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/GuidancesInformationSheetsandNotices/ucm113709.htm.*

Dated: February 21, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2012–4425 Filed 2–24–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0918]

Pediatric Studies of Meropenem Conducted in Accordance With Section 409I of the Public Health Service Act; Establishment of Public Docket

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the opening of a public docket to make available to the public a report of the pediatric studies of meropenem that were conducted in accordance with section 409I of the Public Health Service Act (PHS Act) and submitted to the Director of the National Institutes of Health (NIH) and the Commissioner of Food and Drugs.

DATES: Submit either electronic or written comments by March 28, 2012.

ADDRESSES: You may submit comments, identified by FDA–2011–N–0918, by any of the following methods.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

- *Fax:* 301–827–6870.
- *Mail/Hand delivery/Courier (for paper or CD–ROM submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Agency name and Docket No. for this rulemaking. All comments received may be posted without change to *http://www.regulations.gov,* including any personal information provided.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Denise Pica-Branco, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 6402, Silver Spring, MD 20993–0002, Email: *denise.picabranco@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under section 409I of the PHS Act (42 U.S.C. 284m), the Secretary of the Department of Health and Human Services (the Secretary) acting through the Director of the NIH, in consultation with FDA and experts in pediatric research, must develop, prioritize, and publish a list of priority needs in pediatric therapeutics, including drugs and indications that require study.[1] For drugs and indications on this list, FDA, acting in consultation with NIH, is authorized to issue a written request to holders of a new drug application (NDA) or abbreviated new drug application (ANDA) for a drug for which pediatric studies are needed to provide safety and efficacy information for pediatric labeling. If the sponsors receiving the written request decline to conduct the studies or if FDA does not receive a response to the written request within 30 days of the date the written request was issued, the Secretary, acting through the Director of NIH and in consultation with FDA, must publish a request for proposals to conduct the pediatric studies described in the written request and award funds to an entity with appropriate expertise for the conduct of the pediatric studies described in the written request. Upon completion of the pediatric studies, a study report that includes all data generated in connection with the studies must be submitted to FDA and NIH and placed in a public docket assigned by FDA.

Meropenem, an antibiotic medication, is labeled for pediatric patients from 3 months of age through adolescence as a single agent antimicrobial therapy for meningitis and complicated intra-abdominal infections, and is a recommended option for monotherapy of high severity complicated intra-abdominal infections in adults. Off-label use of meropenem in newborn and infant patients younger than 3 months of age is significant, despite the lack of adequate pharmacokinetic, dosing, tolerability, and safety data for this age group.

On August 13, 2003, NIH published a **Federal Register** notice (68 FR 48402) announcing the addition of several drugs, including meropenem, to the priority list of drugs most in need of

[1] Prior to the 2007 reauthorization of the Best Pharmaceuticals for Children Act (Pub. L. 107–109), the priority list included specific drugs instead of therapeutic areas.

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.

Dated: February 21, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2012–4426 Filed 2–24–12; 8:45 am]

BILLING CODE 4160–01–P

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. 254j (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., nurses, 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.

Dated: February 21, 2012.

Reva Harris,

Acting Director, Division of Policy and Information Coordination.

[FR Doc. 2012–4572 Filed 2–24–12; 8:45 am]

BILLING CODE 4165–15–P