

have a narrow spectrum of activity or are only active against a single genus or species of bacteria).

Efforts to develop new antibacterial drugs have diminished in the past few decades. Because bacteria continue to develop resistance to available antibacterial drugs, an increasing number of patients are suffering from bacterial diseases that do not respond to currently available antibacterial drugs and therefore have unmet medical needs for antibacterial therapy. To foster new antibacterial drug development that will have the potential to keep pace with continued pressures leading to antibacterial resistance, FDA is exploring approaches to help streamline development programs for new antibacterial drugs. This effort is intended not only to spur development of new drugs for populations with infections caused by resistant organisms, but also to facilitate development of drugs for broad indications that are associated with other unmet medical needs. In addition, the draft guidance outlines development approaches for pathogen-focused antibacterial drugs (i.e., drugs that have a narrow spectrum of activity or are only active against a single genus and species of bacteria).

This draft guidance describes some examples of approaches that may be used by sponsors as part of streamlined development programs. Some of these approaches are not novel, but are included to provide examples of various ways of collecting the evidence needed to demonstrate safety and efficacy to address unmet medical needs. FDA is inviting proposals for other innovative approaches that should be considered, particularly for infections caused by resistant organisms. FDA is interested in approaches such as using information from other sites of infection; pooling data from various sites; additional endpoints; an increased emphasis on the use of animal data to complement clinical data; or any other approaches that may be used to generate reliable evidence of efficacy.

As part of FDA's efforts to facilitate the development of antibacterial drugs for serious or life-threatening bacterial infections, particularly in areas of unmet need, this draft guidance specifies how nonclinical and clinical data can be used to inform an efficient and streamlined pathogen-focused antibacterial drug development program and provides advice on approaches for the development of antibacterial drugs that target a more limited spectrum of pathogens. As such, it is intended to fulfill the requirement in section 806(a), Title VIII (entitled "Generating

Antibiotic Incentives Now"), of the Food and Drug Administration Safety and Innovation Act of 2012 (FDASIA) (Pub. L. 112-144), to publish a draft guidance on pathogen-focused antibacterial drug development. After consideration of comments submitted in response to this draft guidance, FDA intends to begin work on finalizing the guidance, as required by section 806(b) of FDASIA.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. The Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR part 312 and 21 part CFR 314 have been approved under OMB control numbers 0910-0014 and 0910-0001, respectively.

III. Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see ADDRESSES). 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. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <http://www.regulations.gov>.

Dated: June 26, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

National Advisory Council on the National Health Service Corps; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Public Law 92-463), notice is hereby given of the following meeting:

Name: National Advisory Council on the National Health Service Corps (NHSC)

Date and Time: July 18, 2013—2:00pm–3:30pm ET

Place: The meeting will be via audio conference call.

Status: The meeting will be open to the public.

Agenda: The Council is holding a meeting via conference call to discuss the Affordable Care Act, NHSC retention resources, and partnerships. The public can join the meeting via audio conference call on the date and time specified above using the following information: Dial-in number: 1-800-857-5081; Passcode: 1060359. There will be an opportunity for the public to comment towards the end of the call.

FOR FURTHER INFORMATION CONTACT:

Njeri Jones, Bureau of Clinician Recruitment and Service, Health Resources and Services Administration, Parklawn Building, Room 13-64, 5600 Fishers Lane, Rockville, MD 20857; email: NJones@hrsa.gov; telephone: 301-443-2541.

Dated: June 25, 2013.

Bahar Niakan,

Director, Division of Policy and Information Coordination.

[FR Doc. 2013-15713 Filed 7-1-13; 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

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

Authority: The National Advisory Council on Nurse Education and Practice is in accordance with the provisions of 42 United

States Code (U.S.C.) 297; Section 845 of the Public Health Service Act, as amended. The Council is governed by provisions of Public Law 92-463, which sets forth standards for the formation and use of advisory committees.

DATES: The Agency must receive nominations on or before September 5, 2013.

ADDRESSES: All nominations are to be submitted either by mail or email to CDR Serina A. Hunter-Thomas, Designated Federal Official, NACNEP, Division of Nursing, Bureau of Health Professions (BHPR), Health Resources and Administration (HRSA), Parklawn Building, Room 9-61, 5600 Fishers Lane, Rockville, MD 20857. CDR Hunter-Thomas' email address is: SHunter-Thomas@Hrsa.gov.

FOR FURTHER INFORMATION CONTACT: For additional information, please contact CDR Hunter-Thomas by email or telephone at (301) 443-4499. A copy of the current committee membership, charter, and reports can be obtained by accessing the NACNEP Web site at <http://bhpr.hrsa.gov/nursing/nacnep.htm>.

SUPPLEMENTARY INFORMATION: Under the authorities that established the NACNEP and the Federal Advisory Committee Act, HRSA is requesting nominations for seven new committee members. The NACNEP advises and makes recommendations to the Secretary and Congress on policy matters arising in the administration of Title VIII including the range of issues relating to the nurse workforce, nursing education, and nursing practice improvement. The Advisory Committee may make specific recommendations to the Secretary and Congress regarding programs administered by the Division of Nursing, Bureau of Health Professions, Health Resources and Services Administration, particularly within the context of the enabling legislation and the Division's mission and strategic directions, as a means of enhancing the health of the public through the development of the nursing workforce. The Advisory Committee provides advice to the Secretary and Congress in preparation of general regulations and with respect to policy matters in the administration of this Title including the range of issues relating to the nurse supply, education, and practice improvement. The Advisory Council shall annually prepare and submit to the Secretary; the Committee on Health, Education, Labor, and Pensions of the Senate; and the Committee on Energy and Commerce of the House of Representatives, a report describing the activities of the Advisory Council

including its findings and recommendations.

The Department of Health and Human Services is requesting a total of seven nominations for members of the NACNEP who are full-time students representing various levels of education in schools of nursing (i.e. both undergraduate and graduate); from the general public; from practicing professional nurses; from among the leading authorities in the various fields of nursing, higher 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), hospitals, and other institutions and organizations which provide nursing services. The majority of members shall be nurses.

HRSA has special interest in the legislative requirements of having a fair balance between the nursing profession, including a broad geographic representation of members from urban and rural communities, and 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 also 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 services in this capacity as described above), a statement that the nominee is willing to serve as a member of NACNEP and appears to have no conflict of interest that would preclude this Committee 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; and (2) the nominator's name, address, and daytime telephone number; the home/or work address, and telephone number; and email address of the individual being nominated. HRSA requests inclusion of a current copy of the nominee's curriculum vitae and 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 a National Advisory Committee.

Committee members are classified as Special Government Employees (SGE).

All SGEs on committees must submit an annual Form OGE 450 Confidential Financial Disclosure Report to the HRSA Ethics Program for analysis using the Ethics statutes, regulations, and policies to which all SGEs must adhere. Members will receive a stipend for each official meeting day of the Committee, 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 a 4-year term.

Dated: June 25, 2013.

Bahar Niakan,

Director, Division of Policy Review and Coordination.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Environmental Health Sciences; 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: Environmental Health Sciences Review Committee.

Date: July 24-26, 2013.

Time: 8:00 a.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: DoubleTree by Hilton, Ballroom, 4810 Page Creek Lane, Durham, NC 27703.

Contact Person: Linda K Bass, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Research and Training, National Institute of Environmental Health Sciences, P.O. Box 12233, MD EC-30, Research Triangle Park, NC 27709, (919) 541-1307.

(Catalogue of Federal Domestic Assistance Program Nos. 93.115, Biometry and Risk