This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on recommendations for sponsors developing human GT products for neurodegenerative disorders affecting adult and pediatric patients. 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

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 50 have been approved under OMB control number 0910–0755; 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 601 have been approved under OMB control number 0910–0338; and the collections of information in the guidance entitled ''Expedited Programs for Serious Conditions—Drugs and Biologics'' have been approved under OMB control number 0910–0765.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either *https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances* or *https://www.regulations.gov.*

Dated: December 22, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2020–29238 Filed 1–5–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–2246]

Withdrawal of FDA Notice Regarding Fee Rates Under the Over-the-Counter Monograph Drug User Fee Program for Fiscal Year 2021

AGENCY: Department of Health and Human Services (HHS), Food and Drug Administration (FDA).

ACTION: Notice; withdrawal.

SUMMARY: The Department of Health and Human Services is issuing this Notice to withdraw FDA's December 29, 2020 **Federal Register** Notice entitled *Fee Rates Under the Over-the-Counter Monograph User Fee Program for Fiscal Year 2021* because FDA lacked the delegated authority to issue the Notice. The Department is further informing the public that FDA has been ordered to cease further collection efforts related to the Over-the-Counter Drug Monograph User Fee Program until further action is announced in the **Federal Register**.

DATES: The Notice, published in the **Federal Register** on December 29, 2020 (85 FR 85646), is withdrawn as of January 6, 2021.

FOR FURTHER INFORMATION CONTACT: David Haas, Office of Financial Management, Food and Drug Administration, 4041 Powder Mill Rd., Rm. 61075, Beltsville, MD 20705–4304, 240–402 4585.

SUPPLEMENTARY INFORMATION: On December 29, 2020, FDA published a Notice in the **Federal Register** entitled *Fee Rates Under the Over-the-Counter Monograph User Fee Program for Fiscal Year 2021.* 85 FR 85646. The Notice purports to implement certain user fee provisions contained in the Coronavirus Aid, Relief, and Economic Security Act (''CARES Act''), Public Law 116–136, 134 Stat. 281 (March 27, 2020). The Notice was issued without approval of the Secretary. For this reason, the Notice, Docket No. FDA–2020–N–2246, as published in the **Federal Register** on December 29, 2020, (85 FR 85646), is hereby withdrawn.

FDA has also been ordered to cease collections activities related to the Over-the-Counter Monograph User Fee Program (''OMUFA'') until, with the approval of the Secretary, the Department issues further direction concerning FDA's administration of OMUFA which provides the public with notice and opportunity for comment.

Dated: December 31, 2020.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

[FR Doc. 2021–00030 Filed 1–4–21; 4:15 pm]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Physician-Focused Payment Model Technical Advisory Committee; Meetings

ACTION: Notice of meetings.

SUMMARY: This notice announces the 2021 meetings of the Physician-Focused Payment Model Technical Advisory Committee (PTAC). These meetings include deliberation and voting on proposals for physician-focused payment models (PFPMs) submitted by individuals and stakeholder entities and may include discussions on topics related to current or previously submitted PFPMs. All meetings are open to the public.

DATES: The 2021 PTAC meetings will occur on the following dates:

- Thursday–Friday, June 10–11, 2021, from 9:00 a.m. to 5:00 p.m. ET
- Monday–Tuesday, September 27–28, 2021, from 9:00 a.m. to 5:00 p.m. ET
- Thursday–Friday, December 16–17, 2021, from 9:00 a.m. to 5:00 p.m. ET

Please note that times are subject to change. If the times change, the ASPE PTAC website will be updated (*https://aspe.hhs.gov/ptac-physician-focused-payment-model-technical-advisory-committee*) and registrants will be notified directly via email.

ADDRESSES: All PTAC meetings will be held virtually or in the Great Hall of the Hubert H. Humphrey Building, 200 Independence Avenue SW, Washington, DC 20201.

FOR FURTHER INFORMATION CONTACT: Stella Mandl, Designated Federal Officer at *stella.mandl@hhs.gov* (202) 690–6870.

SUPPLEMENTARY INFORMATION:

Agenda and Comments. PTAC will hear presentations on proposed PFPMs that have been submitted by individuals and stakeholder entities and/or discussion on topics related to current or previously submitted PFPMs. Regarding proposed PFPMs, following each presentation, PTAC will deliberate on the proposed PFPM. If PTAC completes its deliberation, PTAC will vote on the extent to which the proposed PFPM meets criteria established by the Secretary of Health and Human Services and on an overall

recommendation to the Secretary. Time will be allocated for public comments. The agenda and other documents will be posted on the PTAC section of the ASPE website, *https://aspe.hhs.gov/ptac-physician-focused-payment-model-technical-advisory-committee,* prior to the meeting. The agenda is subject to change. If the agenda does change, registrants will be notified directly via email, the website will be updated, and notification will be sent out through the PTAC email listserv (*https://list.nih.gov/cgi-bin/wa.exe?A0=PTAC* to subscribe).

Meeting Attendance. These meetings are open to the public and may be hosted in-person or virtually. We intend that in-person meetings will be held in the Great Hall of the Hubert H. Humphrey Building. The public may attend in person, when feasible, via conference call, or view the meeting via livestream at *www.hhs.gov/live.* The conference call dial-in information will be sent to registrants prior to the meeting. Space may be limited, and registration is preferred. For meetings that are held virtually, the public may attend via WebEx link (including a dial-in only option) or view the meeting via livestream at *www.hhs.gov/live.* Registration may be completed online at *http://www.cvent.com/d/gbq2tg.* Name, organization name, and email address are submitted when registering. Registrants will receive a confirmation email shortly after completing the registration process.

Special Accommodations. If sign language interpretation or other reasonable accommodation for a disability is needed, please contact ASPE PTAC staff, no later than two weeks prior to the scheduled meeting. Please submit your requests by email to *PTAC@hhs.gov.*

Authority. 42 U.S.C 1395(ee); Section 101(e)(1) of the Medicare Access and CHIP Reauthorization Act of 2015; Section 51003(b) of the Bipartisan Budget Act of 2018.

PTAC is governed by provisions of the Federal Advisory Committee Act, as amended (5 U.S.C App.), which sets forth standards for the formation and use of federal advisory committees.

Dated: December 30, 2020.

Brenda Destro,

Deputy Assistant Secretary for Planning and Evaluation (HSP).

[FR Doc. 2020–29223 Filed 1–5–21; 8:45 am]

BILLING CODE 4150–05–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 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 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 contract proposals, 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; A Solicitation of the National Institutes of Health (NIH) and the Centers for Disease Control and Prevention (CDC) for Small Business Innovation Research (SBIR) Contract Proposals (N01), Topic 098.

Date: January 27, 2021.

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

Agenda: To review and evaluate contract proposals.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3E70A, Rockville, MD 20892 (Virtual Meeting).

Contact Person: Soheyla Saadi, 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 3E70A, Rockville, MD 20852, 301–435–0903, *saadisoh@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: December 30, 2020.

Tyeshia M. Roberson,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–29267 Filed 1–5–21; 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: Integrative, Functional and Cognitive Neuroscience Integrated Review Group; Behavioral Neuroendocrinology, Neuroimmunology, Rhythms, and Sleep Study Section.

Date: February 4–5, 2021.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

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

Contact Person: Michael Selmanoff, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5164, MSC 7844, Bethesda, MD 20892, 301–435–1119, *selmanom@csr.nih.gov.*

Name of Committee: Biological Chemistry and Macromolecular Biophysics Integrated Review Group; Biochemistry and Biophysics of Membranes Study Section.

Date: February 4–5, 2021.

Time: 8:30 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

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

Contact Person: Nuria E Assa-Munt, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4164, MSC 7806, Bethesda, MD 20892, (301) 451–1323, *assamunu@csr.nih.gov.*

Name of Committee: Integrative, Functional and Cognitive Neuroscience Integrated Review Group; Sensory-Motor Neuroscience Study Section.

Date: February 4–5, 2021.

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

Agenda: To review and evaluate grant applications.

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

Contact Person: John Bishop, Ph.D., Scientific Review Officer, Center for