Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

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

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th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 Office of Policy, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Amy Muhlberg, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg., 51, Rm. 3117, Silver Spring, MD 20993–0002, 240–402–6901; or Shanil Haugen, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg., 66, Rm. 2612, Silver Spring, MD 20993–0002, 301–796–0301.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Oral Drug Products Administered Via Enteral Feeding Tube: In Vitro Testing and Labeling Recommendations.'' This draft guidance provides recommendations regarding in vitro testing of oral drug products, other than solutions, administered via enteral feeding tube (hereinafter *enteral tube*) that are subject to: (1) New drug applications (original or supplemental) where applicants are seeking and/or revising enteral tube administration instructions and related information in labeling; (2) abbreviated new drug applications where the reference listed drug contains enteral tube administration instructions and related information in labeling; and (3) investigational new drug applications where the investigational drug product is administered or planned for administration via enteral tube. Specifically, the draft guidance provides recommendations for consistent in vitro testing of oral drug products to demonstrate their suitability to be administered via enteral tube. In addition, it supports the development of clear, product-specific enteral tube administration instructions in labeling for administration to patients unable to ingest oral drug products.

Enteral tubes are critical for patients who are unable to swallow oral dosage forms because of feeding disorders, severe intellectual disabilities, neurological disorders, cancers, and other medical conditions or therapies that compromise swallowing or the function of the proximal gastrointestinal system. It is critical that each drug administered via enteral tube is delivered at the correct dose in a manner that preserves the drug's expected safety and efficacy profile and does not compromise the integrity of the tube.

Some FDA-approved drug products marketed in the United States include instructions for enteral tube administration in their labeling. However, testing is not sufficiently widespread or consistent, and the content and format of labeling statements regarding administration of drug products via enteral tube vary.

The Agency recognizes the need for consistent in vitro testing to ensure safe and effective delivery of drugs that may be administered via enteral tube and to identify drugs that cannot be administered through an enteral tube without altering the safety and effectiveness profile of the drug product or compromising the integrity of the tube.

The draft guidance covers selection of appropriate enteral tubes for testing, selection of the dispersion media and preparation of the drug dispersion, and testing conditions and methods. Additional recommendations are given for modified release drug products. Completion of the recommended testing of a drug product prepared in the same manner as it will be prepared for administration to a patient in the clinical setting should allow applicants to demonstrate whether a drug product is suitable for enteral tube administration and identify drug products that are incompatible with enteral tube administration.

Finally, the draft guidance covers how to summarize information regarding administration of the drug product via enteral tube in labeling, including example labeling statements for drug products that can be safely and effectively administered via enteral tube and labeling statements for drug products that are not recommended for administration via enteral tube.

FDA requests comment from the public regarding the extent to which the recommendations in the guidance could be applicable to nonprescription products marketed under over-the-counter monographs that could be administered via enteral tube.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Oral Drug Products Administered Via Enteral Feeding Tube: In Vitro Testing and Labeling Recommendations.'' 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.

II. Paperwork Reduction Act of 1995

While this draft guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521) is not required for this draft guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR parts 312 and 314 have been approved under OMB control numbers 0910–0014 and 0910–0001, respectively. The collections of information in 21 CFR 201.56 and 201.57 have been approved under OMB control number 0910–0572.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products,* or *https://www.regulations.gov*.

Dated: May 26, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–11622 Filed 6–2–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Complementary & Integrative Health; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as

amended, notice is hereby given of the following meeting.

The meeting 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 applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Center for Complementary and Integrative Health Special Emphasis Panel; ''Limited Competition for the Continuation of a Multisite Clinical Trial Data Coordinating Center (Collaborative U24, Clinical Trial Optional)''.

Date: June 16, 2021.

Time: 2:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Center for Complementary and Integrative Democracy II, 6707 Democracy Blvd., Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Martina Schmidt, Ph.D., Chief, Office of Scientific Review, National Center for Complementary & Integrative Health, NIH, 6707 Democracy Blvd., Suite 401, Bethesda, MD 20892, 301–594–3456, *schmidma@mail.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.213, Research and Training in Complementary and Alternative Medicine, National Institutes of Health, HHS)

Dated: May 27, 2021.

Tyeshia M. Roberson,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–11644 Filed 6–2–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Neurological Disorders and Stroke; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting 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 contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Neurological Disorders and Stroke Special Emphasis Panel; NINDS Special Review Group Contracts.

Date: June 25, 2021.

Time: 10:30 a.m. to 2:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Virtual Meeting).

Contact Person: Marilyn Moore-Hoon, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Activities, National Institute of Neurological Disorders and Stroke, Rockville, MD 20852, 301–827–9087, *mooremar@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.853, Clinical Research Related to Neurological Disorders; 93.854, Biological Basis Research in the Neurosciences, National Institutes of Health, HHS)

Dated: May 27, 2021.

Tyeshia M. Roberson,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–11640 Filed 6–2–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Complementary & Integrative Health; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting 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 applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Center for Complementary and Integrative Health Special Emphasis Panel; Early Phase Clinical Trials of Natural Products (NP).

Date: July 15, 2021.

Time: 12:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Center for Complementary and Integrative, Democracy II, 6707 Democracy Blvd., Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Shiyong Huang, Ph.D., Scientific Review Officer, Office of Scientific Review, Division of Extramural Activities, NCCIH/NIH, 6707 Democracy Boulevard, Suite 401, Bethesda, MD 20817, *shiyong.huang@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.213, Research and Training in Complementary and Alternative Medicine, National Institutes of Health, HHS)

Dated: May 27, 2021.

Tyeshia M. Roberson,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–11643 Filed 6–2–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Secretary; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the Interagency Pain Research Coordinating Committee.

The meeting will be open to the public. Individuals who plan to participate 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.

Name of Committee: Interagency Pain Research Coordinating Committee.

Date: July 6, 2021.

Time: 1:30 p.m. to 4:30 p.m. Eastern Time (ET).

Agenda: The meeting will cover committee business items including updates on NIH HEAL Initiative and Common Fund programs. It will include follow up of IPRCC recommendations and member updates.

Webcast Live: http://videocast.nih.gov/.

Deadline: Submission of intent to submit written/electronic statement for comments: Tuesday, June 29th, by 5:00 p.m. ET.

Place: National Institutes of Health, Building 31, 31 Center Drive Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Linda L. Porter, Ph.D., Director, Office of Pain Policy and Planning, Office of the Director, National Institute of Neurological Disorders and Stroke, NIH, 31 Center Drive, Room 8A31, Bethesda, MD 20892, Phone: (301) 451–4460, Email: *Linda.Porter@nih.gov.*

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when