Requests (PLAIR),'' (March 2022). Historically, when applicants with a pending new drug application, abbreviated new drug application, or Center for Drug Evaluation and Research-regulated biologics licensing application (information collection associated with these submissions is currently approved under OMB control number 0910–0001) sought to import unapproved finished dosage form drug products into the United States in preparation for market launch, we considered such requests, informally referred to as ''PLAIRs,'' on a case-by-case basis. Since implementing the PLAIR program in 2013, interest continues to increase, so we have developed a more formalized process as discussed in the guidance document. The guidance is available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/pre-launch-activities-importation-requests-plair* and was issued consistent with our good guidance practice regulations in 21 CFR 10.115, which provide for public comment on Agency guidance documents at any time. The guidance document instructs that PLAIR submissions should be made using the applicant's letterhead and submitted by email to *CDER-OC-PLAIR@fda.hhs.gov* in a file compatible with Portable Document Format (PDF).

Description of Respondents: Respondents to the information collection are domestic and foreign importers of FDA-regulated articles being imported or offered for import into the United States and entry filers who submit import entries on behalf of these importers.

We estimate the burden of the information collection as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1] [2]

21 CFR part 1, subpart D	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Importers submission of data elements (preparing the required information).	95,307	10.14	967,069	0.05576 (3.346 minutes)	53,924
Entry filers (unique lines only)	4,133	10,804	44,656,657	0.04466 (2.68 minutes)	1,994,336
WEF participants	10	1	10	0.87 (52 minutes)	9
ITACS; creation of new account	500	1	1	0.5 (30 minutes)	250
Form FDA 766 as required under 21 CFR 1.95	324	1	324	0.25 (15 minutes)	81
Form FDA 5054	1,000	1	1,000	.083 (5 minutes)	83
Submissions in accordance w/PLAIR	80	4	320	16	5,120
Total			45,625,381		2,053,803

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Numbers have been rounded to reflect electronic submission data.

Table 1, rows 1 and 2, reflects annual average filing submissions through December 31, 2022. An IOR may be the owner or purchaser of the article being imported or offered for import, or a customs broker licensed by CBP under 19 U.S.C. 1641 who has been designated by the owner, purchaser, or consignee to file the import entry. There is only one IOR per entry.

As reflected in table 1, row 3, we estimate 10 respondents will submit WEFs. Persons wishing to file weekly entries of FDA-regulated products are encouraged to provide the information identified so that FDA can conduct a preliminary admissibility assessment of the associated products and firms. This submission typically contains the information FDA requests for multiple products (*i.e.,* the respondent wishes to file weekly entries for multiple products and submits the information for each product together). Generally, submissions involving multiple products are significantly less burdensome on a per-product basis. Depending on the product and scale of submission, this estimated burden may fluctuate. Filers submitting in ACE typically use software that is developed to specifically automate and expedite the entry submission process and allows filers to automatically upload entry information. While the WEF submission includes an initial one-time submission burden, we expect reduced burden over a long term because filers can subsequently submit one entry covering multiple withdrawals from the FTZ in any given 7-day period.

As reflected in table 1, row 4, we estimate that 500 new ITACS accounts will be created annually. Since developing and implementing ITACS, we have adjusted this estimate downward to reflect the transition from initial program interest to average annual maintenance-level numbers.

As reflected in table 1, row 5, we estimate the submission of 324 Forms FDA 766 in conjunction with FDA-regulated products. This figure is based on Agency import data and our experience with the information collection. We assume it takes respondents 15 minutes to complete and submit Form FDA 766. Although current instructions communicate that four copies be submitted (one copy to be returned to respondent), we plan to update the form to reduce this number.

Based on inquiries already received and processed by FDA, we anticipate 1,000 respondents will annually submit Form 5054 pertaining to general drug import information, as reflected in table 1, row 6.

As shown in table 1, row 7, we estimate 80 respondents to the PLAIR program annually, an increase of 10 since our last evaluation of the information collection. At the same time, we estimate one fewer submission per respondent to correspond with a decrease in submissions received by FDA.

Cumulatively these changes and adjustments result in an increase of 3,067,493 responses and 137,719 hours annually.

Dated: April 5, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–07442 Filed 4–7–23; 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; Ryan White HIV/AIDS Program Parts A and B Unobligated Balances and Rebate Addendum Tables, OMB No. 0906–0047—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 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 May 10, 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 Samantha Miller, the HRSA Information Collection Clearance Officer, at *paperwork@hrsa.gov* or call (301) 594–4394.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: Ryan White HIV/AIDS Program Parts A and B Unobligated Balances and Rebate Addendum Tables—OMB No. 0906–0047—Revision.

Abstract: HRSA's Ryan White HIV/AIDS Program (RWHAP) funds and coordinates with cities, states and territories, and local clinics/community-based organizations to deliver efficient and effective HIV care, treatment, and support to low-income people diagnosed with HIV. Nearly two-thirds of RWHAP clients (patients) live at or below 100 percent of the federal poverty level and approximately three-quarters of RWHAP clients are racial and ethnic minorities. Since 1990, RWHAP has developed a comprehensive system of HIV service providers who deliver high quality direct health care and support services to over half a million people diagnosed with HIV—more than 50 percent of all people diagnosed with HIV in the United States.

Grant recipients funded under parts A and B of RWHAP (codified under title XXVI of the Public Health Service Act) are required to report financial data to HRSA annually in their Federal Financial Report (FFR SF–425). In addition to the FFR, RWHAP parts A and B grant recipients are required to identify and report the unobligated balance (UOB) by itemized subprogram/funding stream source (Formula, Minority AIDS Initiative (MAI), AIDS Drug Assistance Program (ADAP), etc.). As of April 22, 2021, grant recipients must submit the subprogram breakdown of the UOB on their FFR in the Payment Management System. Grant recipients are also required to specify RWHAP Rebate Funding received in the fiscal year in the UOB table. HRSA uses the UOB and rebate addendum financial information to determine formula funding as directed by the RWHAP statute. These data were previously collected when grant recipients submitted their annual FFR SF–425 in hard copy only to HRSA, which then combined the FFR SF–425 data with the UOB and rebate addendum tables that are submitted by recipients on a suggested format through the HRSA Electronic Handbook (EHBs). The purpose of this financial data collection is to streamline the process for the grant recipients by collecting financial information in the same location and at the same time. The FFR SF–425 is now completed in the Payment Management System and is exported automatically to the HRSA EHBs when the recipient completes the FFR. The UOB tables for RWHAP parts A and B will continue to collect the same information with the addition of one column on prior year (fiscal year (FY) 20XX) information. This one column will impact seven recipients out of 111 RWHAP part A and part B recipients in total, annually. Recipients that need to submit data to the added column need to complete one or several fields at the most. (See tables below for reference). The UOB and rebate addendum data tables will be collected in the HRSA EHBs below the FFR SF–425 control number and the Paperwork Burden Statement.

A 60-day notice published in the **Federal Register** on January 24, 2023, 88 FR 4190–4192. There were no public comments.

Need and Proposed Use of the Information: RWHAP part A and part B recipients complete the UOB and rebate addendum tables as a part of their FFR SF–425 submission. This process has decreased administrative burden, increased transparency, and improved the quality of data submitted to HRSA. These UOB and rebate addendum tables are essential for allowing HRSA to ensure that RWHAP recipients are meeting the goal of accountability to Congress, clients, advocacy groups, and the general public. Information provided in the UOB and rebate addendum tables is critical for HRSA, states and territories, local clinics, and individual providers to evaluate the effectiveness of these programs.

Likely Respondents: HRSA RWHAP parts A and B recipients.

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
Part A UOB Table	52	1	52	0.5	26
Part B UOB Table	59	1	59	0.5	29.5
Total	111		111		55.5

Note: Beginning in July 2021, information related to prior year UOB was collected in addition to the existing data in the approved ICR. The additional information collected does not impact all 111 respondents; in FY 2020, seven respondents reported prior year UOB, which equates to only 6 percent of respondents impacted. The estimated burden to potentially impacted respondents is negligible. See the tables below for comparison of the added data point for prior year UOB. No changes were made to the approved ICR for the RWHAP part B rebate table.

2019 APPROVED ICR TABLE FOR RWHAP PART A

UOB of federal funds by subprogram			
Category	Federal funds authorized	Unexpended carryover	Current year (FY 20XX)
Part A Formula Part A Supplemental Part A MAI			

REVISED RWHAP PART A TABLE

UOB of federal funds by subprogram				
Category	Federal funds authorized	Unexpended carryover	Prior year (FY 20XX)	Current year (FY 20XX)
Part A Formula Part A Supplemental Part A MAI				

2019 APPROVED ICR TABLE FOR RWHAP PART B

UOB of federal funds by subprogram			
Category	Federal funds authorized	Unexpended carryover	Current year (FY 20XX)
Part B Base Part B ADAP Part B Emerging Communities Part B MAI Part B ADAP Supplemental Part A Transfer			

REVISED RWHAP PART B TABLE

UOB of federal funds by subprogram				
Category	Federal funds authorized	Unexpended carryover	Prior year (FY 20XX)	Current year (FY 20XX)
Part B Base Part B ADAP Part B Emerging Communities. Part B MAI Part B ADAP Supplemental. Part A Transfer				

RWHAP PART B REBATES TABLE

Ryan White rebate funding	
Total Rebates Available. Expended Rebate Amount Unexpended Rebate Expended Rebate Amount to be Used to Reduce UOB	

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. 2023–07410 Filed 4–7–23; 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 Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting 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; Population-based Research in Vector-borne Disease.

Date: April 17, 2023.

Time: 11:00 a.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: Lisa Steele, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3139, MSC 7770, Bethesda, MD 20892, (301) 257–2638, *steeleln@csr.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: April 4, 2023.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023–07404 Filed 4–7–23; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Arthritis and Musculoskeletal and Skin Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the Board of Scientific Counselors, NIAMS.

The meeting will be closed to the public as indicated below in accordance with the provisions set forth in section 552b(c)(6), title 5 U.S.C., as amended for the review, discussion, and evaluation of individual intramural programs and projects conducted by the NATIONAL INSTITUTE OF ARTHRITIS AND MUSCULOSKELETAL AND SKIN DISEASES, including consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Board of Scientific Counselors, NIAMS.

Date: May 2–3, 2023.

Closed: May 02, 2023, 2:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate personnel qualifications and performance, and competence of individual investigators.

Place: Porter Neuroscience Research Center, Building 35A, 620/630, 35 Convent Drive, Bethesda, MD 20892.

Closed: May 03, 2023, 10:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate personnel qualifications and performance, and competence of individual investigators.

Place: Porter Neuroscience Research Center, Building 35A, 620/630, 35 Convent Drive, Bethesda, MD 20892.

Contact Person: John J. O'Shea, MD, Scientific Director of Intramural Research, National Institute of Arthritis & Musculoskeletal and Skin Diseases, Building 10, Bethesda, MD 20892, (301) 496–2612, *osheaj@mail.nih.gov.*

In the interest of security, NIH has procedures at *https://www.nih.gov/about-nih/visitor-information/campus-access-security* for entrance into on-campus and off-campus facilities. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors attending a meeting on campus or at an off-campus federal facility will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

Additional Health and Safety Guidance: Before attending a meeting at an NIH facility, it is important that visitors review the NIH COVID–19 Safety Plan at *https://ors.od.nih.gov/sr/dohs/safety/NIH-covid-19-safety-plan/Pages/default.aspx* and the NIH testing and assessment web page at *https://ors.od.nih.gov/sr/dohs/safety/NIH-covid-19-safety-plan/COVID-assessment-testing/Pages/visitor-testing-requirement.aspx* for information about requirements and procedures for entering NIH facilities, especially when COVID–19 community levels are medium or high. In addition, the Safer Federal Workforce website has FAQs for visitors at *https://www.saferfederalworkforce.gov/faq/visitors/.* Please note that if an individual has a COVID–19 diagnosis within 10 days of the meeting, that person must attend virtually. (For more information please read NIH's Requirements for Persons after Exposure at *https://ors.od.nih.gov/sr/dohs/safety/NIH-covid-19-safety-plan/COVID-assessment-testing/Pages/persons-after-exposure.aspx* and What Happens When Someone Tests Positive at *https://ors.od.nih.gov/sr/dohs/safety/NIH-covid-19-safety-plan/COVID-assessment-testing/Pages/test-positive.aspx.* Anyone from the public can attend the open portion of the meeting virtually via the NIH Videocasting website (*http://videocast.nih.gov*). Please continue checking these websites, in addition to the committee website listed below, for the most up to date guidance as the meeting date approaches.

(Catalogue of Federal Domestic Assistance Program Nos. 93.846, Arthritis, Musculoskeletal and Skin Diseases Research, National Institutes of Health, HHS)

Dated: April 4, 2023.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023–07403 Filed 4–7–23; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Alcohol Abuse and Alcoholism; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Advisory Council on Alcohol Abuse and Alcoholism.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting. The open session will be videocast and can be accessed from the NIH Videocasting and Podcasting website (*http://videocast.nih.gov/*).

A portion of this meeting will be closed to the public in accordance with