UBRELVY is 2,883 days. Of this time, 2,520 days occurred during the testing phase of the regulatory review period, while 363 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:* February 2, 2012. The applicant claims February 3, 2012, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was February 2, 2012, which was 30 days after FDA receipt of the IND.

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 26, 2018. FDA has verified the applicant's claims that the new drug application (NDA) for UBRELVY (NDA 211765) was initially submitted on December 26, 2018.

3. *The date the application was approved:* December 23, 2019. FDA has verified the applicant's claim that NDA 211765 was approved on December 23, 2019.

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 applications for patent extension, this applicant seeks 555 days or 774 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: August 25, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–18753 Filed 8–30–22; 8:45 am]

BILLING CODE 4164–01–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 Advisory Council, September 19, 2022, 10:00 a.m. to 04:00 p.m., National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Rooms 260 C, D, E and F, Bethesda, MD 20892, which was published in the **Federal Register** on August 24, 2022, FR Doc 2022–18262, 87 FR 52000.

This notice is being amended to remove the visitor testing requirement for entering NIH facilities due to CDC updates published August 11, 2022, regarding screening testing. The meeting is open to the public.

Information is also available on the Institute's/Center's home page: *https://public.csr.nih.gov/AboutCSR/Organization/CSRAdvisoryCouncil*, where an agenda and any additional information for the meeting will be posted when available.

The meeting will be videocast and can be accessed from the NIH Videocasting website (*https://videocast.nih.gov/watch=45767*).

Dated: August 25, 2022.

Tyeshia M. Roberson-Curtis,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–18785 Filed 8–30–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Request for Information: SAMHSA's Role in Possible Agency Actions Regarding Mental Health and Substance Use Wellbeing in the Context of Climate Change and Health Equity

AGENCY: Substance Abuse and Mental Health Services Administration (SAMHSA), Department of Health and Human Services (HHS).

ACTION: Notice of request for information.

SUMMARY: SAMHSA seeks input from members of the public about how it can best address the behavioral health impacts of climate change and health equity considerations. Behavioral health includes mental health conditions and substance use disorders. SAMHSA specifically seeks input on suggested priorities, resources, partners and collaborating agencies and organizations.

DATES: Comments on this notice must be received by October 31, 2022.

ADDRESSES: Please submit all responses via email to *ClimateChange@SAMHSA.HHS.gov* as a Word document, Portable Document Format (PDF) or in the body of an email. Please include ''Request for Information: SAMHSA's Role in Climate Change'' in the subject line of the message.

FOR FURTHER INFORMATION CONTACT: Mitchell Berger, Public Health Advisor, Telephone: 240–276–1757, Email: *Mitchell.Berger@SAMHSA.HHS.gov,* or Maggie Jarry, Emergency Management Specialist, Email: *Maggie.Jarry@samhsa.hhs.gov.*

SUPPLEMENTARY INFORMATION: In January 2021, President Biden signed Executive Order 14008, Tackling the Climate Crisis at Home and Abroad. Recognizing that ''we face a climate crisis that threatens our people and communities, public health and economy, and, starkly, our ability to live on planet Earth,'' the Order called for a ''government-wide approach'' to climate change and development of agency action plans to ''bolster adaptation and increase resilience to the impacts of climate change.'' [1]

President Biden also in January 2021 signed Executive Order 13985, Advancing Racial Equity and Support for Underserved Communities Through the Federal Government, which called upon Agencies to take steps to enhance