have secondary or tertiary amines and are therefore at risk for forming nitrosamine drug substance related impurities (NDSRIs). Hypothetically, under certain conditions related to the formulation and manufacturing process for the drug product, such as residual nitrites in excipients used to formulate the drug product, these APIs could form NDSRIs. Rifampin is one such API at risk of forming 1-methyl-4-nitrosopiperazine (MNP). FDA has tested certain rifampin products for MNP and detected MNP in all such tested rifampin products.[1] FDA has announced recommended acceptable intake limits for MNP in all rifampin products, including a recommended interim acceptable intake limit. Rifadin (rifampin) 150 mg and 300 mg capsules are currently listed in the ''Discontinued Drug Product List'' section of the Orange Book.

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we have at this time, FDA has determined under § 314.161 that RIFADIN (rifampin) capsules, 150 mg and 300 mg, were not withdrawn for reasons of safety or effectiveness to the extent that the drugs can be manufactured or formulated in a manner that satisfies any applicable acceptable intake limit for nitrosamine impurities. The petitioner has identified no data or other information suggesting that RIFADIN (rifampin) capsules, 150 mg and 300 mg, were withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of RIFADIN (rifampin) capsules, 150 mg and 300 mg, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have reviewed the available evidence and determined that these drug products were not withdrawn from sale for reasons of safety or effectiveness to the extent that the drugs can be manufactured or formulated in a manner that satisfies any applicable acceptable intake limit for nitrosamine impurities.

Accordingly, the Agency will continue to list RIFADIN (rifampin) capsules, 150 mg and 300 mg, 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 these drug products. Additional ANDAs for these drug products may also be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs, including satisfying any applicable acceptable intake limit for nitrosamine impurities. If FDA determines that labeling for these drug products should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: August 14, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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BILLING CODE 4164–01–P

[1] Nitrosamine impurities in the drug supply are an important public health concern. As explained in the guidance for industry entitled ''Control of Nitrosamine Impurities in Human Drugs'' published September 2024 (available at *https://www.fda.gov/media/141720/download*) (at 4–5), ''Nitrosamine compounds are potent genotoxic agents in several animal species and some are classified as probable or possible human carcinogens by the International Agency for Research on Cancer. They are referred to as *cohort of concern* compounds in the International Council for Harmonisation of Technical Requirements for . . . Human Use (ICH) guidance for industry *M7(R2) Assessment and Control of DNA Reactive (Mutagenic) Impurities in Pharmaceuticals to Limit Potential Carcinogenic Risk* (July 2023).'' Many drug products have been found to contain levels of nitrosamines that are unacceptable or require further evaluation. FDA's current understanding is that nitrosamine levels in affected drug products have different causes and may be controlled using different strategies, including formulation design (*i.e.,* adding antioxidants or adding pH adjusters that modify the microenvironment to base or neutral pH) and supplier qualification programs.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: Rural Communities Opioid Response Program Performance Measures, OMB No. 0906–0044—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 October 20, 2025.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 14NWH04, 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: Rural Communities Opioid Response Program Performance Measures, OMB No. 0906–0044—Revision.

Abstract: HRSA administers the Rural Communities Opioid Response Program (RCORP), which is authorized by Section 711(b)(5) of the Social Security Act (42 U.S.C. 912(b)(5)) and is a multi-initiative program that aims to: (1) support treatment for and prevention of substance use disorder (SUD), including opioid use disorder (OUD); and (2) reduce morbidity and mortality associated with SUD, including OUD, by improving access to and delivering prevention, treatment, and recovery support services to high-risk rural communities. To support this purpose, RCORP grant initiatives include:

- RCORP—Implementation grants, which fund established networks and consortia to deliver SUD/OUD prevention, treatment, and recovery activities in high-risk rural communities;
- RCORP—Psychostimulant Support grants, which aim to strengthen and expand access to prevention, treatment, and recovery services for individuals in rural areas who misuse psychostimulants, to enhance their ability to access treatment and move toward recovery;
- RCORP—Medication Assisted Treatment Access grants, which aim to establish new access points in rural facilities where none currently exist;
- RCORP—Behavioral Health Care support grants, which aim to expand access to and quality of behavioral health care services at the individual, provider, and community levels;
- RCORP Overdose Response recipients address immediate needs in rural areas through improving access to,

capacity for, and sustainability of prevention, treatment, and recovery services for SUD;

- RCORP Child and Adolescent Behavioral Health grants, which aim to establish and expand sustainable behavioral health care services for children and adolescents aged 5 to 17 years who live in rural communities;
- RCORP—Neonatal Abstinence Syndrome grants, which aim to reduce the incidence and impact of Neonatal Abstinence Syndrome in rural communities; and
- RCORP Impact recipients aim to improve access to integrated, coordinated treatment and recovery services for SUD, including OUD, in rural areas.

Note that additional grant initiatives may be added pending fiscal year 2026 and future fiscal year appropriations.

HRSA currently collects information about RCORP grants using approved performance measures. HRSA developed separate performance measures for the new RCORP-Impact program and seeks OMB approval for the new collection.

Need and Proposed Use of the Information: Due to the growth in the number of grant initiatives included within RCORP, as well as emerging SUD and other behavioral health trends in rural communities, HRSA is submitting a revised ICR that includes measures for the new RCORP-Impact grant program. HRSA developed performance measures to provide data on each RCORP initiative 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 HRSA, including: (a) provision of, and referral to, rural behavioral health care services, including SUD prevention, treatment and recovery support services; (b) behavioral health care, including SUD prevention, treatment, and recovery, process and outcomes; (c) provider prevention, treatment, and recovery services; and (d) sustainability. Performance measures for the RCORP initiative include common elements about consortium/network activities, direct services provided and service access, workforce, and sustainability while also capturing tailored measures for each specific program.

Likely Respondents: The respondents will be the recipients of the RCORP grants.

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.

All changes to the burden for this ICR, compared to the currently approved version (expiration date of August 31, 2027), are due to the addition of the new form for Rural Communities Opioid Response—Impact.

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 Communities Opioid Response Program—Implementation	290	2	580	1.24	719.20
Rural Communities Opioid Response Program—Psychostimulant Support	15	1	15	1.30	19.50
Rural Communities Opioid Response Program—Medication Assisted Treatment Access	11	1	11	1.95	21.45
Rural Communities Opioid Response Program—Behavioral Health Care Support	58	1	58	2.02	117.16
Rural Communities Opioid Response Program—Overdose Response	47	3	141	0.56	78.96
Rural Communities Opioid Response—Child and Adolescent Behavioral Health	9	2	18	0.48	8.64
Rural Communities Opioid Response—Neonatal Abstinence Syndrome	41	4	164	2.31	378.84
Rural Communities Opioid Response—Impact (NEW)	19	1	19	1.15	21.85
Total	490		1,006		1,365.60

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. 2025–15807 Filed 8–18–25; 8:45 am]

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