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This guidance finalizes the draft guidance of the same name issued July 2, 2013 (78 FR 39737). After consideration of comments received in response to the draft guidance, FDA updated the guidance to include clarifications about trial designs for streamlined development programs and statistical approaches.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]

BILLING CODE 4164–01–P

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