components) and any person whose name appears on the label of a licensed biological product.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN—BIOLOGICAL PRODUCTS [1]

21 CFR Section; activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (in hours)	Total hours
600.80(c)(1), 600.80(d), and 600.80(e); postmarketing 15-day Alert Reports	109	3,806.95	414,958	1	414,958
600.82; notification of discontinuance or interruption in manufacturing	23	1.435	33	2	66
600.80(c)(2); Periodic Adverse Experience Reports	109	3,697	402,973	28	11,283,244
600.81; distribution reports	172	5.727	985	1	985
600.80(h)(2), 600.81(b)(2), and 600.90; waiver requests	35	1.886	66	1	66
Total					11,699,319

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

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

21 CFR Section; activity	Number of recordkeepers	Numbers of records per recordkeeper	Total annual records	Average burden per recordkeeper (in hours)	Total hours
600.12 [2]; Maintenance of Records	131	40.145	5,259	32	168,288
600.12(b)(2); Recall Records	216	3.4028	735	24	17,640
600.80(c)(1) and 600.80(k); AER Records	109	7,503.95	817,931	1	817,931
Total					1,003,859

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] The recordkeeping requirements in § 610.18(b) are included in the estimate for § 600.12.

TABLE 3—ESTIMATED ANNUAL REPORTING BURDEN—COMBINATION PRODUCTS [1]

21 CFR Section; activity	Number of respondents	Number of disclosures per respondents	Total annual disclosures	Average burden per disclosure (in hours)	Total hours
4.102, 4.103, 4.104, 4.105; Postmarketing Safety Reporting for Combination Products, including associated reports and sharing information with other constituent part applicants.	11	18	198	0.35 (21 minutes)	69

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

The burden for this information collection has changed since the last OMB approval. The reporting and recordkeeping burden has increased mostly due to an increase in the number of AER reports submitted to FDA and the associated recordkeeping with these reports. We have also added burden we believe attributable to post marketing safety reporting and attendant recordkeeping and disclosures, as required under part 4, subpart B.

Dated: March 7, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–05222 Filed 3–11–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the Presidential Advisory Council on HIV/AIDS

AGENCY: Department of Health and Human Services, Office of the Secretary, Office of the Assistant Secretary for Health.

ACTION: Notice of a meeting.

SUMMARY: As stipulated by the Federal Advisory Committee Act, the U.S. Department of Health and Human Service is hereby giving notice that the Presidential Advisory Council on HIV/AIDS (PACHA or the Council) will convene the 80th full council meeting on Wednesday, March 27–Thursday, March 28, 2024. The meeting will be open to the public and there will be a public comment session during the meeting; pre-registration is required to provide public comment. To pre-register to provide public comment, please send an email to *PACHA@hhs.gov* and include your name, organization, and title by close of business Monday, March 18, 2024. If you decide you would like to provide public comment but do not pre-register, you may submit your written statement by emailing *PACHA@hhs.gov* by close of business Thursday, April 4, 2024. The meeting agenda will be posted on the PACHA page on *HIV.gov* at *https://www.hiv.gov/federal-response/pacha/about-pacha* prior to the meeting.

DATES: The meeting will convene on Wednesday, March 27, 2024 from approximately 10:00 a.m. (Eastern) –7:00 p.m. (Eastern) and Thursday, March 28, 2024 from approximately 10:00 a.m. (Eastern) to 4:45 p.m. (Eastern).

ADDRESSES: Texas Southern University, 3100 Cleburne Avenue, Houston, TX 77004. To attend the meeting virtually, please visit *www.hhs.gov/live.*

FOR FURTHER INFORMATION CONTACT: Ms. Caroline Talev, MPA, Senior Management Analyst, at *PACHA@hhs.gov* or *Caroline.Talev@hhs.gov.* Additional information can be obtained by accessing the Council's page on the *HIV.gov* site at *www.hiv.gov/pacha.*

SUPPLEMENTARY INFORMATION: PACHA was established by Executive Order 12963, dated June 14, 1995, as amended

by Executive Order 13009, dated June 14, 1996 and is currently operating under the authority given in Executive Order 14109, dated September 29, 2023. The Council was established to provide advice, information, and recommendations to the Secretary regarding programs and policies intended to promote effective HIV diagnosis, treatment, prevention, and quality care services. The functions of the Council are solely advisory in nature.

The Council consists of not more than 35 members. Council members are selected from prominent community leaders with particular expertise in, or knowledge of, matters concerning HIV and AIDS, public health, global health, population health, philanthropy, marketing or business, as well as other national leaders held in high esteem from other sectors of society. PACHA selections also include persons with lived HIV experience and persons disproportionately affected by HIV. Council members are appointed by the Secretary.

Dated: February 21, 2024.

Caroline Talev,

Senior Management Analyst, Office of Infectious Disease and HIV/AIDS Policy, Alternate Designated Federal Officer, Presidential Advisory Council on HIV/AIDS, Office of the Assistant Secretary for Health, Department of Health and Human Services.

[FR Doc. 2024–05183 Filed 3–11–24; 8:45 am]

BILLING CODE 4150–43–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS–0990-new]

Agency Information Collection Request. 60-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

DATES: Comments on the ICR must be received on or before May 13, 2024.

ADDRESSES: Submit your comments to *Sherrette.Funn@hhs.gov* or by calling (202) 264–0041 and *PRA@HHS.GOV.*

FOR FURTHER INFORMATION CONTACT: When submitting comments or requesting information, please include the document identifier 0990-New-60D and project title for reference, to Sherrette A. Funn, email: *Sherrette.Funn@hhs.gov, PRA@HHS.GOV* or call (202) 264–0041 the Reports Clearance Officer.

SUPPLEMENTARY INFORMATION: Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (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.

Title of the Collection: OASH Periodic Performance Project Report (PPR) for Grants and Cooperative Agreements.

Type of Collection: New.

OMB No. 0990–NEW–Office of the Assistant Secretary for Health.

Abstract: The Office of the Assistant Secretary for Health (OASH) is seeking OMB approval on a new information collection, the OASH Standard Periodic Performance Project Report (PPR) for Grants and Cooperative Agreements (hereafter the OASH PPR). The purpose of this data collection is to gather quantitative and qualitative information common to the assessment of recipient performance on individual grants and cooperative agreements (collectively, grants) managed in OASH. OASH will collect common data elements measuring the performance of each recipient against the approved grant project plan, including progress toward goals and outcomes as required by 45 CFR 75.342(b)(2).

OASH oversees a broad range of grant programs within the Office of the Secretary (OS), Department of Health and Human Services (HHS). The current active OASH programs with discretionary grants (with assistance listing number) include: Public Awareness Campaigns on Embryo Adoption (93.007); Research on Research Integrity (93.085); Advancing System Improvements for Key Issues in Women's Health (93.088); Community Programs to Improve Minority Health Grant Programs (93.137); Family Planning Services (93.217); Family Planning Personnel Training (93.260); Teenage Pregnancy Prevention Program (93.297); Public Health Service Evaluation Funds (93.343); Research, Monitoring and Outcomes Definitions for Vaccine Safety (93.344); Minority HIV/AIDS Fund (93.899); Family Planning Service Delivery Improvement Research Grants (93.974); and National Health Promotion (93.990). OASH grants span a wide range of project types, including service, demonstration project, evaluation, research, training, and conference projects. Within each program, the awards are subdivided into cohorts aligned with the notices of funding opportunity under which OASH competed the awards. Currently, there are 47 cohorts of active awards across OASH. In any given year, OASH programs collectively monitor 450–550 active awards with another 200–300 inactive awards awaiting final reports as a prerequisite to closing the grant.

The collection is needed to enhance project performance information and simplify reporting under 45 CFR 75.301. Each recipient currently must submit a quarterly Federal Financial Report (FFR or SF–425) (45 CFR 75.341) and a periodic Performance Progress Report (PPR) for each grant (45 CFR 75.342(b)(2). PPR reporting periods in OASH are scheduled quarterly, semi-annually, or annually, depending on the need determined by the program office using a narrative format that can vary by cohort. The PPR schedule is specifically aligned with the quarterly FFRs whenever possible to create a complete snapshot of the project's progress at the end of the reporting period.

The common elements identified in the new collection for OASH programs will standardize the collection of the required information (45 CFR 75.342(b)(2)) including: (1) a comparison of the actual accomplishments to the objectives of the award for the period; (2) the reasons why established goals were not met; and (3) pertinent information, analysis and explanation of cost overruns or high unit costs. The common elements include reporting on publications, including data sets and other work products, to facilitate implementation of OSTP Memorandum Ensuring Free, Immediate, and Equitable Access Federally Funded Research (August 25, 2022). The new information collection will limit the content of the report to those activities taking place during the reporting period (*i.e.,* quarterly, semiannually, or annually). The information collection is structured to facilitate program review across reporting periods. This will allow OASH to identify and improve program outcomes, share lessons learned, and spread the adoption of promising practices among its grant recipients and other HHS awarding agencies.

The content of the new collection is structured for web-based data collection under 7 headings: Report Header; Project Progress; Significant Project