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 medical devices, the testing phase begins with a clinical investigation of the device and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the device and continues until permission to market the device is granted. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award (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 medical device will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(3)(B).

FDA has approved for marketing the medical device THEROX DOWNSTREAM SYSTEM. It is indicated for the preparation and delivery of SuperSaturated Oxygen Therapy to targeted ischemic regions perfused by the patient's left anterior descending coronary artery immediately following revascularization by means of percutaneous coronary intervention with stenting that has been completed within 6 hours after the onset of anterior acute myocardial infarction symptoms caused by a left anterior descending artery infarct lesion. Subsequent to this approval, the USPTO received patent term restoration applications for THEROX DOWNSTREAM SYSTEM (U.S. Patent Nos. 6,582,387; 7,820,102; and 8,264,564) from TherOx Inc., and the USPTO requested FDA's assistance in determining the patents' eligibility for patent term restoration. In a letter dated May 24, 2021, FDA advised the USPTO that this medical device had undergone a regulatory review period and that the approval of THEROX DOWNSTREAM SYSTEM 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 THEROX DOWNSTREAM SYSTEM is 7,386 days. Of this time, 6,824 days occurred during the testing phase of the regulatory review period, while 562 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption for this device, under section 520(g) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360j(g)), became effective:* January 13, 1999. The applicant claims that the investigational device exemptions (IDEs) required under section 520(g) of the FD&C Act for human tests to begin became effective on November 4, 1998, or January 28, 2012. However, FDA records indicate that the IDE was determined substantially complete for clinical studies to have begun on January 13, 1999, which represents the IDE effective date of the earliest IDE received.

2. *The date an application was initially submitted with respect to the device under section 515 of the FD&C Act (21 U.S.C. 360e):* September 18, 2017. The applicant claims September 21, 2017, as the date the premarket approval application (PMA) for THEROX DOWNSTREAM SYSTEM (PMA P170027) was initially submitted. However, FDA records indicate that PMA P170027 was initially submitted on September 18, 2017.

3. *The date the application was approved:* April 2, 2019. FDA has verified the applicant's claim that PMA P170027 was approved on April 2, 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 991 days, 1,591 days, or 1,826 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 Nos. 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. 2022–18754 Filed 8–30–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2021–E–0382 and FDA–2021–E–0383]

Determination of Regulatory Review Period for Purposes of Patent Extension; UBRELVY

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for UBRELVY and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human drug product.

DATES: Anyone with knowledge that any of the dates as published (see **SUPPLEMENTARY INFORMATION**) are incorrect must submit either electronic or written comments and ask for a redetermination by October 31, 2022. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence

during the regulatory review period by February 27, 2023. See ''Petitions'' in the **SUPPLEMENTARY INFORMATION** section for more information.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of October 31, 2022. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

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 Nos. FDA–2021–E–0382 and FDA–2021–E–0383 for ''Determination of Regulatory Review Period for Purposes of Patent Extension; UBRELVY.'' Received comments, those filed in a timely manner (see **ADDRESSES**), 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 § 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.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 numbers, 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.

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 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 drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug 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 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, UBRELVY (ubrogepant). UBRELVY is indicated for the acute treatment of migraine with or without aura in adults. Subsequent to this approval, the USPTO received patent term restoration applications for UBRELVY (U.S. Patent Nos. 8,912,210 and 9,833,448) from Allergan Sales LLC, and the USPTO requested FDA's assistance in determining the patents' eligibility for patent term restoration. In a letter dated June 8, 2021, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of UBRELVY 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

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