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 or biologic 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 biological products, the testing phase begins when the exemption to permit the clinical investigations of the biological product becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human biological product and continues until FDA grants permission to market the biological 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 biological 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 biologic product UPLIZNA (inebilizumab-cdon). UPLIZNA is indicated for the treatment of neuromyelitis optica spectrum disorder in adult patients who are anti-aquaporin-4 antibody positive. Subsequent to this approval, the USPTO received a patent term restoration application for UPLIZNA (U.S. Patent No. 8,323,653) from Viela Bio, Inc., and the USPTO requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated December 14, 2020, FDA advised the USPTO that this human biological product had undergone a regulatory review period and that the approval of UPLIZNA 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 UPLIZNA is 4,033 days. Of this time, 3,666 days occurred during the testing phase of the regulatory review period, while 367 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 (21 U.S.C. 355(i)) became effective:* May 29, 2009. The applicant claims July 5, 2009, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was May 29, 2009, which was the first date after receipt of an earlier IND that the investigational studies were allowed to proceed.

2. *The date the application was initially submitted with respect to the human biological product under section 351 of the Public Health Service Act (42 U.S.C. 262):* June 11, 2019. FDA has verified the applicant's claim that the biologics license application (BLA) for UPLIZNA (BLA 761142) was initially submitted on June 11, 2019.

3. *The date the application was approved:* June 11, 2020. FDA has verified the applicant's claim that BLA 761142 was approved on June 11, 2020.

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 1,557 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: July 1, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–14539 Filed 7–7–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Advisory Committee on Seniors and Disasters and National Advisory Committee on Individuals With Disabilities and Disasters Public Meeting

AGENCY: Office of the Assistant Secretary for Preparedness and Response (ASPR), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: As stipulated by the Federal Advisory Committee Act, the Office of the Assistant Secretary for Preparedness and Response, Department of the Health and Humans Services is hereby giving notice that the National Advisory Committee on Seniors and Disasters (NACSD) and the National Advisory Committee on Individuals with Disabilities and Disasters (NACIDD) will hold public meetings on August 4, 2022.

DATES: The NACSD and the NACIDD will conduct a joint virtual inaugural public meeting on August 4, 2022. The NACSD and the NACIDD will vote on possible recommendations for national public health and medical preparedness, response, and recovery, specific to the needs of older adults and people with disabilities in disasters. A more detailed agenda and meeting registration link will be available on the NACSD and the NACIDD meeting websites which are located at *https://www.phe.gov/nacsd* and at *https://www.phe.gov/nacidd,* respectively.

ADDRESSES: Members of the public may attend the meetings via a toll-free phone number or Zoom teleconference, which requires pre-registration. The meeting links to pre-register will be posted on *https://www.phe.gov/nacsd* and *https://www.phe.gov/nacidd.* Members of the public may provide written comments or submit questions for consideration by the NACSD and NACIDD at any time via

email to *NACSD@hhs.gov* and *NACIDD@hhs.gov,* respectively. Members of the public are also encouraged to provide comments after the meeting.

FOR FURTHER INFORMATION CONTACT: Dr. Maxine Kellman, NACSD Designated Officer, 202–260–0447, *NACSD@hhs.gov* and Tabinda Burney, NACIDD Designated Federal Officer, 202–699–1779, *NACIDD@hhs.gov;* Office of the Assistant Secretary for Preparedness and Response (ASPR), Department of Health and Human Services (HHS), Washington, DC.

SUPPLEMENTARY INFORMATION: The National Advisory Committee on Seniors and Disaster (NACSD) is required by section 2811B of the Public Health Service Act (42 U.S.C. 300hh–10c), as amended, by the Pandemic and All-Hazards Preparedness and Advancing Innovation Act (PAHPAIA), Public Law 116–22. The NACSD is governed by the provisions of the Federal Advisory Committee Act (FACA), Public Law 92–463, as amended (5 U.S.C. App.), which sets forth standards for the formation and use of advisory committees. The NACSD shall provide advice and consultation to the Secretary of HHS to assist them in carrying out these and related activities as they pertain to the unique needs of older adults in preparation for, responses to, and recovery from all-hazards emergencies and disasters. The Secretary of HHS has formally delegated authority to operate the NACSD to ASPR.

The National Advisory Committee on Individuals with Disabilities and Disasters (NACIDD) is required by section 2811C of the PHS Act (42 U.S.C. 300hh–10d) as amended by the Pandemic and All Hazards Preparedness and Advancing Innovation Act (PAHPAIA) of 2019, Public Law 116–22. The Committee is governed by the provisions of the Federal Advisory Committee Act (FACA) (5 U.S.C. App.) and the General Services Administration FACA Final Rule. The NACIDD shall evaluate issues and programs and provide findings, advice, and recommendations to the Secretary of HHS to support and enhance all-hazards public health and medical preparedness, response, and recovery aimed at meeting the needs of people with disabilities (PWD). The Secretary of HHS has formally delegated authority to operate the NACIDD to ASPR.

The NACSD and the NACIDD invite those who are involved in or represent a relevant industry, academia, profession, organization, or U.S. state, tribal, territorial, or local government to request up to four minutes to address the committees via Zoom. Requests to provide remarks to the NACSD and/or the NACIDD during the public meeting must be sent to *NACSD@hhs.gov* and/or *NACIDD@hhs.gov* at least 15 days prior to the meeting along with a brief description of the topic. We would specifically like to request inputs from the public on challenges, opportunities, and strategic priorities for national public health and medical preparedness, response, and recovery specific to the needs of people with disabilities and/or older adults before, during, and after disasters. Presenters who are selected for the public meeting will have audio only for up to four minutes during the meeting. Slides, documents, and other presentation material sent along with the request to speak will be provided to the committee members separately. Please indicate additionally whether the presenter will be willing to take questions from the committee members (at their discretion) immediately following their presentation (for up to four additional minutes).

Dawn O'Connell,

Assistant Secretary for Preparedness and Response.

[FR Doc. 2022–14426 Filed 7–7–22; 8:45 am]

BILLING CODE 4150–37–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Asthma Education Prevention Program Coordinating Committee.

The meeting will be open to the public. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

Name of Committee: National Asthma Education Prevention Program Coordinating Committee.

Date: August 16, 2022.

Time: 12:00 p.m. to 4:00 p.m.

Agenda: Programmatic and Scientific Updates

Place: National Institutes of Health, Rockledge II, 6705 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Virtual Access: https://nih.zoomgov.com/j/1603194596?pwd=ZnhJV3BLcEFOVThvUUdhQnNGOG5xZz09.

Telephone Access: Meeting ID: 160 319 4596. Passcode: 748944. +1 669 254 5252 US (San Jose). +1 646 828 7666 US (New York). +1 551 285 1373 US. +1 669 216 1590 US (San Jose).

Contact Person: Susan Shero, MS, Program Officer, CTRIS, Center for Translational Research and Implementation Science, National Heart, Lung and Blood Institute, National Institutes of Health, 6705 Rockledge Drive, Bethesda, MD 20892, 301–496–1051, *susan.shero@nih.gov*.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Information is also available on the Institute's/Center's home page: *https://www.nhlbi.nih.gov/advisory-and-peer-review-committees/national-asthma-education-and-prevention-program-coordinating,* where an agenda and any additional information for the meeting will be posted when available.

Information is also available on the Institute's/Center's home page: *https://www.nhlbi.nih.gov/advisory-and-peer-review-committees/national-asthma-education-and-prevention-program-coordinating*, where an agenda and any additional information for the meeting will be posted when available.

(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: July 1, 2022.

David W Freeman,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–14559 Filed 7–7–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Environmental Health Sciences; 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 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