the clinical investigations of the biological 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 Patents and Trademarks 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 ADCETRIS (brentuximab vedotin). ADCETRIS as approved under BLA 125388 is indicated for treatment of patients with Hodgkin lymphoma after failure of autologous stem cell transplant (ASCT) or after failure of at least two prior multiagent chemotherapy regimens in patients who are not ASCT candidates. Subsequent to this approval, the Patent and Trademark Office received patent term restoration applications for ADCETRIS (U.S. Patent Nos. 7,090,843 and 7,829,531) from Seattle Genetics, Inc., and the Patent and Trademark Office requested FDA's assistance in determining the patents' eligibility for patent term restoration. In a letter dated February 4, 2013, FDA advised the Patent and Trademark Office that this human biological product had undergone a regulatory review period and that the approval of ADCETRIS under BLA 125388 and BLA 125399 represented the first permitted commercial marketing or use of the product. Thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for ADCETRIS is 1,851 days. Of this time, 1,678 days occurred during the testing phase of the regulatory review period, while 173 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:* July 27, 2006. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on July 27, 2006. This is the same investigational new drug application (IND) and the same date FDA determined was the beginning of the regulatory review period for ADCETRIS approved under BLA 125399. The regulatory review period for ADCETRIS approved under BLA 125399 is publishing elsewhere in this issue of the **Federal Register**.

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*): February 28, 2011. FDA has verified the applicant's claim that the BLA for ADCETRIS (BLA 125388) was initially submitted on February 28, 2011.

3. *The date the application was approved:* August 19, 2011. FDA has verified the applicant's claim that BLA 125388 was approved on August 19, 2011.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,002 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments and ask for a redetermination by July 28, 2014. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by November 24, 2014. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (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.

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) electronic or written comments and written or electronic petitions. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. If you submit a written petition, two copies are required. A petition submitted electronically must be submitted to *http://www.regulations.gov*, Docket No. FDA–2013–S–0610. Comments and petitions that have not been made publicly available on *http://www.regulations.gov* may be viewed in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: May 21, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–12277 Filed 5–27–14; 8:45 am]

BILLING CODE 4160–01–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

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: In compliance with Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the Health Resources and Services Administration (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.

DATES: Comments on this ICR should be received no later than June 27, 2014.

ADDRESSES: Submit your comments, including the Information Collection Request Title, to the desk officer for HRSA, either by email to *OIRA_submission@omb.eop.gov* or by fax to 202–395–5806.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email the HRSA Information Collection Clearance Officer at *paperwork@hrsa.gov* or call (301) 443–1984.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: National Health Service Corps Ambassador Portal.

OMB No. 0915–xxxx—New.

Abstract: The National Health Service Corps (NHSC), administered by the Health Resources and Services Administration, is committed to improving the health of the nation's underserved by uniting communities in need with caring health professionals and by supporting communities' efforts to build better systems of care. The NHSC programs provide scholarships and repay educational loans for primary care physicians, dentists, nurse practitioners, physician assistants, behavioral health providers, and other

primary care providers who agree to practice in areas of the country that need them most.

The NHSC invites individuals who are affiliated with academic, clinical, trade, and other public health related organizations to apply to be volunteers within the NHSC Ambassador Program. NHSC Ambassadors are dedicated volunteers who help educate and inform prospective NHSC members. Ambassadors give their time and talents to spread the word about the opportunities available through the NHSC and serve as additional local resources for current NHSC members. NHSC Ambassadors inspire and motivate students and providers to provide primary health care in communities with limited access to care.

The NHSC Ambassador Portal will serve as both the application interface for interested individuals to apply and become NHSC Ambassadors, as well the public-facing online searchable database of Ambassador contact information. Applicants will create individual Ambassador profiles that will contain information such as name, email address(es), professional/employment information (including organization name and address), (or the school which they attend), phone number(s), which discipline of students and/or professionals they interact with, and a brief reason why they would like to be an Ambassador. Completed applications will be forwarded through the portal to NHSC staff for approval. If approved, the NHSC Ambassador will have the opportunity to add a brief professional biography and social network addresses to their profile. Assistance in completing the application will be provided through prompts via the online portal and also through the NHSC Customer Care Center, if necessary.

Need and Proposed Use of the Information: The need and purpose of this information collection is to create a database where interested parties can search for NHSC Ambassadors (that meet specific search criteria) to serve as local resources on the NHSC programs. The other purpose is that NHSC can have access to volunteers who are available to spread important programmatic information on behalf of the NHSC.

Likely Respondents: Individuals who are affiliated with academic, clinical, trade, and other public health related organizations.

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 Information Collection Request 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
Ambassador Portal—New Applicants	200	1	200	.10	20
Ambassador Portal—Updates to current Ambassador profiles	500	1	500	.10	50
Total	700		700		70

Dated: May 20, 2014.

Jackie Painter,

Deputy Director, Division of Policy and Information Coordination.

[FR Doc. 2014–12324 Filed 5–27–14; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

National Vaccine Injury Compensation Program; List of Petitions Received

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: The Health Resources and Services Administration (HRSA) is publishing this notice of petitions received under the National Vaccine Injury Compensation Program (the Program), as required by Section 2112(b)(2) of the Public Health Service (PHS) Act, as amended. While the Secretary of Health and Human Services is named as the respondent in all proceedings brought by the filing of petitions for compensation under the Program, the United States Court of Federal Claims is charged by statute with the responsibility for considering and acting upon the petitions.

FOR FURTHER INFORMATION CONTACT: For information about requirements for filing petitions, and the Program in general, contact the Clerk, United States Court of Federal Claims, 717 Madison Place NW., Washington, DC 20005, (202) 357–6400. For information on HRSA's role in the Program, contact the Director, National Vaccine Injury Compensation Program, 5600 Fishers Lane, Room 11C–26, Rockville, MD 20857; (301) 443–6593.

SUPPLEMENTARY INFORMATION: The Program provides a system of no-fault compensation for certain individuals who have been injured by specified childhood vaccines. Subtitle 2 of Title XXI of the PHS Act, 42 U.S.C. 300aa–10 *et seq.,* provides that those seeking compensation are to file a petition with the U.S. Court of Federal Claims and to serve a copy of the petition on the Secretary of Health and Human Services, who is named as the respondent in each proceeding. The Secretary has delegated this responsibility under the Program to HRSA. The Court is directed by statute to appoint special masters who take evidence, conduct hearings as appropriate, and make initial decisions as to eligibility for, and amount of, compensation.

A petition may be filed with respect to injuries, disabilities, illnesses, conditions, and deaths resulting from vaccines described in the Vaccine Injury Table (the Table) set forth at Section 2114 of the PHS Act or as set forth at 42 CFR 100.3, as applicable. This Table lists for each covered childhood vaccine