Dated: December 29, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2020–29158 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–D–2101]

Human Gene Therapy for Neurodegenerative Diseases; Draft Guidance for Industry; Availability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is announcing the availability of a draft document entitled ''Human Gene Therapy for Neurodegenerative Diseases; Draft Guidance for Industry.'' Neurodegenerative diseases are a heterogeneous group of disorders characterized by progressive degeneration of the structure and function of the central nervous system or peripheral nervous system. The draft guidance document provides recommendations to sponsors developing a human gene therapy (GT) product for neurodegenerative diseases affecting adult and pediatric patients. The guidance focuses on considerations for product development, preclinical testing, and clinical trial design.

DATES: Submit either electronic or written comments on the draft guidance by April 6, 2021 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.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–2020–D–2101 for ''Human Gene Therapy for Neurodegenerative Diseases; Draft 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 guidance to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist the office in processing your requests. The draft guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 240–402–8010. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Shruti Modi, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft document entitled ''Human Gene Therapy for Neurodegenerative Diseases; Draft Guidance for Industry.'' Neurodegenerative diseases are a heterogeneous group of disorders characterized by progressive degeneration of the structure and function of the central nervous system or peripheral nervous system. The draft guidance document provides recommendations to sponsors developing a GT product for neurodegenerative diseases affecting adult and pediatric patients. This guidance focuses on considerations for product development, preclinical testing, and clinical trial design.

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