FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6250, Silver Spring, MD 20993, 301–796–3600.

SUPPLEMENTARY INFORMATION:

I. Background

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human biological products, the testing phase begins when the exemption to permit the clinical investigations of the biological product becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human biological product and continues until FDA grants permission to market the biological product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human biological product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA has approved for marketing the human biologic product AIMOVIG (erenumab-aooe). AIMOVIG is indicated for the preventive treatment of migraine in adults. Subsequent to this approval, the USPTO received a patent term restoration application for AIMOVIG (U.S. Patent No. 9,102,731) from Amgen, Inc., and the USPTO requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated May 13, 2019, FDA advised the USPTO that this human biological product had undergone a regulatory review period and that the approval of AIMOVIG represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for AIMOVIG is 2,042 days. Of this time, 1,675 days occurred during the testing phase of the regulatory review period, while 367 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) became effective:* October 16, 2012. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on October 16, 2012.

2. *The date the application was initially submitted with respect to the human biological product under section 351 of the Public Health Service Act (42 U.S.C. 262):* May 17, 2017. FDA has verified the applicant's claim that the biologics license application (BLA) for AIMOVIG (BLA 761077) was initially submitted on May 17, 2017.

3. *The date the application was approved:* May 17, 2018. FDA has verified the applicant's claim that BLA 761077 was approved on May 17, 2018.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 689 days of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in § 60.30 (21 CFR 60.30), any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must comply with all the requirements of § 60.30, including but not limited to: Must be timely (see **DATES**), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to *https://www.regulations.gov* at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: November 26, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–26081 Filed 12–2–19; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request Information Collection Request Title: HRSA Ryan White HIV/AIDS Program AIDS Drug Assistance Program Data Report, OMB No. 0915–0345—Revision

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

ACTION: Notice.

SUMMARY: 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 February 3, 2020.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail 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 request collection title for reference, pursuant to Section 3506(c)(2)(A), the Paperwork Reduction Act of 1995.

Information Collection Request Title: HRSA Ryan White HIV/AIDS Program (RWHAP) AIDS Drug Assistance Program Data Report, OMB No. 0915–0345—Revision.

Abstract: HRSA's Ryan White HIV/AIDS Program (RWHAP) AIDS Drug Assistance Program (ADAP) is authorized under Part B of the RWHAP legislation, codified in sections 2611 *et seq.* of the Public Health Service Act, which provides grants to U.S. states and territories. RWHAP ADAP is a state and territory-administered program that provides Food and Drug Administration approved medications to low-income people with HIV who have limited or no health coverage from private insurance, Medicaid, or Medicare. RWHAP ADAP funds may also be used to purchase health insurance for eligible clients and for services that enhance access, adherence, and monitoring of drug treatments.

All 50 states, the District of Columbia, Puerto Rico, Guam, the U.S. Virgin Islands, and the five U.S. Pacific Territories or Associated Jurisdictions receive RWHAP Part B grant awards including funds for RWHAP ADAP. RWHAP Part B reporting requirements include the annual submission of an ADAP Data Report (ADR), including a Recipient Report and a Client Report. The Recipient Report is a collection of basic information about grant recipient characteristics and policies including program administration, purchasing mechanisms, funding, and expenditures. The Client Report is a collection of client-level records (one record for each client enrolled in the RWHAP ADAP), which includes the client's encrypted unique identifier, basic demographic data, enrollment information, services received and clinical data.

HRSA is proposing several changes to the ADR Recipient and Client Reports to improve question clarity, delete obsolete data elements, combine related data elements, add new data elements, and improve response options to reflect program practices and support HRSA's analysis and understanding of program impact. Specifically, the Recipient Report includes the following proposed changes:

- Addition of two new ''Yes/No'' questions,
- addition of one new follow-up question that requests the number of new clients enrolled,
- clarification on two existing questions,
- revision to one existing question that requests program income and manufacturer rebates reinvested in ADAP, and
- deletion of six obsolete data elements.

The Client Report includes the following proposed changes:

- Revision to reporting of RWHAP ADAP-funded medications to include all medications rather than a subset of medications;
- revision to one existing question that requests reporting of all RWHAP ADAP-funded medications using the National Drug Code from the Drug Identification Code (d-codes);
- revision to reporting of clinical data for clients to include all clients rather than a subset of clients; and
- deletion of three data elements that were combined with other existing data elements.

Overall, HRSA does not anticipate these proposed revisions resulting in a change in the reporting burden. New and revised data elements require reporting of information that should already be collected by recipients to meet legislative or programmatic requirements for the proper oversight and administration of the program.

Need and Proposed Use of the Information: RWHAP requires the submission of annual reports by the Secretary of HHS to the appropriate committees of Congress. HRSA uses the ADR to evaluate the national impact of the RWHAP ADAP by providing client-level data on individuals being served, services being delivered, and costs associated with these services. The client-level data is used to monitor health outcomes of people with HIV receiving care and treatment through the RWHAP ADAP, to monitor the use of RWHAP ADAP funds in addressing the HIV epidemic and its impact on vulnerable communities, and to track progress toward achieving the goals identified in the National HIV/AIDS Strategy.

Likely Respondents: State ADAPs of RWHAP Part 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 HOUR

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Grantee Report	54	1	54	6	324
Client-level Report	54	1	54	81	4,374
Total	*54		54		4,698

*The same respondents complete the Grantee Report and the Client-level Report.

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. 2019–26099 Filed 12–2–19; 8:45 am]

BILLING CODE 4165–15–P