the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the ''listed drug,'' which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is known generally as the ''Orange Book.'' Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

SANDOSTATIN (octreotide acetate) injection, EQ 0.2 mg base/mL and EQ 1 mg base/mL, is the subject of NDA 19667, held by Novartis Pharmaceuticals Corporation. NDA 19667 was initially approved on October 21, 1988, and the EQ 0.2 mg base/mL and EQ 1 mg base/mL strengths were approved on June 12, 1991. SANDOSTATIN is indicated to reduce blood levels of growth hormone and IGF–I (somatomedin C) in acromegaly patients who have had inadequate response to or cannot be treated with surgical resection, pituitary irradiation, and bromocriptine mesylate at maximally tolerated doses. SANDOSTATIN is also indicated for the symptomatic treatment of patients with metastatic carcinoid tumors where it suppresses or inhibits the severe diarrhea and flushing episodes associated with the disease. SANDOSTATIN is also indicated for the treatment of profuse watery diarrhea associated with vasoactive intestinal peptide-secreting tumors.

In a letter received by the Agency on May 11, 2020, Novartis Pharmaceuticals Corporation notified FDA that SANDOSTATIN (octreotide acetate) injection, EQ 0.2 mg base/mL and EQ 1 mg base/mL, was being discontinued, and FDA moved the drug product to the ''Discontinued Drug Product List'' section of the Orange Book. Caplin Steriles Limited submitted a citizen petition dated February 5, 2021 (Docket No. FDA–2021–P–0163), under 21 CFR 10.30, requesting that the Agency determine whether SANDOSTATIN (octreotide acetate) injection, EQ 0.2 mg base/mL and EQ 1 mg base/mL, was withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that SANDOSTATIN (octreotide acetate) injection, EQ 0.2 mg base/mL and EQ 1 mg base/mL, was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that SANDOSTATIN (octreotide acetate) injection, EQ 0.2 mg base/mL and EQ 1 mg base/mL, was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of SANDOSTATIN (octreotide acetate) injection, EQ 0.2 mg base/mL and EQ 1 mg base/mL, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have found no information that would indicate that this drug product was withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list SANDOSTATIN (octreotide acetate) injection, EQ 0.2 mg base/mL and EQ 1 mg base/mL, in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. FDA will not begin procedures to withdraw approval of approved ANDAs that refer to this drug product. Additional ANDAs for this drug product may also be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: May 26, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–11575 Filed 6–1–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; Rural Health Care Coordination Program Performance Improvement and Measurement System Database, OMB No. 0906–0024—Reinstate With Changes

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

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, HRSA has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period.

DATES: Comments on this ICR should be received no later than July 2, 2021.

ADDRESSES: Submit your comments, including the ICR Title, to the desk officer for HRSA, either by email to *OIRA_submission@omb.eop.gov* or by fax to (202) 395–5806.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email the HRSA Information Collection Clearance Officer at *paperwork@hrsa.gov* or call (301) 443–1984.

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

Information Collection Request Title: Rural Health Care Coordination Program Performance Improvement and Measurement System Database, OMB No. 0906–0024—Reinstate with Changes.

Abstract: The Rural Health Care Coordination (Care Coordination) program is authorized under Section 330A(e) of the Public Health Service (PHS) Act (42 U.S.C. 254(e)), as amended, to ''improve access and

quality of care through the application of care coordination strategies with the focus areas of collaboration, leadership and workforce, improved outcomes, and sustainability in rural communities.'' This authority permits the Federal Office of Rural Health Policy to support rural health consortiums/networks aiming to achieve the overall goals of improving access, delivery, and quality of care through the application of care coordination strategies in rural communities.

This ICR was discontinued in January 2020. HRSA is requesting a reinstatement with changes as it was decided to re-compete this pilot program.

The proposed Rural Health Care Coordination Program draft measures for information collection reflect changes to the Clinical Measures section which was previously in section eight and now currently in section six. The Clinical Measures Section now expands previous project focus from three chronic diseases (*i.e.,* Type 2 diabetes, Congestive Heart Failure, and Chronic Obstructive Pulmonary Disease) to an inclusive list of clinical measures in order to reflect a patient's overall health and well-being as well as the organizations' overall improved outcomes for the project. Proposed revisions also include measures to examine key elements cited for a successful rural care coordination program: (1) Collaboration, (2) leadership and workforce, (3) improved outcomes, and (4) sustainability.

1. Collaboration—Utilizing a collaborative approach to coordinate and deliver health care services through a consortium, in which member organizations actively engage in integrated, coordinated, patient-centered delivery of health care services.

2. Leadership and Workforce—Developing and strengthening a highly skilled care coordination workforce to respond to vulnerable populations' unmet needs within the rural communities.

3. Improved Outcomes—Expanding access and improving care quality and delivery, and health outcomes through evidence-based model and/or promising practices tailored to meet the local populations' needs.

4. Sustainability—Developing and strengthening care coordination program's financial sustainability by establishing effective revenue sources such as expanded service reimbursement, resource sharing, and/or contributions from partners at the community, county, regional, and state levels.

With the continuing shift in the healthcare environment towards provision of value-based care and utilization of reimbursement strategies through Centers for Medicare and Medicaid Services quality reporting programs, the latest competitive Rural Health Care Coordination Program cohort also aligned with this shift. An increased number of sophisticated applicants leveraging increasingly intricate reporting methodologies for quality, data collection, utilization and analysis has resulted in an estimate of burden hours more in line with the realities of the health care landscape. In addition, the total number of responses has increased to 10 since the previous Notice of Award. This is due to a new Rural Health Care Coordination Program grant cycle with an increased number of awardees therefore an increased number of respondents.

A 60-day notice published in the **Federal Register** on November 30, 2020, vol. 85, No. 230; pp. 76585–86. There were no public comments.

Need and Proposed Use of the Information: For this program, performance measures were drafted to provide data to the program and to enable HRSA to provide aggregate program data required by Congress under the Government Performance and Results Act of 1993. These measures cover the principal topic areas of interest to the Office of Rural Health Policy, including: (a) Access to care; (b) population demographics; (c) staffing; (d) consortium/network; (e) sustainability; and (f) project specific domains. All measures will speak to HRSA's progress toward meeting the goals set.

Likely Respondents: The respondents would be recipients of the Rural Health Care Coordination Program funding.

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
Rural Health Care Coordination Grant Program Measures	10	1	10	3.5	35
Total	10		10		35

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.

[FR Doc. 2021–11542 Filed 6–1–21; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Meeting of the Advisory Committee on Infant Mortality

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

ACTION: Notice.

SUMMARY: In accordance with the Federal Advisory Committee Act, this notice announces that the Advisory Committee on Infant Mortality (ACIM) has scheduled a public meeting. Information about ACIM and the agenda for this meeting can be found on the ACIM website at *https://www.hrsa.gov/advisory-committees/infant-mortality/index.html.*

DATES: June 22, 2021, 12:00 p.m.–4:00 p.m. Eastern Time (ET) and June 23, 2021, 12:00 p.m.–4:00 p.m. ET.

ADDRESSES: This meeting will be held via webinar. *The webinar link and log-in information will be available at ACIM's website before the meeting: https://www.hrsa.gov/advisory-committees/infant-mortality/index.html.*

FOR FURTHER INFORMATION CONTACT: Vanessa Lee, MPH, Acting Designated Federal Official, Maternal and Child Health Bureau, HRSA, 5600 Fishers Lane, Rockville, Maryland 20857; 301–443–0543; or *SACIM@hrsa.gov.*

SUPPLEMENTARY INFORMATION: The ACIM is authorized by section 222 of the Public Health Service Act (42 U.S.C. 217a), as amended. The Committee is governed by provisions of Public Law 92–463, as amended, (5 U.S.C. App. 2), which sets forth standards for the formation and use of Advisory Committees.

The ACIM advises the Secretary of HHS on department activities and programs directed at reducing infant mortality and improving the health status of pregnant women and infants. The ACIM represents a public-private partnership at the highest level to provide guidance and focus attention on the policies and resources required to address the reduction of infant mortality and the improvement of the health status of pregnant women and infants. With a focus on life course, the ACIM addresses disparities in maternal health to improve maternal health outcomes, including preventing and reducing maternal mortality and severe maternal morbidity. The ACIM provides advice on how best to coordinate myriad federal, state, local, and private programs and efforts that are designed to deal with the health and social problems impacting infant mortality and maternal health, including implementation of the Healthy Start program and maternal and infant health objectives from the National Health Promotion and Disease Prevention Objectives (*i.e.,* Healthy People 2030).

The agenda for the June 22–23, 2021, meeting is being finalized and may include the following topics: Discussion of recommendations by ACIM to the Secretary; updates from HRSA's Maternal and Child Health Bureau, and other federal agencies; the Centers for Disease Control and Prevention's Pregnancy Risk Assessment Monitoring System survey; and patient-physician racial concordance in health care. Agenda items are subject to change as priorities dictate. Refer to the ACIM website for any updated information concerning the meeting.

Members of the public will have the opportunity to provide written or oral comments. Requests to submit a written statement or make oral comments to the ACIM should be sent to Vanessa Lee, using the email address above at least 3 business days prior to the meeting. Public participants may submit written statements in advance of the scheduled meeting by emailing *SACIM@hrsa.gov.* Oral comments will be honored in the order they are requested and may be limited as time allows.

Individuals who plan to attend and need special assistance or another reasonable accommodation should notify Vanessa Lee at the contact information listed above at least 10 business days prior to the meeting.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2021–11504 Filed 6–1–21; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health.

National Institute of Neurological Disorders and Stroke; Notice of Closed Meetings

Pursuant to section 10(d) 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: National Institute of Neurological Disorders and Stroke Special Emphasis Panel; Music and Health.

Date: June 24, 2021.

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

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Virtual Meeting).

Contact Person: W. Ernest Lyons, PhD, Scientific Review Administrator, Scientific Review Branch, NINDS/NIH/DHHS, Neuroscience Center, 6001 Executive Blvd., Suite 3208, MSC 9529, Rockville, MD 20852, 301–496–4056, *lyonse@ninds.nih.gov.*

Name of Committee: National Institute of Neurological Disorders and Stroke Special Emphasis Panel; Small Vessel VCID Biomarkers Validation Consortium Sites & Coordinating Center Review (U01 & U24).

Date: June 25, 2021.

Time: 10:30 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Virtual Meeting).

Contact Person: Mir Ahamed Hossain, PhD, Scientific Review Officer, Scientific Review Branch, NINDS/NIH/DHHS, Neuroscience Center, 6001 Executive Blvd., Suite 3208, MSC 9529, Rockville, MD 20852, 301–496–9223, *mirahamed.hossain@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.853, Clinical Research Related to Neurological Disorders; 93.854, Biological Basis Research in the Neurosciences, National Institutes of Health, HHS)