

APPENDIX D

60-day Federal Register Notice



52840

Federal Register / Vol. 83, No. 202 / Thursday, October 18, 2018 / Notices

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 AFSTYLA (Antihemophilic Factor (Recombinant), Single Chain). AFSTYLA is indicated in children and adults with hemophilia A (congenital Factor VIII deficiency) for: (1) On-demand treatment and control of bleeding episodes, (2) routine prophylaxis to reduce the frequency of bleeding episodes, and (3) perioperative management of bleeding. Subsequent to this approval, the USPTO received a patent term restoration application for AFSTYLA (U.S. Patent No. 7,041,635) from SK Chemicals Co, LTD., and the USPTO requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated August 1, 2017, FDA advised the USPTO that this human biological product had undergone a regulatory review period and that the approval of AFSTYLA 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 AFSTYLA is 1,734 days. Of this time, 1,371 days occurred during the testing phase of the regulatory review period, while 363 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:* August 28, 2011. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on August 28, 2011.

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 29, 2015. FDA has

verified the applicant's claim that the biologics license application (BLA) for AFSTYLA (BLA 125591) was initially submitted on May 29, 2015.

3. *The date the application was approved:* May 25, 2016. FDA has verified the applicant's claim that BLA 125591 was approved on May 25, 2016.

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 1,047 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: October 12, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018-22696 Filed 10-17-18; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request: Information Collection Request Title: Bureau of Health Workforce Performance Data Collection, OMB No. 0915-0061—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 December 17, 2018.

ADDRESSES: Submit your comments to paperwork@hrsa.gov or mail the HRSA Information Collection Clearance Officer, Room 14N39, 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.

Information Collection Request Title: Bureau of Health Workforce Performance Data Collection, OMB No. 0915-0061—Revision.

Abstract: Over 40 Bureau of Health Workforce (BHW) programs award grants to health professions schools and training programs across the United States to develop, expand, and enhance training, and to strengthen the distribution of the health workforce. These programs are governed by the Public Health Service Act (42 U.S.C. 201 *et seq.*), specifically Titles III, VII, and VIII. Performance information about these health professions programs is

collected in the HRSA Performance Report for Grants and Cooperative Agreements. Specific performance measurement requirements for each program may be found on the HRSA website at <https://bhw.hrsa.gov/grants/reportonyourgrant>. Data collection activities consist of two reports, an annual progress and annual performance report that are submitted by awardees to comply with statutory and programmatic requirements for performance measurement and evaluation (including specific Title III, VII and VIII requirements), as well as the Government Performance and Results Act of 1993 (GPRA) and the GPRA Modernization Act of 2010 requirements. The performance measures were last revised in 2016 to ensure they addressed programmatic changes, met evolving program management needs, and responded to emerging workforce concerns. As these changes successfully enabled BHW to demonstrate accurate outputs and outcomes associated with the health professions programs, BHW will continue with its current performance

management strategy and make only minor changes that reflect new HHS and HRSA priorities with the addition of a question asking awardees how many trainees received training in telehealth, substance use treatment, and/or medication-assisted treatment.

Need and Proposed Use of the Information: The purpose of the proposed data collection is to continue analysis and reporting of awardee training activities and educational programs, identify intended practice locations, and report outcomes of funded initiatives. Data collected from these grant programs will also provide a description of the program activities of approximately 1,500 reporting grantees to inform policymakers on the barriers, opportunities, and outcomes involved in health care workforce development. The proposed measures focus on five key outcomes: (1) Increasing the workforce supply of well-educated practitioners in needed professions; (2) increasing the number of practitioners that practice in underserved and rural areas; (3) enhancing the quality of education; (4) increasing the

recruitment, training, and placement of under-represented groups in the health workforce; and (5) supporting educational infrastructure to increase the capacity to train more health professionals in high demand areas.

Likely Respondents: Respondents are awardees of BHW health professions grant programs.

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
Direct Financial Support Program	500	1	500	3.1	1,550
Infrastructure Program	100	1	100	4.5	450
Multipurpose or Hybrid Program	900	1	900	4.3	3,870
	1,500	1,500	5,870