requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for TUDORZA PRESSAIR is 3,136 days. Of this time, 2,739 days occurred during the testing phase of the regulatory review period, while 397 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 (the FD&C Act) (21 U.S.C. 355(i)) became effective:* December 24, 2003. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on December 24, 2003.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the FD&C Act:* June 23, 2011. FDA has verified the applicant's claim that the new drug application (NDA) for TUDORZA PRESSAIR (NDA 202–450) was submitted on June 23, 2011.

3. *The date the application was approved:* July 23, 2012. FDA has verified the applicant's claim that NDA 202–450 was approved on July 23, 2012.

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 1,679 or 1,298 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 6, 2015. 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 2, 2015. 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: April 28, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–10336 Filed 5–1–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Service Administration

Council on Graduate Medical Education; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), notice is hereby given of the following meeting:

Name: Council on Graduate Medical Education (COGME).

Dates and Times: May 21, 2015 (10:00 a.m.–4:00 p.m. EST).

Place: Webinar, and Conference Call Format.

Status: The meeting will be open to the public.

Purpose: The COGME provides advice and recommendations to the Secretary of the Department of Health and Human Services and to Congress on a range of issues including the supply and distribution of physicians in the United States, current and future physician shortages or excesses, issues relating to foreign medical school graduates, the nature and financing of medical education training, and the development of performance measures and longitudinal evaluation of medical education programs. The COGME members will continue their discussion on Graduate Medical Education (GME) innovations.

Agenda: The COGME agenda includes an opportunity for members to continue their discussion on Graduate Medical Education (GME) innovations including GME architecture, reform, and financing.

The official agenda will be available 2 days prior to the meeting on the HRSA Web site at *http://www.hrsa.gov/advisorycommittees/bhpradvisory/cogme/index.html*

SUPPLEMENTARY INFORMATION: Members of the public will have the opportunity to provide comments. Requests to make oral comments or provide written comments to the COGME should be sent to Dr. Joan Weiss, Designated Federal Official, using the address and phone number below. Individuals who plan to participate on the conference call or webinar should notify Dr. Weiss at least 3 days prior to the meeting, using the address and phone number below. Interested parties should refer to the meeting subject as the HRSA Council on Graduate Medical Education.

The conference call-in number is: 888–566–5974. The passcode is: 4439136.

The webinar link is *https://hrsa.connectsolutions.com/bhw_cogmemay2015/.*

Contact: Anyone requesting information regarding the COGME should contact Dr. Joan Weiss, Designated Federal Official within the Bureau of Health Workforce, Health Resources and Services Administration, in one of three ways: (1) Send a request to the following address: Dr. Joan Weiss, Designated Federal Official, Bureau of Health Workforce, Health Resources and Services Administration, Parklawn Building, Room 12C–05, 5600 Fishers Lane, Rockville, Maryland 20857; (2) call (301) 443–0430; or (3) send an email to *jweiss@hrsa.gov.*

Jackie Painter,

Director, Division of the Executive Secretariat.

[FR Doc. 2015–10354 Filed 5–1–15; 8:45 am]

BILLING CODE 4165–15–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 3, 2015.

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) 594–4306.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: Partnerships for Care (P4C) Supplemental Funding Progress Reports

OMB No. 0915–xxxx—New

Abstract: Partnerships for Care (P4C): Health Departments and Health Centers Collaborating to Improve HIV Health Outcomes is a 3-year partnership cross-HHS project. The activities described in this notice were funded in part by HRSA through the Secretary's Minority AIDS Initiative Fund, established by annual appropriations acts (most recently, the Consolidated and Further Continuing Appropriations Act, 2015, Public Law 113–235, Division G, title II) and the Community Health Center Fund established by section 10503 of the Affordable Care Act, Public Law 111–148, as amended. The goals of the P4C project are to build sustainable partnerships between HRSA-funded health centers and CDC-funded state health departments (including Massachusetts, New York, Maryland, and Florida) to support expanded HIV service delivery in communities highly impacted by HIV, especially among racial/ethnic minorities. State health departments and health centers will work together to increase the identification of undiagnosed HIV infection, establish new access points for HIV care and treatment, and improve HIV outcomes along the continuum of care for people living with HIV (PLWH) (see P4C fact sheet at *http://www.cdc.gov/hiv/prevention/demonstration/p4c/index.html* and HHS press release at *http://www.hhs.gov/news/press/2014pres/07/20140715a.html*). Eligible health centers (22 in 4 states) will receive up to $500,000 annually in HRSA supplemental funding (totaling $33M across the 3-year project period) to integrate high-quality, comprehensive HIV services into their primary care programs; and to work in collaboration with their state health department to (1) identify people with undiagnosed HIV infection, (2) link newly diagnosed individuals to care, and (3) retain patients living with HIV in care. Health centers must implement activities in five focus areas, including workforce development, infrastructure development, HIV service delivery, partnership development, and quality improvement and evaluation. Health centers must demonstrate progress toward implementing all required P4C activities and improving health care outcomes across the HIV care continuum (see *http://aids.gov/federal-resources/policies/care-continuum/*).

Need and Proposed Use of the Information: HRSA/Bureau of Primary Healthcare (BPHC) proposes standardized data collection and reporting through submission of five progress reports by the 22 health centers participating in the 3-year P4C project to achieve the following purposes:

1. Ensure appropriate stewardship of federal funds.
2. Support HHS efforts to streamline HIV data collection and reporting.
3. Assess health center progress in implementing approved work plans and meeting other P4C goals and objectives.
4. Assess health center progress in improving HIV outcomes across the HIV care continuum.
5. Support health center use of patient data to improve quality of HIV care.
6. Identify training and technical assistance needs among participating health centers.
7. Support identification and dissemination of effective models and promising practices for the integration of HIV services into primary care.

Proposed data collection closely aligns with (1) core HIV indicators established by HHS (see *http://blog.aids.gov/2012/08/secretary-sebelius-approves-indicators-for-monitoring-hhs-funded-hiv-services.html*), (2) measures endorsed by the National Quality Forum (see *http://www.qualityforum.org/News_And_Resources/Press_Releases/2013/NQF_Endorses_Infectious_Disease_Measures.aspx*), (3) performance measures used by the Ryan White HIV/AIDS Program (see *http://hab.hrsa.gov/deliverhivaidscare/habperformmeasures.html*), (4) the Health Center Program's Uniform Data System (see *http://bphc.hrsa.gov/healthcenterdatastatistics/index.html#whatisuds*), and (5) P4C project requirements. Specifically, HRSA/BPHC proposes submission of two progress reports each year by participating health centers to include aggregate, HIV-related, patient data (quantitative) and other information regarding implementation of approved work plans and budgets (narrative).

Likely Respondents: Health Center Program grantees receiving supplemental awards under the P4C project (22 total).

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. As health centers develop reporting proficiencies and advance from initial start-up activities to establishing routine data abstraction methods for the new outcome measures, it is expected that the annualized burden will decrease by 20% each year.

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
Implementation Progress Report	22	1	22	5	110
Outcomes Progress Report	22	1	22	25	550
Total	22		44		660

Jackie Painter,

Director, Division of the Executive Secretariat.

[FR Doc. 2015–10355 Filed 5–1–15; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

National Advisory Council on Nurse Education and Practice; Notice for Request for Nominations

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

ACTION: Notice.

SUMMARY: The Health Resources and Services Administration (HRSA) is requesting nominations to fill at least 16 vacancies on the National Advisory Council on Nurse Education and Practice (NACNEP).

DATES: The Agency must receive nominations on or before July 15, 2015.

ADDRESSES: All nominations are to be submitted either by email to Kristen Hansen, Acting Designated Federal Official, NACNEP, at *nacnep@hrsa.gov* or by mail to Kristen Hansen, Division of Nursing and Public Health, Bureau of Health Workforce, Health Resources and Administration, Parklawn Building, Room 9–89, 5600 Fishers Lane, Rockville, Maryland 20857.

FOR FURTHER INFORMATION CONTACT: For additional information, contact Kristen Hansen, Division of Nursing and Public Health, Bureau of Health Workforce, by email at *nacnep@hrsa.gov* or telephone at (301) 443–2796. A copy of the current committee membership, charter, and reports can be obtained by accessing the NACNEP Web site (*http://www.hrsa.gov/advisorycommittees/bhpradvisory/nacnep/index.html*).

SUPPLEMENTARY INFORMATION: Under the authorities that established the NACNEP and the Federal Advisory Committee Act, HRSA is requesting nominations for at least 16 new committee members. The NACNEP provides advice and recommendations to the Secretary and Congress in preparation of general regulations and concerning policy matters arising in the administration of Title VIII, including the range of issues related to nurse workforce education and practice improvement. Annually, the NACNEP prepares and submits to the Secretary, the Committee on Labor and Human Resources of the Senate, and the Committee on Commerce of the House of Representatives, a report describing the activities of the council, including findings and recommendations made by the NACNEP concerning the activities under Title VIII.

The Department of Health and Human Services is requesting at least 16 nominations for members of the NACNEP from leading authorities in the various fields of nursing, higher and secondary education, and associate degree schools of nursing; and from representatives of advanced education nursing groups (such as nurse practitioners, nurse midwives, and nurse anesthetists); from hospitals and other institutions and organizations which provide nursing services; from practicing professional nurses; from the general public; and full-time students enrolled in schools of nursing. The majority of NACNEP members shall be nurses.

HRSA has special interest in the legislative requirements of having a fair balance between the nursing profession with a broad geographic representation of members, a balance between urban and rural members, and the adequate representation of minorities. HRSA encourages nominations from qualified candidates from these groups as well as individuals with disabilities and veterans.

Interested persons may nominate one or more qualified persons for membership. Self-nominations are accepted. Nominations must be typewritten. The following information should be included in the package of materials submitted for each individual being nominated: (1) a letter of nomination that clearly states the name and affiliation of the nominee, the basis for the nomination (*i.e.,* specific attributes that qualify the nominee for service in this capacity), a statement that the nominee is willing to serve as a member of the council and appears to have no conflict of interest that would preclude this council membership. Potential candidates will be asked to provide detailed information concerning such matters as financial holdings, consultancies, research grants, and/or contracts to permit an evaluation of possible sources of conflicts of interest; (2) the nominator's name, address, and daytime telephone number; the home/or work address and telephone number; and the email address of the individual being nominated; (3) a current copy of the nominee's curriculum vitae; and (4) a statement of interest from the nominee to support experience working with Title VIII nursing programs, expertise in the field, and a personal desire in participating on the NACNEP.

Members will receive a stipend for each official meeting day of the NACNEP, as well as per diem and travel expenses as authorized by section 5 U.S.C. 5703 for persons employed intermittently in government service.

Appointments shall be made without discrimination on the basis of age, ethnicity, gender, sexual orientation and cultural, religious, or socioeconomic status. Qualified candidates will be invited to serve up to a 4-year term.

Authority: The National Advisory Council on Nurse Education and Practice is in accordance with the provisions of 42 United States Code (U.S.C.) 297t; section 851 of the Public Health Service Act, as amended. The Council is governed by provisions of Pub. L. 92–463, which sets forth standards for the formation and use of advisory committees.

Jackie Painter,

Director, Division of the Executive Secretariat.

[FR Doc. 2015–10356 Filed 5–1–15; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel; Short-Term Training to Promote Diversity in Health Research.

Date: May 28, 2015.

Time: 2:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Room 7198, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Stephanie L. Constant, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7189, Bethesda, MD 20892, 301–443–8784, *constantsl@nhlbi.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases