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 § 10.20 (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.gpo.gov/fdsys/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.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6250, Silver Spring, MD 20993, 301–796–3600.

SUPPLEMENTARY INFORMATION:

I. Background

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA has approved for marketing the human drug product OZEMPIC (semaglutide). OZEMPIC is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Subsequent to this approval, the USPTO received a patent term restoration application for OZEMPIC (U.S. Patent No. 8,129,343) from Novo Nordisk A/S, and the USPTO requested FDA's assistance in determining the patent's eligibility for patent term restoration. In a letter dated September 18, 2018, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of OZEMPIC represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for OZEMPIC is 3,336 days. Of this time, 2,970 days occurred during the testing phase of the regulatory review period, while 366 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(i)) became effective:* October 19, 2008. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on October 19, 2008.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the FD&C Act:* December 5, 2016. FDA has verified the applicant's claim that the new drug application (NDA) for OZEMPIC (NDA 209637) was initially submitted on December 5, 2016.

3. *The date the application was approved:* December 5, 2017. FDA has verified the applicant's claim that NDA 209637 was approved on December 5, 2017.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,040 days of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in § 60.30 (21 CFR 60.30), any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must comply with all the requirements of § 60.30, including but not limited to: Must be timely (see **DATES**), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to *https://www.regulations.gov* at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: November 21, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–25850 Filed 11–27–19; 8:45 am]

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 2020 meetings of the Physician-Focused

Payment Model Technical Advisory Committee (PTAC). These meetings will include deliberation and voting on proposals for physician-focused payment models (PFPMs) submitted by individuals and stakeholder entities. All meetings are open to the public.

DATES: The 2020 PTAC meetings will occur on the following dates:

- Monday, March 16, 2020, from 9:00 a.m. to 5:00 p.m. ET
- Monday–Tuesday, June 22–23, 2020, from 9:00 a.m. to 5:00 p.m. ET
- Tuesday–Wednesday, September 15–16, 2020, from 9:00 a.m. to 5:00 p.m. ET
- Monday–Tuesday, December 7–8, 2020, from 9:00 a.m. to 5:00 p.m. ET

Please note that times are subject to change. If the times change, registrants will be notified directly via email.

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

FOR FURTHER INFORMATION CONTACT: Sarah Selenich, Designated Federal Officer, (202) 690–6870.

SUPPLEMENTARY INFORMATION:

Agenda and Comments. PTAC will hear presentations on proposed PFPMs that have been submitted by individuals and stakeholder entities. 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 (go to *https://list.nih.gov/cgi-bin/wa.exe?A0=PTAC* to subscribe).

Meeting Attendance. These meetings are open to the public. The public may attend in person, 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. 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* or by calling 202–690–6870.

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: November 22, 2019.

Brenda Destro,

Deputy Assistant Secretary for Planning and Evaluation (HSP).

[FR Doc. 2019–25898 Filed 11–27–19; 8:45 am]

BILLING CODE 4150–05–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood 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 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 Heart, Lung, and Blood Institute Special Emphasis Panel; Regenerative Medicine 2020.

Date: January 6, 2020.

Time: 8:30 a.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda Marriott Suites, 6711 Democracy Boulevard, Bethesda, MD 20817.

Contact Person: Kristin Goltry, Ph.D. Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7198, Bethesda, MD 20892, 301–435–0297, *goltrykl@mail.nih.gov*.

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel; Complications of Hemolysis and Transfusion Therapy.

Date: January 16, 2020.

Time: 1:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: NIH, RKL II, 6701 Rockledge Drive, Bethesda, MD 21892 (Telephone Conference Call).

Contact Person: Melissa E. Nagelin, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7202, Bethesda, MD 20892, 301–435–0297, *nagelinmh2@nhlbi.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: November 22, 2019.

Ronald J. Livingston, Jr.,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–25845 Filed 11–27–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Center for Scientific Review Special Emphasis Panel, Member Conflict: Topics in Bacterial Pathogenesis and Host Interactions, December 10, 2019, 10:00 a.m. to December 10, 2019, 5:00 p.m., National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 which was published in the **Federal Register** on November 19, 2019, 84 FR 63883.

The meeting start date is being changed to December 16, 2019. The meeting start time and location remains the same. The meeting is closed to the public.

Dated: November 22, 2019.

Ronald J. Livingston, Jr.,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–25846 Filed 11–27–19; 8:45 am]

BILLING CODE 4140–01–P