Implementation of PCOR Evidence (R18)'' are to be reviewed and discussed at this meeting. 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.

Francis D. Chesley, Jr.,

Acting Deputy Director.

[FR Doc. 2019–03382 Filed 2–26–19; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Notice of Meeting

AGENCY: Agency for Healthcare Research and Quality, HHS.

ACTION: Notice.

SUMMARY: The Agency for Healthcare Research and Quality (AHRQ) is announcing a Special Emphasis Panel (SEP) meeting on Conference Grants (R13).

DATES: April 4, 2019 (Open on April 4th from 10:00 a.m. to 10:15 a.m. and closed for the remainder of the meeting).

ADDRESSES: Agency for Healthcare Research and Quality (AHRQ), 5600 Fishers Lane, Rockville, MD 20850.

FOR FURTHER INFORMATION CONTACT: Anyone wishing to obtain a roster of members, agenda or minutes of the non-confidential portions of this meeting should contact: Heather Phelps, Acting Committee Management Officer, Office of Extramural Research, Education and Priority Populations, AHRQ, 5600 Fishers Lane, Rockville, Maryland 20850, Telephone: (301) 427–1128.

Agenda items for this meeting are subject to change as priorities dictate.

SUPPLEMENTARY INFORMATION: An SEP is a group of experts in fields related to health care research who are invited by the Agency for Healthcare Research and Quality (AHRQ), and agree to be available, to conduct on an as needed basis, scientific reviews of applications for AHRQ support. Individual members of the Panel do not attend regularly-scheduled meetings and do not serve for fixed terms or a long period of time. Rather, they are asked to participate in particular review meetings which require their type of expertise.

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (5 U.S.C. App. 2), announcement is made of an AHRQ SEP meeting on Conference Grants (R13).

Each SEP meeting will commence in open session before closing to the public for the duration of the meeting. The SEP meeting referenced above will be closed to the public in accordance with the provisions set forth in 5 U.S.C. App. 2, section 10(d), 5 U.S.C. 552b(c)(4), and 5 U.S.C. 552b(c)(6). Grant applications for Conference Grants (R13) are to be reviewed and discussed at this meeting. 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.

Francis D. Chesley, Jr.,

Acting Deputy Director.

[FR Doc. 2019–03383 Filed 2–26–19; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–D–0298]

Quality Considerations for Continuous Manufacturing; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Quality Considerations for Continuous Manufacturing.'' This draft guidance provides information regarding FDA's current thinking on the quality considerations for continuous manufacturing of small molecule, solid oral drug products that are regulated by the Center for Drug Evaluation and Research (CDER). The draft guidance describes several key quality considerations and provides recommendations for how applicants should address these considerations in new drug applications (NDAs), abbreviated new drug applications (ANDAs), and supplemental NDAs and ANDAs, for small molecule, solid oral drug products that are produced via a continuous manufacturing process. FDA supports the development and implementation of continuous manufacturing for drug substances and all finished dosage forms where appropriate, including those submitted in NDAs, ANDAs, drug master files, biologics license applications (BLAs), and nonapplication over the counter products. Scientific principles described in this draft guidance may also be applicable to continuous manufacturing technologies used for these drugs. However, this draft guidance is not intended to provide recommendations specific to continuous manufacturing technologies used for biological products under a BLA.

DATES: Submit either electronic or written comments on the draft guidance by May 28, 2019 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and

identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2019–D–0298 for ''Quality Considerations for Continuous Manufacturing.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked 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 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. 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: Sau L. Lee, Center for Drug Evaluation and Research, Food and Drug Administration (HFD–600), 10903 New Hampshire Ave., Bldg. 22, Rm. 2130, Silver Spring, MD 20993–0002, 301–796–2905.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Quality Considerations for Continuous Manufacturing.'' The draft guidance was prepared by CDER's Office of Pharmaceutical Quality, which is committed to supporting and enabling pharmaceutical innovation and modernization as part of the Agency's mission to protect and promote public health. While the implementation of emerging technology, such as continuous manufacturing, is critical to modernizing pharmaceutical manufacturing and improving quality, FDA also recognizes that innovative approaches to manufacturing may represent challenges to industry and regulators. By the very nature of an approach being innovative, a limited knowledge and experiential base about the technology may exist. Pharmaceutical companies may have concerns that using continuous manufacturing could result in delays while FDA reviewers and investigators familiarize themselves with the new technologies and determine how they fit within existing regulatory approaches.

This draft guidance provides information regarding FDA's current thinking on the quality considerations for continuous manufacturing of small molecule, solid oral drug products that are regulated by CDER. The draft guidance describes several key quality considerations and provides recommendations for how applicants should address these considerations in NDAs, ANDAs, and supplemental NDAs and ANDAs, for small molecule, solid oral drug products that are produced via a continuous manufacturing process.

The draft guidance takes into account the comments that were submitted to Docket No. FDA–2017–N–2697 (''Submission of Proposed Recommendations for Industry on Developing Continuous Manufacturing of Solid Dosage Drug Products in Pharmaceutical Manufacturing; Establishment of Public Docket''). FDA invites general comments on the quality considerations described in the draft guidance, including comments on control strategy, facility, and process validation considerations for continuous manufacturing of small molecule, solid oral drug products.

In addition to this draft guidance, pharmaceutical manufacturers with product-specific continuous manufacturing questions may submit a proposal to the Emerging Technology program. Refer to FDA guidance for industry, ''Advancement of Emerging Technology Applications for Pharmaceutical Innovation and Modernization'' (September 2017) at *https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-drugs-gen/documents/document/ucm478821.pdf.*

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 ''Quality Considerations for Continuous Manufacturing.'' 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. Additional Issues for Consideration

In addition to comments on the draft guidance generally, FDA is requesting comments and related supporting information on the following topics: (1) Data storage and handling from process analytical technology systems, (2) potential approaches for situations where direct attribute measurement is not possible (*e.g.,* low-dose compounds), (3) contract manufacturers employing continuous manufacturing, (4) risk-based reporting of routine model maintenance and updates, and (5) statistical approaches using large samples (*e.g.,* Large N). FDA is seeking public comment on topics for potential inclusion in the final guidance or additional guidance and any other alternative approaches.

III. Paperwork Reduction Act of 1995

This draft guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520). The collections of information in 21 CFR parts 210–211 have been approved under OMB control number 0910–0139. The submission of INDs under 21 CFR 312.23 is approved by OMB control

number 0910–0014. The submission of BLAs under 21 CFR 601.2 and 601.12 is approved by OMB control number 0910–0338. The submission of NDAs and ANDAs under 21 CFR 314.50, 314.70, 314.71, 314.94, and 314.97 is approved by OMB control number 0910–0001. The information to be included in a meeting request for a product submitted in an IND, BLA, or NDA is approved by OMB control number 0910–0429 (''Guidance for Industry on Formal Meetings Between the FDA and Sponsors or Applicants'' (December 2017)). Information to be included in a meeting request for a product submitted in an ANDA is approved by OMB control number 0910–0797 (''Guidance on Controlled Correspondence Related to Generic Drug Development'' (December 2015)).

IV. Electronic Access

Persons with access to the internet may obtain the draft guidance at either *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *https://www.regulations.gov.*

Dated: February 22, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.

[FR Doc. 2019–03413 Filed 2–26–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; 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 Institute on Aging Initial Review Group; Neuroscience of Aging Review Committee, NIA–N.

Date: June 4–5, 2019.

Time: 11:00 a.m. to 11:00 a.m.

Agenda: To review and evaluate grant applications.

Place: Hotel Kabuki, 1625 Post Street, San Francisco, CA 94155.

Contact Person: Greg Bissonette, Ph.D., Scientific Review Officer, Scientific Review Branch, National Institute on Aging, 7201 Wisconsin Avenue, Gateway Building, Suite 2W200, Bethesda, MD 20892, 301–402–1622, *bissonettegb@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: February 21, 2019.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–03346 Filed 2–26–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging: 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 Institute on Aging Initial Review Group; Behavior and Social Science of Aging Review Committee, NIA–S.

Date: June 5–6, 2019.

Time: 11:00 a.m. to 11:00 a.m.

Agenda: To review and evaluate grant applications.

Place: Hotel Kabuki, 1625 Post Street, San Francisco, CA 94155.

Contact Person: Carmen Moten, Ph.D., MPH, Scientific Review Officer, National Cancer Institute, 6116 Executive Blvd., Suite 602, MSC 8341, Rockville, MD 20852–8341, 301–496–8589, *cmoten@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: February 21, 2019.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–03351 Filed 2–26–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

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

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

Name of Committee: Center for Scientific Review Special Emphasis Panel; Program Projects: HIV Eradication and Substance Abuse.

Date: March 14, 2019.

Time: 2:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Shiv A. Prasad, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5220, MSC 7852, Bethesda, MD 20892, 301–443–5779, *prasads@csr.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.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR 17–158: Secondary Data Analyses For NIMH Research Domain Criteria (R03).

Date: March 21, 2019.

Time: 2:00 p.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Julius Cinque, MS, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5186, MSC 7846, Bethesda, MD 20892, (301) 435–1252, *cinquej@csr.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)