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]

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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