TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Focus groups and individual in-depth interviews	12,000	1	12,000	1.75	21,000

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The estimated burden for the information collection reflects an overall increase of 5,600 hours and a corresponding increase of 3,200 responses. We have added individual in-depth interviews as a method of information gathering. In addition, we are consolidating ICR 0910–0677, ''Focus Groups About Drug Products as Used by the Food and Drug Administration'' into this request for extension.

Dated: October 13, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–23011 Filed 10–18–23; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2020–D–1057 and FDA–2020–D–1136]

Food and Drug Administration; Center of Drug Evaluation and Research Guidance Documents Related to Coronavirus Disease 2019, Expiration

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the withdrawal of guidances for industry entitled ''Notifying FDA of a Permanent Discontinuance or Interruption in Manufacturing Under Section 506C of the FD&C Act,'' which posted March 2020 to communicate recommendations for notifying the Agency about the permanent discontinuance or interruption in manufacturing of certain drug products; and ''COVID–19: Potency Assay Consideration for Monoclonal Antibodies and Other Therapeutic Proteins Targeting SARS–CoV–2 Infectivity'' which posted January 2021 to communicate information on the development of monoclonal antibodies (mAbs) and other therapeutic proteins for use as COVID–19 therapeutics. FDA is withdrawing these two guidance documents because new draft guidances are available that reflect comments received on the COVID–19 guidances, and many of the recommendations set forth in the COVID–19 guidances are applicable outside the context of the public health emergency (PHE) and included in the draft guidances.

DATES: The expiration date is November 7, 2023.

FOR FURTHER INFORMATION CONTACT: Kimberly Thomas, Office of Regulatory Policy, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301–796–2357.

SUPPLEMENTARY INFORMATION:

I. Background

As part of FDA's commitment to providing timely guidance to support response efforts to the Coronavirus Disease 2019 (COVID–19) [1] pandemic, the Agency published on the FDA website the guidance for industry entitled ''Notifying FDA of Permanent Discontinuance or Interruption in Manufacturing Under Section 506C of the FD&C Act'' in March 2020, and announced its availability in the **Federal Register** on April 6, 2020 (85 FR 18247), (Notifying FDA Guidance); and in January 2021, the Agency published on the FDA website the guidance for industry entitled ''COVID–19: Potency Assay Considerations for Monoclonal Antibodies and Other Therapeutic Proteins Targeting SARS–CoV–2 Infectivity'' and announced its availability in the **Federal Register** February 19, 2021 (86 FR 10285), (Potency Assay Guidance). The Notifying FDA Guidance explained that during the COVID–19 pandemic FDA had been closely monitoring the medical supply chain with the expectation that it may be impacted by the COVID–19 outbreak, potentially leading to supply disruptions or shortages of drug and biological products in the United States. The Notifying FDA Guidance, therefore, communicated the Agency's recommendations for providing timely, informative notifications about changes in the production of certain drugs and biological products to help the Agency in its efforts to prevent or mitigate shortages of such products. The Potency Assay Guidance communicated information to assist sponsors in the development of mAbs and other therapeutic proteins for use as COVID–19 therapeutics and described how potency assay methods required for release and stability testing can be shown to assess known or potential mechanism(s) of action of the product. The guidance also described methods that applicants should use to ensure the potency of mAbs and other therapeutic proteins proposed for use in as anti-infective agents for COVID–19. FDA issued both guidances to communicate its recommendations for the duration of the COVID–19 PHE declared by the Secretary of Health and Human Services (HHS) on January 31, 2020, including any renewals made by the HHS Secretary in accordance with section 319(a)(2) of the Public Health Service Act (42 U.S.C. 247d(a)(2)). We also said in both guidances that we expected their recommendations would continue to apply in circumstances outside the context of the PHE and that following the end of the COVID–19 PHE, FDA intended to revise and replace the guidances with updated guidances that incorporated any appropriate changes based on comments received and the Agency's experience with implementation. Furthermore, in the **Federal Register** of March 13, 2023 (88 FR 15417), FDA listed the COVID–19-related guidance documents that will no longer be in effect with the expiration of the COVID–19 PHE declaration on May 11, 2023, guidances that FDA revised to continue in effect for 180 days after the expiration of the COVID–19 PHE declaration to provide a period for stakeholder transition and then would no longer be in effect, and guidances that FDA revised to continue in effect for 180 days after the expiration of the PHE declaration during which time FDA planned to further revise the guidances. The Notifying FDA Guidance and the Potency Assay Guidance were included in the latter category and were revised to remain in effect for 180 days post expiration of the PHE declaration.

FDA also stated in the **Federal Register** of March 13, 2023, that the

[1] The virus has been named ''SARS–CoV–2'' and the disease it causes has been named ''Coronavirus Disease 2019'' (COVID–19).

Agency ''continues to assess the needs and circumstances related to the policies in our COVID–19-related guidances, and we may alter our approach for individual guidances listed in this notice.'' (88 FR 15417 at 15418). Following the expiration of the COVID–19 PHE declaration on May 11, 2023, FDA has reviewed the Notifying FDA Guidance and the Potency Assay Guidance and determined that these two guidances are no longer needed because new draft guidances are available.

In March 2023 (88 FR 13126), the Agency issued the draft guidance document entitled ''Potency Assay Considerations for Monoclonal Antibodies and Other Therapeutic Proteins Targeting Viral Pathogens,'' which provides information to assist in the development of mAbs and other therapeutic proteins directly targeting viral proteins or host cell proteins mediating pathogenic mechanisms of infection. The draft guidance also provides detailed recommendations for drug developers with the goal of helping to ensure that drug developers provide adequate information to assess potency at each stage of a product's life cycle. FDA believes that many of the recommendations set forth in the 2021 Potency Assay Guidance are applicable outside the context of the COVID–19 PHE and are applicable to mAbs and other therapeutic protein directly targeting any viral surfaces (glycol) proteins mediating pathogenic mechanisms of infection, not just those that directly target SARS–CoV–2. In preparing the draft guidance, FDA considered comments received regarding the 2021 Potency Assay Guidance as well as the Agency's experience with SARS–CoV–2 and other viruses.

In April 2023 (88 FR 20526), the Agency issued the draft guidance for industry entitled ''Notification of a Permanent Discontinuance or Interruption in Manufacturing Under Section 506C of the FD&C Act'' to assist applicants and manufacturers in providing FDA timely, informative notifications about changes in the production of certain finished drugs and biological products as well as certain active pharmaceutical ingredients (API) that may, in turn, help the Agency in its effort to prevent and mitigate shortages. The draft guidance discusses the notification requirements under section 506C of the Federal Food, Drug and Cosmetic Act (FD&C Act) (21 U.S.C. 356c), including requirements added by the Coronavirus Aid, Relief, and Economic Security Act (CARES Act)[2] related to notifying FDA about finished product and API manufacturing discontinuances and interruptions. The draft guidance provides recommendations for applicants and manufacturers to provide additional details and follow additional procedures to ensure FDA has the specific information it needs to help prevent or mitigate shortages. In addition, the draft guidance explains how FDA communicates information about products in shortage to the public. In preparing the draft guidance, FDA considered comments received on the 2020 Notifying FDA Guidance.

For the reasons discussed above, FDA is announcing the guidance entitled ''Notifying FDA of Permanent Discontinuance or Interruption in Manufacturing Under Section 506C of the FD&C Act'' (March 2020) and the guidance entitled ''COVID–19: Potency Assay Consideration for Monoclonal Antibodies and Other Therapeutic Proteins Targeting SARS–CoV–2 Infectivity'' (January 2021) will expire on November 7, 2023.

II. Expiration Date

The expiration date for the guidance documents in this document is November 7, 2023.

Dated: October 16, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–23071 Filed 10–18–23; 8:45 am]

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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; Rapid Uptake of Disseminated Interventions Evaluation, OMB No. 0906-xxxx

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

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, HRSA 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 November 20, 2023.

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 a copy of the clearance requests submitted to OMB for review, email Joella Roland, the HRSA Information Collection Clearance Officer, at *paperwork@hrsa.gov* or call (301) 443–3983.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: Rapid Uptake of Disseminated Interventions (RUDI) Evaluation, OMB No. 0906-xxxx—New.

Abstract: HRSA dedicated significant resources and effort to developing novel intervention strategies aimed at eliminating disparities and improving HIV-related health outcomes for people with HIV. HRSA encourages and supports Ryan White HIV/AIDS Program (RWHAP) providers to implement interventions developed through its RWHAP Part F Special Projects of National Significance program and technical assistance initiatives that have been found to be effective, with adaptations for priority populations served as applicable. HRSA disseminates its RWHAP Part F Special Projects of National Significance and technical assistance initiative resources and products across a variety of dissemination channels, hoping to reach a maximum number of RWHAP recipients and subrecipients for whom these resources may meet an important need. This mixed-methods RUDI evaluation will use a web-based survey and virtual site visits to collect information from RWHAP recipients and subrecipients on the uptake, utility, and efficacy of the resources and products HRSA disseminates; the effectiveness of its dissemination processes; and the reach of its dissemination channels. HRSA will use

[2] The CARES Act (Pub. L. 116–136) was enacted on March 27, 2020. The CARES Act amendments to section 506C of the FD&C Act took effect on September 23, 2020. See section 3112(g) of the CARES Act.