TABLE 1—NEW DRAFT PRODUCT-SPECIFIC GUIDANCES FOR DRUG PRODUCTS

Active ingredient(s)
Aclidinium bromide; Formoterol fumarate.
Apomorphine hydrochloride.
Atropine sulfate.
Brilliant blue G.
Capmatinib hydrochloride.
Cladribine.
Dicyclomine hydrochloride.
Dolutegravir sodium.
Enzalutamide.
Estradiol (multiple referenced listed drugs).
Etelcalcetide.
Flortaucipir F-8.
Fluoroestradiol F-18.
Heparin sodium.
Irinotecan hydrochloride.
Leuprolide acetate (multiple referenced listed drugs).
Mirabegron.
Nusinersen sodium.
Posaconazole.
Progesterone.
Remdesivir (multiple referenced listed drugs).
Ripretinib.
Selpercatinib.
Selumetinib sulfate.
Sodium chloride.
Vasopressin.
Viloxazine hydrochloride.

III. Drug Products for Which Revised Draft Product-Specific Guidances Are Available

FDA is announcing the availability of revised draft product-specific guidances for industry for drug products containing the following active ingredients:

TABLE 2—REVISED DRAFT PRODUCT-SPECIFIC GUIDANCES FOR DRUG PRODUCTS

Active ingredient(s)
Apixaban.
Clozapine (multiple referenced listed drugs).
Enzalutamide.
Estradiol.
Gefitinib.
Liothyronine sodium.
Methylprednisolone acetate.
Mycophenolate mofetil.
Osimertinib mesylate.
Ruxolitinib phosphate.
Valbenazine tosylate.

For a complete history of previously published **Federal Register** notices related to product-specific guidances, go to *https://www.regulations.gov* and enter Docket No. FDA–2007–D–0369.

These draft guidances are being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). These draft guidances, when finalized, will represent the current thinking of FDA on, among other things, the product-specific design of BE studies to support ANDAs. They do not establish any rights for any person and are not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

IV. Paperwork Reduction Act of 1995

FDA tentatively concludes that these draft guidances contain no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

V. Electronic Access

Persons with access to the internet may obtain the draft guidances at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/regulatory-information/search-fda-guidance-documents, or https://www.regulations.gov.*

Dated: February 10, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–03248 Filed 2–17–22; 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; Proposed Collection: Public Comment Request; 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 of 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. OMB may act on HRSA's ICR only after the 30-day comment period for this Notice has closed.

DATES: Comments on this ICR should be received no later than March 21, 2022.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function.

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 acting HRSA Information Collection Clearance Officer, at (301) 443–9094.

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

Information Collection Request Title: Rural Communities Opioid Response Program (RCORP) Performance Measures, OMB No. 0906–0044—Revision.

Abstract: RCORP 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, to include 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 to fund established networks and consortia to deliver SUD/OUD prevention, treatment, and recovery activities in high-risk rural communities;
- RCORP-Medication Assisted Treatment Expansion grants to enhance access to medication-assisted treatment within eligible hospitals, health clinics, or tribal organizations in high-risk rural communities;
- RCORP-Neonatal Abstinence Syndrome grants to reduce the incidence and impact of Neonatal Abstinence Syndrome in rural communities by improving systems of care, family supports, and social determinants of health;
- RCORP-Psychostimulant Support grants to strengthen and expand prevention, treatment, and recovery services for individuals in rural areas who misuse psychostimulants; to enhance their ability to access treatment and move towards recovery; and

• Note that additional grant programs may be added pending Fiscal Year 2022 and future Fiscal Year appropriations.

Additionally, all RCORP grant award recipients are supported by eight cooperative agreements: RCORP-Technical Assistance, which provides extensive technical assistance to award recipients; RCORP-Evaluation, which evaluates the impact of the RCORP initiative on rural communities; three RCORP-Behavioral Health Care Workforce Centers, which provide workforce training and education initiatives in the region served by the Northern Border Regional Commission; and three RCORP-Centers of Excellence, which disseminate best practices related to the treatment for and prevention of substance use disorders within rural communities.

A 60-day notice published in the **Federal Register**, 86 FR 69655 (December 8, 2021). There were no public comments.

Need and Proposed Use of the Information: Due to the growth in the number of grant programs included in the RCORP initiative, as well as emerging SUD and other behavioral health trends in rural communities, HRSA is submitting a revised package that includes changes to existing RCORP performance measures as well as new performance measures that better demonstrate the impact of the initiative on rural communities and reduce burden on the grant recipients.

For this program, performance measures were developed 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 the Federal Office of Rural Health Policy, 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) education of health care providers and community members; (d) emerging trends in rural behavioral health care needs and areas of concern; and (e) consortium strength and sustainability. All measures will speak to the Federal Office of Rural Health Policy's progress toward meeting the goals set.

Likely Respondents: The respondents will be the grant award recipients of the RCORP initiatives.

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.

The below burden estimate is significantly lower than the original package submitted in 2019 (2,750 total burden hours). This is likely due to the fact that (1) many of the grant recipients HRSA consulted to obtain the burden estimate for this ICR revision have been collecting and reporting RCORP performance measures since March 2020 and have a better understanding of the burden required; (2) HRSA eliminated and/or streamlined some of the more burdensome prevalence and workforce measures; and (3) grant recipients of the RCORP-Psychostimulant program will only report on an annual (vs. biannual) basis.

TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS

Form name	Number of respondents	Number of responses per respondent (annually)	Total responses	Average burden per response (in hours)	Total burden hours
Rural Communities Opioid Response Program-Implementation/Neonatal Abstinence Syndrome/MAT Expansion ..	290	2	580	1.24	719.20
Rural Communities Opioid Response Program-Psychostimulant Support	15	1	15	1.30	19.50
Total	305	.....	595	.....	738.70

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. 2022–03499 Filed 2–17–22; 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 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: Center for Scientific Review Special Emphasis Panel; RFA–TR–20–001: Ethical Issues in Translational Science Research (R01 Clinical Trial Optional).

Date: March 15, 2022.

Time: 2:00 p.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Sara Louise Hargrave, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of