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

number in brackets in the heading of this document.

DATES: The decision was submitted to the docket on March 26, 2026.

FOR FURTHER INFORMATION CONTACT: Rachael Vieder Linowes, Office of Scientific Integrity, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4206, Silver Spring, Maryland 20993, 240–402–5931.

SUPPLEMENTARY INFORMATION:

I. Background

On September 18, 2023, Vanda submitted NDA 218489 for TRADIPITANT capsules, 85 milligrams (mg), pursuant to section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)(1)) with the proposed indication for ''the treatment of [symptoms of] or [nausea in] in gastroparesis'' (''symptoms of gastroparesis''). TRADIPITANT is a selective neurokinin-1 (NK–1) receptor antagonist.

On September 18, 2024, the Office of Immunology and Inflammation (OII) in CDER issued a complete response letter (CRL) to Vanda under 21 CFR 314.110, stating that NDA 218489 could not be approved in its present form. The CRL described specific deficiencies and, where possible, recommended ways that Vanda might remedy those deficiencies. On November 25, 2024, Vanda indicated that it wished to receive approval of its application or a notice of opportunity for a hearing (NOOH). On January 7, 2025, CDER sent Vanda a NOOH and proposal to refuse approval of TRADIPITANT to treat gastroparesis, which was then published in the **Federal Register** on January 16, 2025 (90 FR 4748).

On January 28, 2025, Vanda provided a notice of participation and request for a hearing. On March 17, 2025, Vanda submitted documentation and analysis in support of a request for summary judgment, or alternatively, a hearing. On July 18, 2025, CDER submitted a Proposed Order denying Vanda's request for a hearing, and on September 17, 2025, Vanda submitted its reply to CDER's Proposed Order.

After considering the parties' submissions, on March 26, 2026, FDA issued a decision regarding Vanda's request for a hearing on CDER's proposal to refuse to approve NDA 218489.

II. Docket Access

For access to the docket to read the final decision and other documents pertaining to this matter, 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.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–06187 Filed 3–30–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: Black Lung Clinics Program Performance Measures, OMB No. 0915–0292—Revision

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

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this ICR should be received no later than June 1, 2026.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 13N82, 5600 Fishers Lane, Rockville, Maryland 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call Samantha Miller, the HRSA Information Collection Clearance Officer, at (301) 443–3983.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the ICR title for reference.

Information Collection Request Title: Black Lung Clinics Program Measures, OMB No. 0915–0292—Revision

Abstract: The Black Lung Clinics Program (BLCP) is authorized under Sec. 427(a) of the Federal Mine Safety and Health Act of 1977 (30 U.S.C. 937(a)) and accompanying regulations (42 CFR part 55a). The purpose of the BLCP is to reduce the morbidity and mortality associated with occupationally related coal mine dust lung disease through the screening, diagnosis, and treatment of active, inactive, retired, and/or disabled coal miners. HRSA currently collects information about BLCP awards using an OMB-approved set of performance measures and seeks to revise the approved collection. The proposed changes are a result of keeping this instrument relevant, responsive to the BLCP needs, and to improve clarity and ease of reporting for respondents.

Need and Proposed Use of the Information: HRSA has revised the performance measures, in which BLCP awardees will submit to HRSA on an annual basis. The purpose of the revised data collection is to assess BLCP awardees' progress toward meeting BLCP program goals (as stated in the authorizing statute) and how well each awardee is meeting the needs of these miners in their communities. The proposed changes include deleting five questions, adding three new questions, and changing three existing questions. These updates were made to streamline data collection and improve usability. Clinical diagnosis fields will be consolidated into a single datapoint, replacing separate fields for primary, secondary, and other diagnoses. The difference between these categories was often subjective, limiting HRSA's ability to use the data to monitor for black lung rates. Filling out three separate questions about diagnoses was also burdensome for clinics. Additionally, COVID-related data fields are removed due to decreased relevance, reducing the reporting burden on awardees. A new cardiology diagnosis field is added to better capture conditions closely linked to pulmonary disease and assist HRSA in tracking population needs and making relevant programmatic updates based on those needs. Benefits counseling measures are also enhanced to collect filing dates and case status details. This update will help HRSA track case timelines, which translates to better monitoring of implementation of benefits counseling services. These changes strengthen HRSA's monitoring and assessment of the impact of the BLCP program and ensure that funds are effectively used to provide services that meet the target population's needs. There is no change in the burden hours.

Likely Respondents: Respondents will be the BLCP award recipients.

Burden Statement: Burden in this context means the time expended by