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 human drug products, the testing phase begins when 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, VOCABRIA (cabotegravir sodium) indicated in combination with EDURANT (rilpivirine) for short-term treatment of Human Immunodeficiency Virus-1 (HIV–1) infection in adults who are virologically suppressed (HIV–1 RNA less than 50 copies/mL) on a stable antiretroviral regimen with no history of treatment failure and with no known or suspected resistance to either cabotegravir or rilpivirine, for use as:

- oral lead-in to assess the tolerability of cabotegravir prior to administration of CABENUVA (cabotegravir; rilpivirine) extended-release injectable suspensions and
- oral therapy for patients who will miss planned injection dosing with CABENUVA.

Subsequent to this approval, the USPTO received a patent term restoration application for VOCABRIA (U.S. Patent No. 8,410,103) from ViiV Healthcare Company and the USPTO requested FDA's assistance in determining the patent's eligibility for patent term restoration. In a letter September 28, 2022, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of VOCABRIA 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 VOCABRIA is 4,719 days. Of this time, 4,085 days occurred during the testing phase of the regulatory review period, while 634 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:* February 22, 2008. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on February 22, 2008.

2. *The date the application was initially submitted with respect to the human drug product under section 505 of the FD&C Act:* April 29, 2019. FDA has verified the applicant's claim that the new drug application (NDA) for VOCABRIA (NDA 212887) was initially submitted on April 29, 2019.

3. *The date the application was approved:* January 21, 2021. FDA has verified the applicant's claim that NDA 212887 was approved on January 21, 2021.

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 1,742 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: January 22, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–01438 Filed 1–24–24; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Solicitation of Nominations for Membership To Serve on the National Advisory Council on Nurse Education and Practice

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

ACTION: Request for nominations.

SUMMARY: HRSA is seeking nominations of qualified candidates to consider for appointment as members of the National Advisory Council on Nurse Education and Practice (NACNEP). NACNEP provides advice and recommendations to the Secretary of HHS (Secretary) on policy, program development, and other matters of significance concerning the activities under Title VIII of the Public Health Service (PHS) Act, including the range of issues relating to the nurse workforce, education, and practice improvement. NACNEP also prepares and submits an annual report to the Secretary and Congress describing its activities, including NACNEP's findings and recommendations concerning activities under Title VIII, as required by the PHS Act. HRSA is seeking nominations of qualified candidates to fill up to 11 open positions on NACNEP.

DATES: HRSA will accept nominations for membership on NACNEP on a continuous basis.

ADDRESSES: Nomination packages may be submitted electronically by email to *BHWAdvisoryCouncil@hrsa.gov.* Nomination packages may also be submitted by mail addressed to Advisory Council Operations, Bureau of Health Workforce, HRSA, 5600 Fishers Lane, Room 15W10, Rockville, Maryland 20857.

FOR FURTHER INFORMATION CONTACT: Dr. Justin Bala-Hampton, Designated Federal Officer, NACNEP, by phone at (301) 443–2866, or by email at *BHWNACNEP@hrsa.gov.* A copy of the

NACNEP charter and a list of the current membership may be obtained by accessing the NACNEP website at *https://www.hrsa.gov/advisory-committees/nursing.*

SUPPLEMENTARY INFORMATION: NACNEP advises and makes recommendations to the Secretary and Congress on policy matters arising in the administration of Title VIII of the PHS Act, including the range of issues relating to the nurse workforce, nursing education, and nursing practice improvement, as a means of enhancing the health of the public through the development of the nurse workforce. NACNEP meets at least twice each calendar year or may meet more frequently at the discretion of the Designated Federal Officer in consultation with the Chair.

Nominations: HRSA is requesting nominations for voting members to serve as Special Government Employees (SGE) on NACNEP to fill open positions. The Secretary appoints NACNEP members with the expertise needed to fulfill the duties of the Advisory Council. The membership requirements are set forth at section 851(b) of Title VIII of the PHS Act, as amended.

Nominees sought are individuals representing leading authorities in the various fields of nursing, higher and secondary education, and associate degree schools of nursing; representatives of advanced education nursing groups (such as nurse practitioners, nurse midwives, clinical nurse specialists, and nurse anesthetists); hospitals and other institutions and organizations which provide nursing services; practicing professional nurses; the general public; and full-time students enrolled in schools of nursing. In making such appointments, the Secretary shall ensure a fair balance between the nursing specialties, a broad geographic representation of members, and a balance between urban and rural members. Members shall be appointed based on their competence, interest, and knowledge of the mission of the profession involved. As required by PHS Act section 851(b)(3), the Secretary shall ensure the adequate representation of minorities. HRSA is particularly interested in seeking nominations from individuals who can represent underrepresented groups in the nursing profession.

The majority of NACNEP members shall be nurses. Interested applicants may self-nominate or be nominated by another individual or organization.

Individuals selected for appointment to NACNEP will be invited to serve a term of 4 years. Members appointed as SGEs receive a stipend and reimbursement for per diem and travel expenses incurred for attending NACNEP meetings and/or conducting other business on behalf of NACNEP, as authorized by section 5 U.S.C. 5703 for persons employed intermittently in government service and PHS Act section 762(g).

The following information must be included in the package of materials submitted for each individual nominated for consideration: (1) if nominated by another individual or organization, a letter of nomination from the nominator stating the basis for the nomination (*i.e.,* what specific attributes, perspectives, and/or skills does the individual possess that would benefit the workings of NACNEP, and the nominee's field(s) of expertise), as well as the nominator's name, affiliation, and contact information (address, daytime telephone number, and email address); (2) letter of interest from the applicant stating the reasons the applicant would like to serve on NACNEP; (3) a biographical sketch of the applicant, including the applicant's curriculum vitae and contact information (address, daytime telephone number, and email address). Nomination packages may be submitted directly by the applicant or by the person/organization nominating the candidate.

HHS endeavors to ensure that the membership of NACNEP is balanced fairly in terms of points of view represented. Appointments shall be made without discrimination of age, race, ethnicity, gender, sexual orientation, or cultural, religious, or socioeconomic status.

Individuals who are selected to be considered for appointment will be required to provide detailed information regarding their financial holdings, consultancies, and research grants or contracts. Disclosure of this information is required for HRSA ethics officials to determine whether there is a potential conflict of interest between the SGE's public duties as a member of NACNEP and their private interests, including an appearance of a loss of impartiality as defined by federal laws and regulations, and to identify any required remedial action needed to address the potential conflict.

Authority: NACNEP is authorized by section 851 of the PHS Act (*42 U.S.C. 297t*), as amended. NACNEP is governed by provisions of the Federal Advisory Committee Act of 1972 (5 U.S.C. Chapter 10).

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2024–01396 Filed 1–24–24; 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 (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: HRSA is publishing this notice of petitions received under the National Vaccine Injury Compensation Program (the Program), as required by the Public Health Service (PHS) Act, as amended. While the Secretary of HHS 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 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 Lisa L. Reyes, Clerk of Court, 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 08W–25A, Rockville, Maryland 20857; (301) 443–6593, or visit our website at: *https://www.hrsa.gov/vaccinecompensation/index.html.*

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 United States Court of Federal Claims and to serve a copy of the petition to the Secretary of HHS, 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