to serve for overlapping terms of up to 4 years. Almost all non-Federal members of this committee serve as Special Government Employees. Ex Officio voting members, one each from the Department of Health and Human Services, the Centers for Disease Control and Prevention, and the National Institutes of Health, may be included. The core of voting members may include one technically qualified member, selected by the Commissioner or designee, who is identified with consumer interests and is recommended by either a consortium of consumer-oriented organizations or other interested persons. In addition to the voting members, the Committee may include one nonvoting member who is identified with industry interests. There may also be an alternate industry representative.

The Commissioner or designee shall have the authority to select members of other scientific and technical FDA advisory committees (normally not to exceed 10 members) to serve temporarily as voting members and to designate consultants to serve temporarily as voting members when: (1) expertise is required that is not available among current voting standing members of the Committee (when additional voting members are added to the Committee to provide needed expertise, a quorum will be based on the combined total of regular and added members) or (2) to comprise a quorum when, because of unforeseen circumstances, a quorum is or will be lacking. Because of the size of the Committee and the variety in the types of issues that it will consider, FDA may, in connection with a particular committee meeting, specify a quorum that is less than a majority of the current voting members. The Agency's regulations (21 CFR 14.22(d)) authorize a committee charter to specify quorum requirements.

If functioning as a medical device panel, an additional nonvoting representative of consumer interests and a nonvoting representative of industry interests will be included in addition to the voting members.

Further information regarding the most recent charter and other information can be found at *https://www.fda.gov/advisory-committees/vaccines-and-related-biological-products-advisory-committee/charter-vaccines-and-related-biological-products-advisory-committee* or by contacting the Designated Federal Officer (see **FOR FURTHER INFORMATION CONTACT**). In light of the fact that no change has been made to the committee name or description of duties, no amendment will be made to 21 CFR 14.100.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app.). For general information related to FDA advisory committees, please visit us at *https://www.fda.gov/AdvisoryCommittees/default.htm.*

Dated: January 23, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–01585 Filed 1–25–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–D–0810]

Conducting Remote Regulatory Assessments—Questions and Answers; Revised 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 for comment of a revised draft guidance for industry entitled ''Conducting Remote Regulatory Assessments—Question and Answers.'' FDA has revised and is reissuing the draft guidance in response to public comments and recent amendments to the Federal Food, Drug, and Cosmetic Act (FD&C Act). When finalized, this guidance will describe FDA's current thinking regarding its use of remote regulatory assessments (RRAs). FDA has used RRAs to conduct oversight, mitigate risk, meet critical public health needs, and help maximize compliance of FDA-regulated products. This revised draft guidance provides answers to frequently asked questions regarding RRAs.

DATES: Submit either electronic or written comments on the draft guidance by March 26, 2024 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–2022–D–0810 for ''Conducting Remote Regulatory Assessments; Questions and Answers; Guidance for Industry.'' 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, 240–402–7500.

- 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.govinfo.gov/content/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, 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 Operational Policy, Office of Regulatory Affairs, Food and Drug Administration, Element Building, 12420 Parklawn Dr., Rockville, MD 20852. Send one self-addressed adhesive label to assist the office in processing your requests. The draft guidance may also be obtained by mail by emailing ORA at *orapolicystaffs@fda.hhs.gov.* See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Ben Firschein, Office of Regulatory Affairs, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Silver Spring, MD 20993–0002, *Ben.Firschein@fda.hhs.gov,* 240–402–0613; or Patrick Clouser, Office of Regulatory Affairs, Food and Drug Administration, Element Building, 12420 Parklawn Dr., Rockville, MD 20857, *Patrick.Clouser@fda.hhs.gov,* 240–402–5276.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a revised draft guidance for industry entitled ''Conducting Remote Regulatory Assessments—Questions and Answers.'' This draft revises the draft guidance entitled ''Conducting Remote Regulatory Assessments—Questions and Answers; Draft Guidance for Industry,'' which was announced in the **Federal Register** on July 25, 2022 (87 FR 44129) (hereafter, the ''original draft guidance''). FDA issued the original draft guidance to describe the Agency's thinking regarding its use of RRAs, to help increase the industry's understanding of voluntary and mandatory RRAs, and to facilitate FDA's process for conducting remote assessments for all types of FDA-regulated products outside of the COVID–19 public health emergency. The comment period for the original draft guidance ended on September 23, 2022.

One of the mandatory RRAs FDA discussed in the original draft guidance was the requirement that establishments engaged in manufacturing, preparing, propagating, compounding, or processing drugs produce, upon request from FDA, records or other information by in advance of or in lieu of an inspection, under section 704(a)(4) of the FD&C Act.

In the revised draft guidance we have clarified our answers to questions regarding: (1) the benefits of an RRA, and any consequences for not participating; (2) how a facility will know an RRA is being requested, and whether it is mandatory or voluntary; (3) when and how FDA may initiate an RRA; (4) how FDA may conduct RRAs in relation to FDA inspections or to activities by state and foreign regulatory partners; (5) what an establishment should expect during an RRA, including overall process and technological expectations, and how consent may be established for a voluntary RRA; (6) how FDA will seek to provide for ongoing communication between FDA and an establishment; and (7) what may occur upon the completion of an RRA.

The revised draft guidance also contains revisions to align with recent changes to section 704(a)(4) of the FD&C Act made by the Food and Drug Omnibus Reform Act of 2022 (FDORA).[1] Specifically, FDORA amended section 704(a)(4) of the FD&C Act in several ways:

1. FDORA sections 3611(b)(1)(A) and 3612(a) expanded those subject to mandatory requests for records or other information under section 704(a)(4) of the FD&C Act to include: (a) establishments that engage in the manufacture, preparation, propagation, compounding, or processing of a device, and (b) sites or facilities that are subject to inspection under section 704(a)(5)(C) (*i.e.,* bioresearch monitoring inspections) (21 U.S.C. 374(a)(5)).

2. FDORA section 3611(b)(1)(B) added a requirement that FDA provide a rationale for requesting records or other information under section 704(a)(4) of the FD&C Act.

3. FDORA section 3613(b) inserted new section 704(a)(4)(C) of the FD&C Act providing that FDA may rely on any records or other information obtained under section 704(a)(4) to satisfy requirements that may pertain to a preapproval or risk-based inspection, or to resolve deficiencies identified during such inspections, if applicable and appropriate.

4. FDORA required FDA to issue or update guidance describing the circumstances under which the Agency intends to use its authority to issue requests for records or other information under section 704(a)(4) of the FD&C Act (as amended by FDORA), the processes for firms to respond, and the factors for determining whether a facility has appropriately and timely responded (FDORA section 3611(b)(2)).

FDA seeks public comment on the revised draft guidance. We are particularly interested in receiving comments that relate to revisions the Agency is proposing to address the above FDORA requirements.

This revised 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 ''Conducting Remote Regulatory Assessments.'' 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

FDA tentatively concludes that this revised draft guidance contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

III. Electronic Access

Persons with access to the internet may obtain the revised draft guidance at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents, https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs,* or *https://www.regulations.gov.*

[1] On December 29, 2022, the President signed into law FDORA, which was enacted as part of the Consolidated Appropriations Act, 2023, Public Law 117–328 (2022).

Dated: January 23, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–01589 Filed 1–25–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meetings of the Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria

AGENCY: Department of Health and Human Services, Office of the Secretary, Office of the Assistant Secretary for Health.

ACTION: Notice.

SUMMARY: As stipulated by the Federal Advisory Committee Act, the Department of Health and Human Services (HHS) is hereby giving notice that a meeting is scheduled to be held for the Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria (PACCARB). The meeting will be streamed live on *hhs.gov/live.* A pre-registered public comment session will be held during the virtual meeting. Pre-registration is required for members of the public who wish to present their comments live during the meeting. Individuals who wish to send in their written public comment should send an email to *CARB@hhs.gov.* Registration information is available on the website *http://www.hhs.gov/paccarb* and must be completed by February 15, 2024, for the February 22, 2024, Public Meeting. Additional information about registering for the meeting and providing public comment can be obtained at *http://www.hhs.gov/paccarb* on the Upcoming Meetings page.

DATES: The meeting is scheduled to be held on February 22, 2024, from 9 a.m. to 4 p.m. ET (times are tentative and subject to change). The confirmed times and agenda items for the meeting will be posted on the website for the PACCARB at *http://www.hhs.gov/paccarb* when this information becomes available. Pre-registration for attending the meeting is strongly suggested and should be completed no later than February 15, 2024.

ADDRESSES: The virtual meeting can be accessed through a live webcast on the day of the meeting. Additional instructions regarding attending this meeting virtually will be posted at least one week prior to the meeting at: *http://www.hhs.gov/paccarb.*

FOR FURTHER INFORMATION CONTACT: Jomana Musmar, M.S., Ph.D., Designated Federal Officer, Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria, Office of the Assistant Secretary for Health, U.S. Department of Health and Human Services, 1101 Wootton Parkway, Rockville, MD 20852. Phone: 202–746–1512; Email: *CARB@hhs.gov.*

SUPPLEMENTARY INFORMATION: The Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria (PACCARB), established by Executive Order 13676, is continued by section 505 of Public Law 116–22, the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2019 (PAHPAIA). Activities and duties of the PACCARB are governed by the provisions of the Federal Advisory Committee Act (FACA), Public Law 92–463, as amended (5 U.S.C. app.), which sets forth standards for the formation and use of Federal advisory committees.

The PACCARB shall advise and provide information and recommendations to the Secretary of Health and Human Services (Secretary) regarding programs and policies intended to reduce or combat antibiotic-resistant bacteria that may present a public health threat and improve capabilities to prevent, diagnose, mitigate, or treat such resistance. The PACCARB shall function solely for advisory purposes.

Such advice, information, and recommendations may be related to improving: the effectiveness of antibiotics; research and advanced research on, and the development of, improved and innovative methods for combating or reducing antibiotic resistance, including new treatments, rapid point-of-care diagnostics, alternatives to antibiotics, including alternatives to animal antibiotics, and antimicrobial stewardship activities; surveillance of antibiotic-resistant bacterial infections, including publicly available and up-to-date information on resistance to antibiotics; education for health care providers and the public with respect to up-to-date information on antibiotic resistance and ways to reduce or combat such resistance to antibiotics related to humans and animals; methods to prevent or reduce the transmission of antibiotic-resistant bacterial infections; including stewardship programs; and coordination with respect to international efforts in order to inform and advance the United States capabilities to combat antibiotic resistance.

The February 22, 2024, meeting will serve as a critical platform for key international stakeholders, and non-government organizations, to share their latest strategies and progress in tackling the global threat of antimicrobial resistance. The focus will be on both showcasing successful international and regional initiatives and identifying areas for enhanced collaboration and knowledge exchange. The meeting agenda will be posted on the PACCARB website at *http://www.hhs.gov/paccarb* when it has been finalized. All agenda items are tentative and subject to change. Instructions regarding attending the meeting virtually will be posted at least one week prior to the meeting at: *http://www.hhs.gov/paccarb.*

Members of the public will have the opportunity to provide comments virtually during the February meeting by pre-registering online at *http://www.hhs.gov/paccarb;* pre-registration is required for participation in this session with limited spots available. Written public comments can also be emailed to *CARB@hhs.gov* by midnight February 15, 2024, and should be limited to no more than one page. All public comments received prior to February 15, 2024, will be provided to the PACCARB members.

Dated: January 10, 2024.

Jomana F. Musmar,

Designated Federal Officer, Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria, Office of the Assistant Secretary for Health.

[FR Doc. 2024–01545 Filed 1–25–24; 8:45 am]

BILLING CODE 4150–44–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 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; Member Conflict: Biological Chemistry and Macromolecular Biophysics.

Date: February 21, 2024.

Time: 10:00 a.m. to 6:00 p.m.