docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

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 medical devices, the testing phase begins with a clinical investigation of the device and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the device and continues until permission to market the device is granted. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award (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 medical device will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(3)(B).

FDA has approved for marketing the medical device BAROSTIM NEO. BAROSTIM NEO is indicated for the improvement of symptoms of heart failure, quality of life, six-minute hall walk and functional status, for patients who remain symptomatic despite treatment with guideline-directed medical therapy, are New York Heart Association Class III or Class II (who had a recent history of Class III), have a left ventricular ejection fraction <=35%, a NT-proBNP <1,600 picograms/milliliter and excluding patients indicated for Cardiac Resynchronization Therapy according to American Heart Association/American College of Cardiology/European Society of Cardiology Committee guidelines. Subsequent to this approval, the USPTO received patent term restoration applications for BAROSTIM NEO (U.S. Patent Nos. 8,606,359; 9,044,609; and 9,427,583) from CVRx, Inc., and the USPTO requested FDA's assistance in determining the patents' eligibility for patent term restoration. In a letter dated July 14, 2020, FDA advised the USPTO that this medical device had undergone a regulatory review period and that the approval of BAROSTIM NEO 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 BAROSTIM NEO is 2,550 days. Of this time, 2,310 days occurred during the testing phase of the regulatory review period, while 240 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption for this device, under section 520(g) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360j(g)), became effective:* August 24, 2012. The applicant claims that the investigational device exemption (IDE) required under section 520(g) of the FD&C Act for human tests to begin became effective on October 10, 2012. However, FDA records indicate that the IDE was determined substantially complete for clinical studies to have begun on August 24, 2012, which represents the IDE effective date.

2. *The date an application was initially submitted with respect to the device under section 515 of the FD&C Act (21 U.S.C. 360e):* December 20, 2018. The applicant claims December 19, 2018, as the date the premarket approval application (PMA) for BAROSTIM NEO (PMA 180050) was initially submitted. However, FDA records indicate that PMA 180050 was submitted on December 20, 2018.

3. *The date the application was approved:* August 16, 2019. FDA has verified the applicant's claim that PMA 180050 was approved on August 16, 2019.

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 541 days, 768 days, or 1,038 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: March 19, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–06210 Filed 3–24–21; 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; Information Collection Request Title: Radiation Exposure Screening and Education Program, OMB No. 0906–0012—EXTENSION

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 has 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 April 26, 2021.

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 Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer at *paperwork@hrsa.gov* or call (301) 443–1984.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: Radiation Exposure Screening and Education Program, OMB No. 0906–0012, Extension.

Abstract: The Radiation Exposure Screening and Education Program (RESEP) is authorized by section 417C of the Public Health Service Act (42 U.S.C. 285a–9). The purpose of RESEP is to assist individuals who live (or lived) in areas where U.S. nuclear weapons testing occurred and who are diagnosed with cancer and other radiogenic diseases caused by exposure to nuclear fallout or nuclear materials such as uranium. RESEP funds support eligible health care organizations in implementing cancer screening programs; developing education programs; disseminating information on radiogenic diseases and the importance of early detection; screening eligible individuals for cancer and other radiogenic diseases; providing appropriate referrals for medical treatment; and facilitating documentation of radiation exposure.

A 60-day notice was published in the **Federal Register** on October 30, 2020, vol. 85, No. 211, p. 68889–90. There were no public comments.

Need and Proposed Use of the Information: For this program, performance measures were drafted to provide data useful to the program and to enable HRSA to provide aggregate program data required by Congress under the Government Performance and Results Act of 1993 (Pub. L. 103–62). These measures cover the principal topic areas of interest to the Federal Office of Rural Health Policy, including: (a) Demographics for the RESEP program user population; (b) medical screening activities for cancers and other radiogenic diseases; (c) exposure and presentation types for eligible radiogenic malignant and nonmalignant diseases; (d) referrals for appropriate medical treatment; (e) eligibility counseling and referral assistance for the Radiation Exposure Compensation Act; and (f) program outreach and education activities. These measures will speak to the Office's progress toward meeting the goals set.

Likely Respondents: Radiation Exposure Screening and Education Program award 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
Radiation Expose Screening and Education Program	8	1	8	12	96
Total	8	.....	8	.....	96

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. 2021–06141 Filed 3–24–21; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Recharter for the Advisory Committee on Training in Primary Care Medicine and Dentistry

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

ACTION: Notice.

SUMMARY: In accordance with the Federal Advisory Committee Act, HHS is hereby giving notice that the Advisory Committee on Training in Primary Care Medicine and Dentistry (ACTPCMD) has been rechartered. The effective date of the recharter is March 24, 2021.

FOR FURTHER INFORMATION CONTACT: Shane Rogers, Designated Federal Official, Division of Medicine and Dentistry, Bureau of Health Workforce, HRSA, 5600 Fishers Lane, Rockville, Maryland 20857; 301–443–5260; or email *BHWACTPCMD@hrsa.gov.*

SUPPLEMENTARY INFORMATION: ACTPCMD provides advice and recommendations to the Secretary of HHS (Secretary) on policy, program development, and other matters of significance concerning the activities under section 747 of Title VII of the Public Health Service (PHS) Act, as it existed upon the enactment of Section 749 of the PHS Act in 1998. ACTPCMD