This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on recommendations for sponsors developing human GT products for neurodegenerative disorders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Persons with access to the internet may obtain the draft guidance at either *https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances* or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