

as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://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 Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002, or the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 240–402–8010. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT:

Regarding the guidance: Alicia Mozzachio, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 3308, Silver Spring, MD 20993–0002, 301–796–3206; or Anna Flynn, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 5070, Silver Spring, MD 20993–0002, 240–402–9156.

Regarding the ICH: Amanda Roache, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 1176, Silver Spring, MD 20993–0002, 301–796–4548.

SUPPLEMENTARY INFORMATION:

I. Background

In recent years, regulatory authorities and industry associations from around

the world have participated in many important initiatives to promote international harmonization of regulatory requirements under ICH. FDA has participated in several ICH meetings designed to enhance harmonization, and FDA is committed to seeking scientifically based harmonized technical procedures for pharmaceutical development. One of the goals of harmonization is to identify and reduce differences in technical requirements for drug development among regulatory agencies.

ICH was established to provide an opportunity for harmonization initiatives to be developed with input from both regulatory and industry representatives. FDA also seeks input from consumer representatives and others. ICH is concerned with harmonization of technical requirements for the registration of pharmaceutical products for human use among regulators around the world. The six founding members of ICH are the European Commission; the European Federation of Pharmaceutical Industries Associations; FDA; the Japanese Ministry of Health, Labour, and Welfare; the Japanese Pharmaceutical Manufacturers Association; and the Pharmaceutical Research and Manufacturers of America. The Standing Members of the ICH Association also include Health Canada and Swissmedic. Any party eligible as a Member in accordance with the ICH Articles of Association can apply for membership in writing to the ICH Secretariat. The ICH Secretariat, which coordinates the preparation of documentation, operates as an international nonprofit organization and is funded by the Members of the ICH Association.

The ICH Assembly is the overarching body of the Association and includes representatives from each ICH member and observer. The Assembly is responsible for the endorsement of draft guidelines and adoption of final guidelines. FDA publishes ICH guidelines as FDA guidance.

A final draft of the guidance was submitted to the ICH Assembly and endorsed by the regulatory agencies in June 2015. The guidance provides clarification on the implementation of good manufacturing practices for APIs, as described in ICH Q7.

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 “Q7 Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients: Questions and Answers.” 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 guidance is not subject to Executive Order 12866.

II. Electronic Access

Persons with access to the internet may obtain the guidance at <https://www.regulations.gov>, <https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>, or <https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>.

Dated: April 13, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–08252 Filed 4–19–18; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

National Advisory Council on Nurse Education and Practice

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice of Federal Advisory Committee meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, this notice announces that the National Advisory Council on Nurse Education and Practice (NACNEP) will hold a public meeting.

DATES: Wednesday, May 16, 2018, from 11:00 a.m. to 4:00 p.m. ET.

ADDRESSES: This meeting is a teleconference and webinar. The conference call-in number is 1–800–619–2521 and the passcode is 9271697. The webinar link is <https://hrsa.connectsolutions.com/nacnep/>.

FOR FURTHER INFORMATION CONTACT:

Anyone requesting information regarding the NACNEP meeting should contact CDR Antoine Smith, Designated Federal Official (DFO), Bureau of Health Workforce (BHW), HRSA, in one of three ways: (1) Send a request to the following address: CDR Antoine Smith, DFO, BHW, HRSA, 5600 Fishers Lane, Room 11N120, Rockville, Maryland 20857; (2) call 301–443–3726; or (3) send an email to asmith@hrsa.gov.

SUPPLEMENTARY INFORMATION: NACNEP provides advice and recommendations

to the Secretary of HHS and the U.S. Congress on policy issues related to the activities under section 851 of Title VIII of the Public Health Service Act (PHSA). The Secretary of HHS, and by delegation the Administrator of HRSA, is charged under Title VIII of the PHSA as amended, with responsibility for a wide range of activities in support of nursing education and practice which include: enhancement of the composition of the nursing workforce; improvement of the distribution and utilization of nurses to meet the health needs of the nation; expansion of the knowledge, skills, and capabilities of nurses to enhance the quality of nursing practice; development and dissemination of improved models of organization; financing and delivery of nursing services; and promotion of interdisciplinary approaches to the delivery of health services particularly in the context of public health and primary care.

During the May 16, 2018, meeting, NACNEP members will be oriented to the work of the Council and identify a topic for 2018. The NACNEP final agenda will be available on the NACNEP website three (3) days prior to the meeting at <https://www.hrsa.gov/advisory-committees/nursing/index.html>. Please note that agenda items are subject to change as priorities dictate.

Members of the public will have the opportunity to provide comments, which are part of the official Committee record. Oral comments will be honored in the order they are requested and may be limited as time allows. Requests to make oral comments or provide written comments to the NACNEP should be sent to CDR Antoine Smith, DFO, using the contact information above, at least three (3) business days prior to the meeting.

Amy P. McNulty,

Acting Director, Division of the Executive Secretariat.

[FR Doc. 2018-08263 Filed 4-19-18; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Advisory Committee on Children and Disasters Public Teleconference

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

ACTION: Notice.

SUMMARY: As stipulated by the Federal Advisory Committee Act, the

Department of Health and Human Services is hereby giving notice that the National Advisory Committee on Children and Disasters (NACCD) will hold a public teleconference on May 1, 2018.

DATES: The NACCD Teleconference is May 1, 2018, from 3:00 p.m. to 4:00 p.m. Eastern Standard Time EST.

ADDRESSES: We encourage members of the public to attend the teleconference. To register, send an email to naccd@hhs.gov with "NACCD Registration" in the subject line. Submit your comments to naccd@hhs.gov or on the NACCD Contact Form located at <https://www.phe.gov/Preparedness/legal/boards/naccd/Pages/contact.aspx>. For additional information, visit the NACCD website located at <https://www.phe.gov/naccd>.

SUPPLEMENTARY INFORMATION: Pursuant to the Federal Advisory Committee Act of 1972 (5 U.S.C., Appendix, as amended), and section 2811A of the Public Health Service 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 Teleconference on May 1, 2018, is dedicated to the presentation, deliberation, and vote on the NACCD Funding Strategies Report.

Availability of Materials: We will post all teleconference materials and any modifications to the agenda prior to May 1, 2018, on the NACCD website, located at <https://www.phe.gov/naccd>.

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

We encourage members of the public to provide written comments that are relevant to the NACCD Teleconference prior to May 1, 2018. Send written comments by email to naccd@hhs.gov with "NACCD Public Comment" in the subject line. The NACCD Chair will respond during the meeting to comments received by April 30, 2018, during the teleconference.

Dated: April 9, 2018.

Robert P. Kadlec,

Assistant Secretary for Preparedness and Response.

[FR Doc. 2018-08278 Filed 4-19-18; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 60-Day Comment Request; NIH NeuroBioBank Tissue Access Request Form, National Institute of Mental Health

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995 to provide opportunity for public comment on proposed data collection projects, the National Institute of Mental Health (NIMH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

DATES: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

FOR FURTHER INFORMATION CONTACT: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Melba Rojas, NIMH Project Clearance Liaison, Science Policy and Evaluation Branch, Office of Science Policy, Planning and Communications, NIMH, Neuroscience Center, 6001 Executive Boulevard, MSC 9667, Bethesda, Maryland 20892, call 301-443-4335, or email your request, including your mailing address, to nimhprapubliccomments@mail.nih.gov. Formal requests for additional plans and instruments must be requested in writing.

SUPPLEMENTARY INFORMATION: Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires: Written comments and/or suggestions from the public and affected agencies are invited to address one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the