monitoring program; and (3) outsourcing facilities registered under section 503B (21 U.S.C. 356b) of the FD&C Act. FDA may consider the use of a remote interactive evaluation for any of the inspection program areas described in the draft guidance.

During the Coronavirus Disease 2019 (COVID–19) pandemic, FDA expanded our use of alternative tools for evaluating drug manufacturing facilities to support regulatory decision-making. When an inspection was not feasible or practical because of the public health emergency (PHE), FDA used other available tools and information to support regulatory decisions and oversight of facilities. FDA announced its policy for using these alternative tools in a guidance entitled ''Remote Interactive Evaluations of Drug Manufacturing and Bioresearch Monitoring Facilities During the COVID–19 Public Health Emergency'' posted in April 2021 and announced in the **Federal Register** on May 27, 2021 (86 FR 28627) (''2021 COVID–19 Remote Interactive Evaluations Guidance''). FDA issued the guidance to communicate its policy for the duration of the COVID–19 PHE declared by the Secretary of Health and Human Services (HHS) on January 31, 2020, including any renewals made by the HHS Secretary in accordance with section 319(a)(2) of the Public Health Service Act (42 U.S.C. 247d(a)(2)). Furthermore, in the **Federal Register** of March 13, 2023 (88 FR 15417) FDA listed the: (1) guidances that will no longer be effective with the expiration of the PHE declaration, (2) guidances that FDA was revising to continue in effect for 180 days after the expiration of the PHE declaration to provide a period for stakeholder transition and then would no longer be in effect, and (3) guidances that FDA was revising to continue in effect for 180 days after the expiration of the PHE declaration during which time FDA planned to further revise the guidances. The 2021 COVID–19 Remote Interactive Evaluations Guidance is included in the latter category and was revised to remain in effect for 180 days post expiration of the PHE declaration. Although the HHS Secretary of has announced that the COVID–19 public health emergency declaration has ended and FDA has largely resumed inspections, FDA has determined that continued use of alternative tools, including remote interactive evaluations, based on risk and program needs, will enhance our ability to assess facilities.

This draft guidance describes the various remote interactive tools we may request to use to conduct an evaluation. In this draft guidance, we refer to our use of any combination of these interactive tools as a *remote interactive evaluation.* FDA may request to conduct a remote interactive evaluation prior to or following other types of regulatory oversight activities (*e.g.,* an inspection or a request for records or other information). In preparing this draft guidance, FDA considered comments received on the 2021 COVID–19 Remote Interactive Evaluations Guidance.

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 ''Remote Interactive Evaluations of Drug Manufacturing and Bioresearch Monitoring Facilities.'' 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.

FDA also is announcing that the 2021 COVID–19 Remote Interactive Evaluations Guidance will be withdrawn upon publication of this draft guidance. FDA has determined that the 2021 COVID–19 Remote Interactive Evaluations Guidance is no longer needed because this new draft guidance is available and its recommendations, when finalized, will be applicable outside the context of the COVID–19 public health emergency.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA). The collections of information in 21 CFR part 312 have been approved under OMB control number 0910–0014. The collections of information in 21 CFR part 314 have been approved under OMB control number 0910–0001. The collections of information in 21 CFR part 58 pertaining to good laboratory practices have been approved under OMB control number 0910–0119. The collection of information pertaining to current good manufacturing practices have been approved under OMB control number 0910–0139. The collections of information relating to the registration of human drug compounding outsourcing facilities under section 503B of the FD&C Act and associated fees under section 744K of the FD&C Act (21 U.S.C. 379j–62) have been approved under OMB control number 0910–0776. The collections of information pertaining to human drug compounding under sections 503A (21 U.S.C. 356a) and 503B of the FD&C Act have been approved under OMB control number 0910–0800. The collections of information in 21 CFR part 11 have been approved under OMB control number 0910–0303. The collections of information in 21 CFR parts 50 and 56 have been approved under OMB control number 0910–0130.

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/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances*, *https://www.fda.gov/regulatory-information/search-fda-guidance-documents*, or *https://www.regulations.gov.*

Dated: October 23, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–23677 Filed 10–25–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 1009 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 of Allergy and Infectious Diseases Special Emphasis Panel; NIAID Investigator Initiated Program Project Applications (P01 Clinical Trial Not Allowed).

Date: November 15, 2023.

Time: 10:30 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3F58, Rockville, MD 20892 (Virtual Meeting).

Contact Person: Mario Cerritelli, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3F58, Rockville, MD 20852, 240–669–5199, *cerritem@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: October 20, 2023.

David W. Freeman,

Supervisory Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023–23626 Filed 10–25–23; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse; Notice of Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Advisory Council on Drug Abuse.

The meeting will be held as a virtual meeting and is open to the public, as indicated below. Individuals who plan to view the virtual meeting and need special assistance such as sign language interpretation or other reasonable accommodations to view the meeting, should notify Dr. Jeanette Marketon via email at *jeanette.marketon@nih.gov* five days in advance of the meeting. The open session will be videocast and can be accessed from the NIH Videocasting and Podcasting website (*http://videocast.nih.gov/*).

A portion of 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 intramural programs and projects as well as the grant applications and/or contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with intramural programs and projects as well as the grant applications and/or contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Advisory Council on Drug Abuse.

Date: February 6, 2024.

Closed: 10:30 a.m. to 11:45 a.m. *Agenda:* To review and evaluate grant applications.

Closed: 11:45 a.m. to 12:15 p.m. *Agenda:* Report to Council from the NIDA Board of Scientific Counselors (BSC).

Open: 12:45 p.m. to 5:00 p.m. *Agenda:* Presentations and other business of the Council.

Place: National Institutes of Health, National Institute on Drug Abuse, 301 North Stonestreet Avenue, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Susan R.B. Weiss, Ph.D., Director, Division of Extramural Research, Office of the Director, National Institute on Drug Abuse, NIH, Three White Flint North, RM 09D08, 11601 Landsdown Street, Bethesda, MD 20852 301–443–6480 *sweiss@nida.nih.gov.*

Contact Person: Jeanette Marketon, Ph.D., Director, Office of Extramural Policy, Division of Extramural Research Office of Extramural Policy, National Institute on Drug Abuse, NIH, Three White Flint North, RM 09C68, 11601 Landsdown Street, Bethesda, MD 20852, 301–443–5239 *jeanette.marketon@nih.gov.*

Any interested person may file written comments with the committee by forwarding the statement to Dr. Jeanette Marketon at *jeanette.marketon@nih.gov.* The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Information is also available on the Institute's/Center's home page: *www.drugabuse.gov/NACDA/NACDAHome.html,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.277, Drug Abuse Scientist Development Award for Clinicians, Scientist Development Awards, and Research Scientist Awards; 93.278, Drug Abuse National Research Service Awards for Research Training; 93.279, Drug Abuse and Addiction Research Programs, National Institutes of Health, HHS)

Dated: October 20, 2023.

David W. Freeman,

Supervisory Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023–23628 Filed 10–25–23; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 1009 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 of Allergy and Infectious Diseases, Special Emphasis Panel; NIAID Investigator Initiated Program Project Applications (P01 Clinical Trial Not Allowed).

Date: November 20, 2023.

Time: 9:00 a.m. to 12:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 903 South 4th Street, Room RML 31/3118, Hamilton, MT 59840 (Virtual Meeting).

Contact Person: Kristin L. McNally, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 903 South 4th Street, Room RML 31/3118, Hamilton, MT 59840, *mcnallyk@niaid.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: October 20, 2023.

David W. Freeman,

Supervisory Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023–23627 Filed 10–25–23; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID: FEMA—2023–0029; OMB No. 1660–0016]

Agency Information Collection Activities: Proposed Collection, Comment Request; Revision to National Flood Insurance Program Maps: Application Forms and Instructions for LOMRs and CLOMRs

AGENCY: Federal Emergency Management Agency, Department of Homeland Security.

ACTION: 60-Day notice of renewal and request for comments.

SUMMARY: The Federal Emergency Management Agency (FEMA), as part of its continuing effort to reduce paperwork and respondent burden, invites the general public to take this opportunity to comment on a renewal of