the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug 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 drug 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 drug product, TEGSEDI (inotersen sodium) indicated for treatment of the polyneuropathy of hereditary transthyretin-mediated amyloidosis in adults. Subsequent to this approval, the USPTO received patent term restoration applications for TEGSEDI (U.S. Patent Nos. 8,101,743; 9,061,044; 9,399,774) from Ionis Pharmaceuticals, Inc. and the USPTO requested FDA's assistance in determining the patents' eligibility for patent term restoration. In, letters dated October 29, 2019, and November 29, 2019, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of TEGSEDI 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 TEGSEDI is 2,158 days. Of this time, 1,824 days occurred during the testing phase of the regulatory review period, while 334 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 (FD&C Act) (21 U.S.C. 355(i)) became effective: November 9, 2012. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on November 9, 2012.

2. The date the application was initially submitted with respect to the human drug product under section 505 of the FD&C Act: November 6, 2017. FDA has verified the applicant's claim that the new drug application (NDA) for TEGSEDI (NDA 211172) was initially submitted on November 6, 2017.

3. The date the application was approved: October 5, 2018. FDA has verified the applicant's claim that NDA 211172 was approved on October 5, 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 applications for patent extension, this applicant seeks 526 days or 1,246 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 Nos. 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: March 17, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–05906 Filed 3–22–23; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

[OMB No. 0906–0029—Extension]

Agency Information Collection Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: Shortage Designation Management System (SDMS)

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

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 April 24, 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 Acting HRSA Information Collection Clearance Officer, at *paperwork@hrsa.gov* or call 301–594–4394.

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

Information Collection Request Title: Shortage Designation Management System.

OMB No.: 0906–0029—Extension.

Abstract: HRSA is committed to improving the health of the nation's underserved communities by developing, implementing, evaluating, and refining programs that strengthen the nation's health workforce. The Department of Health and Human Services relies on two federal shortage designations to identify and dedicate

resources to areas and populations in greatest need of providers: Health Professional Shortage Area (HPSA) designations and Medically Underserved Area/Medically Underserved Population (MUA/P) designations. HPSA designations are geographic areas, population groups, and facilities that are experiencing a shortage of health professionals. The authorizing statute for the National Health Service Corps (NHSC) created HPSAs to fulfill the statutory requirement that NHSC personnel be directed to areas of greatest need. To further differentiate areas of greatest need, HRSA calculates a score for each HPSA. There are three categories of HPSAs based on health discipline: primary care, dental health, and mental health. Scores range from 1 to 25 for primary care and mental health and from 1 to 26 for dental, with higher scores indicating greater need. They are used to prioritize applications for NHSC Loan Repayment Program award funding and determine service sites eligible to receive NHSC Scholarship and Students-to-Service participants.

MUA/P designations are geographic areas, or population groups within geographic areas, that are experiencing a shortage of primary care health care services based on the Index of Medical Underservice. MUAs are designated for the entire population of a particular geographic area. MUP designations are limited to a particular subset of the population within a geographic area. Both designations were created to aid the federal government in identifying areas with healthcare workforce shortages.

As part of HRSA's cooperative agreement with the State Primary Care Offices (PCOs), the State PCOs conduct needs assessments in their states, determine what areas are eligible for designations, and submit designation applications for HRSA review via the Shortage Designation Management System (SDMS). Requests that come from other sources are referred to the PCOs for their review, concurrence, and submission via SDMS. In order to obtain a federal shortage designation for an area, population, or facility, PCOs must submit a shortage designation application through SDMS for review and approval by HRSA. Both the HPSA and MUA/P application request local, state, and national data on the population that is experiencing a shortage of health professionals and the number of health professionals relative to the population covered by the proposed designation. The information collected on the applications is used to determine which areas, populations, and facilities have qualifying shortages.

In addition, interested parties, including the Governor, the State PCO, state professional associations, etc. are notified of each designation request submitted via SDMS for their comments and recommendations.

HRSA reviews the HPSA applications submitted by the State PCOs, and—if they meet the designation eligibility criteria for the type of HPSA or MUA/P in the application—designates the HPSA or MUA/P on behalf of the Secretary. HPSAs are statutorily required to be annually reviewed and revised as necessary after initial designation to reflect current data. HPSA scores, therefore, may and do change from time to time. MUA/Ps do not have a statutorily mandated review period.

The lists of designated HPSAs are published annually in the **Federal Register**. In addition, lists of HPSAs are updated on the HRSA website, so that interested parties can access the information.

A 60-day Notice was published in the **Federal Register**, 88, FR pp. 360–361 (January 4, 2023). There were no public comments.

Need and Proposed Use of the Information: The information obtained from the SDMS application is used to determine which areas, populations, and facilities have critical shortages of health professionals per PCO application submission. The SDMS HPSA application and SDMS MUA/P application are used for these designation determinations. Applicants must submit a SDMS application to the HRSA Bureau of Health Workforce to obtain a federal shortage designation. The application asks for local, state, and national data required to determine the application's eligibility to obtain a federal shortage designation. In addition, applicants must enter detailed information explaining how the area, population, or facility faces a critical shortage of health professionals.

Likely Respondents: State PCOs interested in obtaining a primary care, dental, or mental HPSA designation or a MUA/P in their state.

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
Designation Planning and Preparation	54	48	2,592	8	20,736
SDMS Application	54	83	4,482	4	17,928
Total	54	.....	7,074	.....	38,664

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. 2023–05986 Filed 3–22–23; 8:45 am]

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