain.

Given the expanding technological opportunities for the use of DHTs in clinical drug and biological product development, we are seeking public feedback on the opportunities and challenges that sponsors, and other interested parties are experiencing in the use of DHTs in clinical investigations of drugs and biological products. The information and comments received in response to this notice will inform the development of guidance documents, and other Agency activities to support the appropriate use of DHTs in clinical investigations of drugs and biological products.

II. Request for Information and Comments

Considering the progress around the use of DHTs in drug and biological product development and the potential application of these technologies as described above, CDER and CBER are requesting information and comments on the questions below.

1. What regulatory challenges do DHT manufacturers, sponsors or other interested parties face regarding the use of DHTs in clinical investigations of drugs and biological products?

2. What opportunities are there for CDER and CBER to support and facilitate the adoption of DHTs in clinical investigations of drugs and biological products?

3. What areas of guidance would support the use of DHTs in clinical investigations?

4. What specific DHT related topics, such as digitally derived endpoints in certain disease areas, would benefit from discussion in a public workshop?

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–06184 Filed 3–30–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–5933]

Notice of Decision on a Hearing Request Regarding a Proposal To Refuse To Approve a New Drug Application for TRADIPITANT Capsules

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of its decision on a request for a hearing regarding the proposal of FDA's Center for Drug Evaluation and Research (CDER) to refuse to approve a new drug application (NDA) 218489, submitted by Vanda Pharmaceuticals, Inc. (Vanda), for TRADIPITANT capsules (85 mg) with the proposed indication for ''the treatment of [symptoms of] or [nausea in] in gastroparesis'' (''symptoms of gastroparesis''). The decision is available in the docket identified by the