sponsors. Known as “Information Sheets,” these guidances have provided recommendations to IRBs, clinical investigators, and sponsors to help them fulfill their responsibilities to protect human subjects who participate in research regulated by the FDA. The Information Sheet Guidance Initiative is intended to ensure that the Information Sheets are updated, consistent with the FDA’s good guidance practices (GGPs). As part of the initiative, which will be ongoing, the Agency plans to rescind Information Sheets that are obsolete, revise and reissue guidances that address current issues, and develop new guidance documents as needed.

The guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The guidance represents FDA’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. Comments

Interested persons may submit to the Division of Dockets Management (see ADDRESSES) either electronic or written comments regarding this document. 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.

III. Electronic Access

Persons with access to the Internet may obtain the document at either http://www.regulations.gov or http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/GuidanceInformationSheetsandNotices/ucm113709.htm.


Leslie Kux,
Acting Assistant Commissioner for Policy.

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study for use by children to ensure their safety and efficacy. A written request for pediatric studies of meropenem was issued on September 10, 2004, to AstraZeneca Pharmaceuticals, the holder of the new drug application for meropenem. FDA did not receive a response to the written request. Accordingly, NIH issued a request for proposals to conduct the pediatric studies described in the written request on August 15, 2005, and awarded funds to Duke University on September 28, 2007, to complete the studies described in the written request. Upon completion of the pediatric studies, a report of the pediatric studies of meropenem was submitted to NIH and FDA. As required under section 409I of the PHS act, FDA opened a public docket and NIH placed in the docket the report of pediatric studies of meropenem that was submitted to NIH and FDA. The report includes all data generated in connection with the study, including the written request.

We invite interested parties to review the report and submit comments to the docket. The public docket is available for public review in the Division of Dockets Management (see ADDRESSES) between 9 a.m. and 4 p.m., Monday through Friday.


Leslie Kux,
Acting 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; 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 five vacancies on the National Advisory Council (NAC) on the National Health Service Corps (NHSC). The NAC on the NHSC was established in 1978.

DATES: The agency must receive nominations on or before March 28, 2012.

ADDRESSES: All nominations should be sent electronically to Njeri Jones at NJones@hrsa.gov or mailed to 5600 Fishers Lane, Room 13–64, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Kim Huffman, Executive Secretary, National Advisory Council on the National Health Service Corps, at (301) 443–3863 or via email at KHuffman@hrsa.gov.

SUPPLEMENTARY INFORMATION: The National Advisory Council on the National Health Service Corps (hereafter referred to as NAC) was established under 42 U.S.C. 254 (Section 337 of the Public Health Service Act), as amended by Section 10501 of the Affordable Care Act. The NAC is governed by provisions of Public Law 92–463 (5 U.S.C. App. 2), also known as the Federal Advisory Committee Act, which sets forth standards for the formation and use of advisory committees.

The NAC on the NHSC is a group of health care providers and health care site administrators who are experts in the issues that communities with a shortage of primary care professionals face in meeting their health care needs. The NAC is a frontline source of information to the NHSC senior management. The NAC is committed to effectively implementing its mandate to advise the Secretary of the Department of Health and Human Services (HHS) and, by designation, the Administrator of the Health Resources and Services Administration (HRSA).

The NAC consists of 15 members who are Special Government Employees. Responsibilities of the Council include: (1) Serving as a forum to identify the priorities for the NHSC and bring forward and anticipate future program issues and concerns through ongoing communication with program staff, professional organizations, communities and program participants; (2) functioning as a sounding board for proposed policy changes by utilizing the varying levels of expertise represented on the Council to advise on specific program areas; (3) developing and distributing white papers and briefs that clearly state issues and/or concerns relating to the NHSC with specific recommendations for necessary policy revisions.

Specifically, HRSA is requesting nominations for individuals with a background in primary care, dental health, and mental health, representing the following areas of expertise: Working with underserved populations, health care policy, recruitment and retention, site administration, customer service, marketing, organizational partnerships, research, and clinical practice. We are looking for nominees that either currently or have previously filled a role as site administrators, physicians, dentists, mid-level professionals (i.e., nurse, physician assistants), mental or behavioral health professionals, and NHSC scholars or loan repayors. Nominees will be invited to serve a 3-year term beginning after July 2012.

HHS will consider nominations of all qualified individuals with a view to ensuring that the NAC includes the areas of subject matter expertise noted above and reflects the diverse primary care health care workforce and health delivery sites. Individuals may nominate themselves or other individuals, and professional associations and organizations may nominate one or more qualified persons for membership on the Council.

Nominations shall state that the nominee is willing to serve as a member of the NAC and appears to have no conflict of interest that would preclude the membership. Potential candidates will be asked to provide detailed information concerning financial interests, consultancies, research grants, and/or contracts that might be affected by recommendations of the Committee to permit evaluation of possible sources of conflicts of interest.

A nomination package should include the following information for each nominee: (1) A Letter of nomination stating the name, affiliation, and contact information for the nominee, the basis for the nomination (i.e., what specific attributes, perspectives, and/or skills does the individual possess that would benefit the workings of NAC), and the nominee’s field(s) of expertise; (2) a biographical sketch of the nominee and a copy of his/her curriculum vitae; and (3) the name, address, daytime telephone number, and email address at which the nominator can be contacted.

HHS has special interest in assuring that women, minority groups, and the physically disabled are adequately represented on advisory committees; and therefore, extends particular encouragement to nominations for appropriately qualified female, minority, or disabled candidates.


Reva Harris,
Acting Director, Division of Policy and Information Coordination.
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