

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 (OI) 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](mailto: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](mailto: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

persons to generate, maintain, retain, disclose, or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install, and utilize technology and systems for the purpose

of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search

data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Black Lung Clinics Program Performance Measures .....	15	1	15	7	105
Total .....	15	1	15	7	105

HRSA specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

**Maria G. Button,**

*Director, Executive Secretariat.*

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**BILLING CODE 4165-15-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**Center for Scientific Review; Notice of Closed Meetings**

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings 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:* Center for Scientific Review Special Emphasis Panel; RFA-AI-25-018: Mucosal Immunology Studies Team (MIST) (U01).

*Date:* April 20, 2026.

*Time:* 1:00 p.m. to 2:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Address:* National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

*Meeting Format:* Virtual Meeting.

*Contact Person:* Marilyn Moore-Hoon, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 594-9295, [mooremar@mail.nih.gov](mailto:mooremar@mail.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; NIH Health Services and Systems: Career Development Award Grant Review.

*Date:* April 24, 2026.

*Time:* 9:00 a.m. to 6:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Address:* National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

*Meeting Format:* Virtual Meeting.

*Contact Person:* Claudio Dario Ortiz, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institute of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (240) 869-9245, [claudio.ortiz@nih.gov](mailto:claudio.ortiz@nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Member Conflict: Respiratory Topics.

*Date:* April 24, 2026.

*Time:* 9:00 a.m. to 6:30 p.m.

*Agenda:* To review and evaluate grant applications.

*Address:* National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

*Meeting Format:* Virtual Meeting.

*Contact Person:* Hangyi Yan, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 480-2061, [Hannah.Yan@NIH.gov](mailto:Hannah.Yan@NIH.gov).

*Name of Committee:* Endocrinology, Metabolism, Nutrition and Reproductive Sciences Integrated Review Group; Cell Signaling and Molecular Endocrinology Study Section.

*Date:* April 24, 2026.

*Time:* 9:00 a.m. to 6:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Address:* National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

*Meeting Format:* Virtual Meeting.

*Contact Person:* Andrew M. Wolfe, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6214, Bethesda, MD 20892, [andrew.wolfe@nih.gov](mailto:andrew.wolfe@nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; PAR Panel: Biomarkers, Immunotherapy, and Biospecimen Science Technologies.

*Date:* April 24, 2026.

*Time:* 9:00 a.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Address:* National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

*Meeting Format:* Virtual Meeting.

*Contact Person:* Robert F. Gahl, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (240) 276-7869, [robert.gahl@nih.gov](mailto:robert.gahl@nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Topics in Clinical Data Management, Analysis, Informatics and Digital Health A.

*Date:* April 24, 2026.

*Time:* 9:00 a.m. to 6:30 p.m.

*Agenda:* To review and evaluate grant applications.

*Address:* National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

*Meeting Format:* Virtual Meeting.

*Contact Person:* Rhoda Keese Moise, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (304) 594-0702 [rhoda.moise@nih.gov](mailto:rhoda.moise@nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Fellowships: Vascular and Hematological Systems, Surgical Sciences, Biomedical Imaging, and Bioengineering.

*Date:* April 24, 2026.

*Time:* 9:00 a.m. to 6:30 p.m.

*Agenda:* To review and evaluate grant applications.

*Address:* National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

*Meeting Format:* Virtual Meeting.