guidance, when finalized, will describe procedures under which meeting requesters can meet with appropriate FDA officials to obtain recommendations on the studies and other information necessary to support submissions under section 505G of the FD&C Act, to obtain information on other matters relevant to the regulation of nonprescription drugs, and to obtain recommendations on the development of new OTC monograph drugs. As required by section 505G(i) of the FD&C Act, this draft guidance, when finalized, will also describe procedures to facilitate efficient participation in joint meetings by multiple meeting requestors and/or organizations nominated by them to represent their interests.

This draft guidance does not apply to meetings for the development of nonprescription drug products intended for submission in new drug applications or abbreviated new drug applications under section 505 of the FD&C Act. This draft guidance does not apply to meetings between FDA and pre-investigational new drug or investigational new drug sponsors. For the purposes of this draft guidance, a *formal meeting* includes any meeting that is requested by a meeting requester following the procedures provided in this draft guidance and includes meetings conducted in any format (*i.e.,* face to face, teleconference/videoconference, or written response only).

In support of the CARES Act, FDA agreed to specific performance goals and procedures described in the document ''Over-the-Counter Monograph User Fee Program Performance Goals and Procedures—Fiscal Years 2018–2022,'' commonly referred to as the OMUFA Commitment Letter (the document can be accessed at *https://www.fda.gov/media/106407/download* and the document with updated goal dates for fiscal years 2021–2025 can be accessed at *https://www.fda.gov/media/146283/download*). The OMUFA Commitment Letter includes meeting management goals for formal meetings that occur between FDA and meeting requesters. In the OMUFA Commitment Letter, FDA committed to issuing this draft guidance under specific timelines.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Formal Meetings Between FDA and Sponsors or Requestors of Over-the-Counter Monograph Drugs; Draft Guidance for Industry.'' 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

Under section 505G(o) of the FD&C Act, the Paperwork Reduction Act of 1995 does not apply to collections of information made under section 505G of the FD&C Act. The information collections made in this guidance implement the provisions of three subsections of section 505G: (1) Section 505G(l)(1), which requires FDA to issue guidance that specifies the procedures and principles for formal meetings between FDA and sponsors or requestors for drugs subject to section 505G; (2) section 505G(h), which requires FDA to establish procedures under which meeting requestors can meet with appropriate FDA officials to obtain advice on the studies and other information necessary to support submissions under section 505G, other matters relevant to the regulation of nonprescription drugs, and the development of new nonprescription drugs under section 505G; and (3) section 505G(i), which requires FDA to, among other things, establish procedures to facilitate efficient participation in joint meetings by multiple meeting requesters and/or organizations nominated by them to represent their interests. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required for these collections of information.

III. Electronic Access

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

Dated: February 1, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–02446 Filed 2–4–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse; 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 and the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel; NIH Support for Conferences and Scientific Meetings.

Date: March 4, 2022.

Time: 1:00 p.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

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

Contact Person: Gerald L. McLaughlin, Ph.D., Scientific Review Officer, Office of Extramural Policy and Review, National Institute on Drug Abuse, NIH, 301 North Stonestreet Avenue, MSC 6021, Bethesda, MD 20892, (301) 827–5819, *gm145a@nih.gov.*

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel; Fentanyl and its Analogs: Effects and Consequences for Treatment of Addiction and Overdose (UG3/UH3 Clinical Trial Optional).

Date: March 9, 2022.

Time: 9:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

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

Contact Person: Preethy Nayar, Ph.D., Scientific Review Officer, Scientific Review Branch, National Institute on Drug Abuse, NIH, 301 North Stonestreet Avenue, MSC 6021, Bethesda, MD 20892, 301–443–4577, *nayarp2@csr.nih.gov.*

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel; SEP for Centers Review.

Date: March 9, 2022.

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

Agenda: To review and evaluate grant applications.

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

Contact Person: Sheila Pirooznia, Ph.D., Scientific Review Officer, Scientific Review Branch, National Institute on Drug Abuse, NIH, 301 North Stonestreet Avenue, MSC 6021, Bethesda, MD 20892, (301) 496–9350, *sheila.pirooznia@nih.gov.*

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel; for Avenir Review.

Date: March 21, 2022.

Time: 3:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

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

Contact Person: Ipolia R. Ramadan, Ph.D., Scientific Review Officer, Office of Extramural Policy and Review, National Institute on Drug Abuse, NIH, 301 North Stonestreet Avenue, MSC 6021, Bethesda, MD 20892, (301) 827–4471, *ramadanir@mail.nih.gov.*

(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: February 1, 2022.

Tyeshia M. Roberson-Curtis,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–02469 Filed 2–4–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; 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/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 the grant applications and/or contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Institute Special Emphasis Panel; A Multilevel Approach to Connecting Underrepresented Populations to Clinical Trials (CUSP2CT).

Date: March 9, 2022.

Time: 11:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Cancer Institute at Shady Grove, 9609 Medical Center Drive, Room 7W140, Rockville, Maryland 20850 (Telephone Conference Call).

Contact Person: David G. Ransom, Ph.D., Chief, Scientific Review Officer, Special Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W140, Rockville, Maryland 20850, 240–276–6351, *david.ransom@nih.gov.*

Name of Committee: National Cancer Institute Special Emphasis Panel; The Role of Epstein Barr Virus (EBV) Infection in Non-Hodgkin Lymphoma (NHL) and Hodgkin Disease (HD) Development with or without an Underlying HIV Infection (U01).

Date: March 24, 2022.

Time: 9:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Cancer Institute Shady Grove, 9609 Medical Center Drive, Room 7W104, Rockville, Maryland 20850 (Telephone Conference Call).

Contact Person: Robert F. Gahl, Ph.D., Scientific Review Officer, Special Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9606 Medical Center Drive, Room 7W104, Rockville, Maryland 20850, 240–276–7869, *robert.gahl@nih.gov.*

Name of Committee: National Cancer Institute Special Emphasis Panel; R13 Conference Grant Review.

Date: March 24, 2022.

Time: 11:00 a.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Cancer Institute at Shady Grove, 9609 Medical Center Drive, Room 7W552, Rockville, Maryland 20850 (Telephone Conference Call).

Contact Person: Jeanette Irene Marketon, Ph.D., Scientific Review Officer, Program Coordination and Referral Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W552, Rockville, Maryland 20850, 240–276–6780, *jeanette.marketon@nih.gov.*

Name of Committee: National Cancer Institute Special Emphasis Panel; TEP–11: SBIR Contract Review Meeting.

Date: March 31, 2022.

Time: 11:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Cancer Institute Shady Grove, 9609 Medical Center Drive, Room 7W126, Rockville, Maryland 20850 (Telephone Conference Call).

Contact Person: Susan Lynn Spence, Ph.D., Scientific Review Officer, Research Technology and Contract Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W126, Rockville, Maryland 20850, 240–620–0819, *susan.spence@nih.gov.*

Name of Committee: National Cancer Institute Special Emphasis Panel; Cancer Center Support Grant.

Date: May 12, 2022.

Time: 2:00 p.m. to 3:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Cancer Institute at Shady Grove, 9609 Medical Center Drive, Room 7W612, Rockville, Maryland 20850 (Telephone Conference Call).

Contact Person: CAPT Shari Williams Campbell, DPM, MSHS, Scientific Review Officer, Resources and Training Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W612, Rockville, Maryland 20850, 240–276–7381, *shari.campbell@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: February 2, 2022.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–02476 Filed 2–4–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The invention listed below is owned by an agency of the U.S. Government and is available for licensing to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

FOR FURTHER INFORMATION CONTACT: Elizabeth Pitts, Ph.D., 240–669–5299; *elizabeth.pitts@nih.gov.* Licensing information and copies of the patent applications listed below may be obtained by communicating with the indicated licensing contact at the Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases, 5601 Fishers Lane, Rockville, MD 20852; tel. 301–496–2644. A signed Confidential Disclosure Agreement may be required to receive any unpublished information.

SUPPLEMENTARY INFORMATION: Technology description follows:

Monoclonal Antibodies To Prevent or Treat SARS–CoV–2 Infection

Description of Technology

The ongoing COVID–19 pandemic, caused by severe respiratory syndrome coronavirus 2 (SARS–CoV–2), has