transfer fee, especially for international wire transfers. Applicable wire transfer fees must be included with payment to ensure fees are paid in full. Questions about wire transfer fees should be addressed to the financial institution. The account information for wire transfers is as follows: U.S. Department of the Treasury, TREAS NYC, 33 Liberty St., New York, NY 10045, Acct. No.: 75060099, Routing No.: 021030004, SWIFT: FRNYUS33. If needed, FDA's tax identification number is 53–0196965.

B. Prescription Drug Program Fees

FDA will issue invoices and payment instructions for FY 2022 program fees under the new fee schedule in August 2021. Payment will be due on October 1, 2021. FDA will issue invoices in December 2021 for products that qualify for FY 2022 program fee assessments after the August 2021 billing.

Dated: August 11, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–17505 Filed 8–13–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–0739]

International Drug Scheduling; Convention on Psychotropic Substances; Single Convention on Narcotic Drugs; 4F–MDMB–BICA (4F–MDMB–BUTICA); Brorphine; Metonitazene; Eutylone (bk-EBDB); BMDP (3,4-Methylenedioxy-N-benzylcathinone); Kratom (mitragynine, 7-hydroxymitragynine); Phenibut; Reopening Comment Period

AGENCY: Food and Drug Administration, Department of Health and Human Services (HHS).

ACTION: Notice; reopening comment period.

SUMMARY: The Food and Drug Administration (FDA or Agency) is reopening the comment period for the notice entitled ''International Drug Scheduling; Convention on Psychotropic Substances; Single Convention on Narcotic Drugs; 4F–MDMB–BICA (4F–MDMB–BUTICA); Brorphine; Metonitazene; Eutylone (bk-EBDB); BMDP (3,4-Methylenedioxy-N-benzylcathinone); Kratom (mitragynine, 7-hydroxymitragynine); Phenibut'' that appeared in the **Federal Register** of July 23, 2021. The Agency is taking this action to allow interested persons additional time to submit comments. These comments will be considered in preparing a response from the United States to the World Health Organization (WHO) regarding the abuse liability and diversion of these drugs. WHO will use this information to consider whether to recommend that certain international restrictions be placed on these drug substances.

DATES: FDA is reopening the comment period for the notice published July 23, 2021 (86 FR 39038). Submit either electronic or written comments by August 24, 2021.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before August 24, 2021. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of August 24, 2021. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2021–N–0739 for ''International Drug Scheduling; Convention on Psychotropic Substances; Single Convention on Narcotic Drugs; 4F–MDMB–BICA (4F–MDMB–BUTICA); Brorphine; Metonitazene; Eutylone (bk-EBDB); BMDP (3,4-Methylenedioxy-N-benzylcathinone); Kratom (mitragynine, 7-hydroxymitragynine); Phenibut; Request for Comments.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in 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: James R. Hunter, Center for Drug Evaluation and Research, Controlled Substance Staff, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 5150, Silver Spring, MD 20993–0002, 301–796–3156, *james.hunter@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of July 23, 2021 (86 FR 39038), FDA published a notice entitled ''International Drug Scheduling; Convention on Psychotropic Substances; Single Convention on Narcotic Drugs; 4F–MDMB–BICA (4F–MDMB–BUTICA); Brorphine; Metonitazene; Eutylone (bk-EBDB); BMDP (3,4-Methylenedioxy-N-benzylcathinone); Kratom (mitragynine, 7-hydroxymitragynine); Phenibut'' that requested comments for consideration in preparing a response from the United States to the WHO regarding the abuse liability and diversion of these drugs. WHO will use this information to consider whether to recommend that certain international restrictions be placed on these drug substances. To allow interested persons additional time to submit comments, FDA is reopening the comment period until August 24, 2021.

Dated: August 11, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–17498 Filed 8–11–21; 4:15 pm]

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: The HRSA Community-Based Outreach Reporting Module, OMB # 0906–0064, Extension

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

ACTION: Notice.

SUMMARY: HRSA requests an extension to continue data collection for the Community-Based Workforce for COVID–19 Vaccine Outreach Programs (CBO Programs) (OMB # 0906–0064). 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 15, 2021.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or by mail to the HRSA Information Collection Clearance Officer, Room 14N136B, 5600 Fishers Lane, Rockville, MD 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 Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer, at (301) 443–1984.

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

Information Collection Request Title: The HRSA Community-Based Outreach Reporting Module, OMB # 0906–0064, Extension.

Abstract: HRSA requests approval of an extension of the current emergency ICR to continue data collection for the Community-Based Workforce for COVID–19 Vaccine Outreach Programs (CBO Programs), which support nonprofit private or public organizations to establish, expand, and sustain a public health workforce to prevent, prepare for, and respond to COVID–19. This data is needed to comply with requirements to monitor funds distributed under the American Rescue Plan Act of 2021 and in accordance with OMB Memorandum M–21–20.

Need and Proposed Use of the Information: HRSA is requesting approval from OMB for an extension of the current emergency data collection module to support HRSA's Healthcare Systems Bureau and Office of Planning, Analysis, and Evaluation requirements to monitor and report on funds distributed. As part of the American Rescue Plan Act of 2021, signed into law on March 11, 2021 (Pub. L. 117–2), HRSA has awarded nearly $250 million to develop and support a community-based workforce that will engage in locally tailored efforts to build vaccine confidence and bolster COVID–19 vaccinations in underserved communities. In June and July, under the CBO Programs, HRSA awarded funding to over 140 local and national organizations. These organizations are responsible for educating and assisting individuals in accessing and receiving COVID–19 vaccinations. This includes activities such as conducting direct face-to-face outreach and other forms of direct outreach to community members to educate them about the vaccine, assisting individuals in making a vaccine appointment, providing resources to find convenient vaccine locations, and assisting individuals with transportation or other needs to get to a vaccination site. The program will address persistent health disparities by offering support and resources to vulnerable and medically underserved communities, including racial and ethnic minority groups and individuals living in areas of high social vulnerability.

HRSA is proposing a new data reporting module—the Community-Based Vaccine Outreach Program Reporting Module—to collect information on CBO Program-funded activities. The CBO Program will collect monthly progress report data from funded organizations. This data will be related to the public health workforce, the vaccine outreach activities performed by this workforce, and the individuals who received vaccinations by this workforce in a manner that assesses equitable access to vaccine services and that the most vulnerable populations and communities are reached. This data will allow HRSA to clearly identify how the funds are being used and monitored throughout the period of performance and to ensure that high-need populations are being reached and vaccinated. Responses to some data requirements are only reported during the initial reporting cycle (*e.g.,* the name, location, affiliation, etc. of the individual supporting community outreach), though respondents may update the data should any of that change during the duration of the reporting period.

Likely Respondents: Respondents are community outreach workers employed by entities supported by HRSA grant funding over a period of either 6 months (HRSA–21–136) or 12 months (HRSA–21–140).

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain,