

antibacterial drugs. This guidance outlines approaches for streamlined development programs that are consistent with FDA's longstanding commitment to regulatory flexibility regarding the evidence required to support drug approval for patient populations with serious disease and limited or no treatment options, while meeting appropriate standards for safety and effectiveness (see, for example, 21 CFR 312, subpart E, Drugs Intended to Treat Life-threatening and Severely-debilitating Illnesses).

This guidance finalizes the draft guidance of the same name issued July 2, 2013 (78 FR 39737). After consideration of comments received in response to the draft guidance, FDA updated the guidance to include clarifications about trial designs for streamlined development programs and statistical approaches. In addition, the guidance outlines development approaches for antibacterial drugs that are pathogen-focused (*i.e.*, drugs that are intended to treat a single species or a few species of bacteria) and, accordingly, fulfills the requirements of section 806(a), Title VIII (entitled "Generating Antibiotic Incentives Now") of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112-144).

FDA notes that section 3042 of the 21st Century Cures Act (Pub. L. 114-255), which establishes a limited population pathway for certain antibacterial and antifungal drugs (LPAD) that are intended to treat a serious or life-threatening infection in a limited population of patients with unmet needs, was enacted shortly before publication of this guidance. Some antibacterial drugs that are candidates for a streamlined development program may also be candidates for LPAD. FDA intends to issue separate guidance regarding LPAD. Sponsors are encouraged to discuss proposed approaches with the Division of Anti-Infective Products.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This is not a significant regulatory action subject to Executive Order 12866.

II. The Paperwork Reduction Act of 1995

This 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 parts 312 and 314 have been approved under OMB control numbers 0910-0014 and 0910-0001, respectively.

III. Electronic Access

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

Dated: July 27, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017-16228 Filed 8-1-17; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the National Advisory Committee on Children and Disasters

AGENCY: Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: As stipulated by the Federal Advisory Committee Act, the Department of Health and Human Services (HHS) is hereby giving notice that the National Advisory Committee on Children and Disasters (NACCD) will hold a public meeting on September 7, 2017.

DATES: The NACCD meeting is September 7, 2017, from 3:00 p.m. to 4:00 p.m. EST.

ADDRESSES: We encourage members of the public to attend the teleconference. To register, go to <https://www.phe.gov/naccd> and click on the Contact Us link to open the Contact NACCD form, and then fill out the form with NACCD Registration in the subject line. Submit your comments on the NACCD Contact Form located at <https://www.phe.gov/NACCDComments>.

FOR FURTHER INFORMATION CONTACT: CDR Evelyn Seel, (202) 205-7960, evelyn.seel@hhs.gov. Visit the NACCD Web site located at <https://www.phe.gov/naccd>.

SUPPLEMENTARY INFORMATION: Pursuant to the Federal Advisory Committee Act (FACA) of 1972 (5 U.S.C., Appendix, as amended), and section 2811A of the Public Health Service (PHS) Act (42 U.S.C. 300hh-10a), as added by section

103 of the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (Pub. L. 113-5), the HHS Secretary, in consultation with the Secretary of the U.S. Department of Homeland Security, established the NACCD. The purpose of the NACCD is to provide advice and consultation to the HHS Secretary with respect to the medical and public health needs of children in relation to disasters.

Background: The NACCD public meeting on September 7, 2017, is dedicated to the deliberation and vote on the Human Services Working Group Report. We will post modifications to the agenda on the NACCD September 7, 2017 meeting Web page, which is located at <https://www.phe.gov/naccd>.

Availability of Materials: We will post all meeting materials prior to the meeting on the NACCD September 7, 2017 meeting Web page located at <https://www.phe.gov/naccd>.

Procedures for Providing Public Input: Members of the public attend by teleconference via a toll-free call-in phone number, which is available on the NACCD Web site at <http://www.phe.gov/naccd>.

We encourage members of the public to provide written comments that are relevant to the NACCD teleconference prior to September 7, 2017. Send written comments by email via the "Contact Us" link on <https://www.phe.gov/naccd> with "NACCD Public Comment" in the subject line. The NACCD will respond to comments received by close-of-business September 7, 2017, during the meeting.

Dated: July 13, 2017.

George W. Korch Jr.,

Acting Assistant Secretary for Preparedness and Response.

[FR Doc. 2017-15853 Filed 8-1-17; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Solicitation of Nominations for Membership on the Secretary's Advisory Committee on Human Research Protections

AGENCY: Office of the Assistant Secretary for Health, Office for Human Research Protections, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: The Office for Human Research Protections (OHRP), a program office in the Office of the Assistant Secretary for Health, Department of Health and Human Services (HHS), is

seeking nominations of qualified candidates to be considered for appointment as members of the Secretary's Advisory Committee on Human Research Protections (SACHRP). SACHRP provides advice and recommendations to the Secretary, HHS (Secretary), through the Assistant Secretary for Health, on matters pertaining to the continuance and improvement of functions within the authority of HHS directed toward protections for human subjects in research. SACHRP was established by the Secretary on October 1, 2002. OHRP is seeking nominations of qualified candidates to fill four positions on the Committee membership that will be vacated during the 2018 calendar year.

DATES: Nominations for membership on the Committee must be received no later than September 18, 2017.

ADDRESSES: Nominations should be mailed or delivered to Dr. Jerry Menikoff, Director, Office for Human Research Protections, Department of Health and Human Services, 1101 Wootton Parkway, Suite 200, Rockville, MD 20852. Nominations will not be accepted by email or by facsimile.

FOR FURTHER INFORMATION CONTACT: Julia Gorey, Executive Director, SACHRP, Office for Human Research Protections, 1101 Wootton Parkway, Suite 200, Rockville, MD 20852, telephone: 240-453-8141. A copy of the Committee charter and list of the current members can be obtained by contacting Ms. Gorey, accessing the SACHRP Web site at www.hhs.gov/ohrp/sachrp, or requesting via email at sachrp@osophs.dhhs.gov.

SUPPLEMENTARY INFORMATION: The Committee provides advice on matters pertaining to the continuance and improvement of functions within the authority of HHS directed toward protections for human subjects in research. Specifically, the Committee provides advice relating to the responsible conduct of research involving human subjects with particular emphasis on special populations such as neonates and children, prisoners, the decisionally impaired, pregnant women, embryos and fetuses, individuals and populations in international studies, investigator conflicts of interest and populations in which there are individually identifiable samples, data or information.

In addition, the Committee is responsible for reviewing selected ongoing work and planned activities of the OHRP and other offices/agencies within HHS responsible for human subjects protection. These evaluations

may include, but are not limited to, a review of assurance systems, the application of minimal research risk standards, the granting of waivers, education programs sponsored by OHRP, and the ongoing monitoring and oversight of institutional review boards and the institutions that sponsor research.

Nominations: The OHRP is requesting nominations to fill four positions for voting members of SACHRP. One position will become vacant in January 2018, with three others becoming vacant in October 2018. Nominations of potential candidates for consideration are being sought from a wide array of fields, including, but not limited to: public health and medicine, behavioral and social sciences, health administration, and biomedical ethics. To qualify for consideration of appointment to the Committee, an individual must possess demonstrated experience and expertise in any of the several disciplines and fields pertinent to human subjects protection and/or clinical research.

The individuals selected for appointment to the Committee can be invited to serve a term of up to four years. Committee members receive a stipend and reimbursement for per diem and any travel expenses incurred for attending Committee meetings and/or conducting other business in the interest of the Committee. Interested applicants may self-nominate.

Nominations should be typewritten. The following information should be included in the package of material submitted for each individual being nominated for consideration: (1) A letter of nomination that clearly states the name and affiliation of the nominee, the basis for the nomination (*i.e.*, specific attributes which qualify the nominee for service in this capacity), and a statement that the nominee is willing to serve as a member of the Committee; (2) the nominator's name, address, daytime telephone number, and the home and/or work address, telephone number, and email address of the individual being nominated; and (3) a current copy of the nominee's curriculum vitae. Federal employees should not be nominated for consideration of appointment to this Committee.

The Department makes every effort to ensure that the membership of HHS Federal advisory committees is fairly balanced in terms of points of view represented and the committee's function. Every effort is made to ensure that individuals from a broad representation of geographic areas, women and men, ethnic and minority groups, and the disabled are given

consideration for membership on HHS Federal advisory committees. Appointment to this Committee shall be made without discrimination on the basis of age, race, ethnicity, gender, sexual orientation, disability, and 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 necessary in order to determine if the selected candidate is involved in any activity that may pose a potential conflict with the official duties to be performed as a member of SACHRP.

Authority: 42 U.S.C. 217a, Section 222 of the Public Health Service Act, as amended. The Committee is governed by the provisions of Public Law 92-463, as amended (5 U.S.C. Appendix 2), which sets forth standards for the formation and use of advisory committees.

Dated: July 26, 2017.

Julia Gorey,

Executive Director, Secretary's Advisory Committee on Human Research Protections, Office for Human Research Protections
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of meetings of the National Diabetes and Digestive and Kidney Diseases Advisory Council.

The meetings will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meetings 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