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, CAPLYTA (lumateperone tosylate). CAPLYTA is indicated for the treatment of schizophrenia. Subsequent to this approval, the USPTO received a patent term restoration application for CAPLYTA (U.S. Patent Nos. 8,598,119 and 8,648,077) from Intra-Cellular Therapies, Inc., and the USPTO requested FDA's assistance in determining the patent's 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 CAPLYTA 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 CAPLYTA is 4,421 days. Of this time, 3,970 days occurred during the testing phase of the regulatory review period, while 451 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:* November 15, 2007. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on November 15, 2007.

2. *The date the application was initially submitted with respect to the human drug product under section 505 of the FD&C Act:* September 27, 2018. FDA has verified the applicant's claim that the new drug application (NDA) for CAPLYTA (NDA 209500) was initially submitted on September 27, 2018.

3. *The date the application was approved:* December 20, 2019. FDA has verified the applicant's claim that NDA 209500 was approved on December 20, 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 1,294 days or 1,329 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: September 7, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–19898 Filed 9–14–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–E–1080]

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

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 TAVALISSE 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 may submit either electronic or written comments and ask for a redetermination by November 14, 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 March 14, 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

November 14, 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 No. FDA–2019–E–1080 for ''Determination of Regulatory Review Period for Purposes of Patent Extension; TAVALISSE.'' 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 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.

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 TAVALISSE (fostamatinib disodium hexahydrate). TAVALISSE is indicated for the treatment of thrombocytopenia in adult patients with chronic immune thrombocytopenia who have had an insufficient response to a previous treatment. Subsequent to this approval, the USPTO received a patent term restoration application for TAVALISSE (U.S. Patent No. 7,449,458) from Rigel Pharmaceuticals, Inc. and the USPTO requested FDA's assistance in determining the patent's eligibility for patent term restoration. In a letter dated June 12, 2019, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of TAVALISSE 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 TAVALISSE is 4,564 days. Of this time, 4,198 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 20, 2005. FDA has verified the applicant's claim that the date the investigational

new drug application became effective was on October 20, 2005.

2. *The date the application was initially submitted with respect to the human drug product under section 505 of the FD&C Act:* April 17, 2017. FDA has verified the applicant's claim that the new drug application (NDA) for TAVALISSE (NDA 209299) was initially submitted on April 17, 2017.

3. *The date the application was approved:* April 17, 2018. FDA has verified the applicant's claim that NDA 209299 was approved on April 17, 2018.

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 5 years 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: September 8, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–19993 Filed 9–14–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Notice of Availability of Health Center Program Scope of Project and Telehealth Policy Information Notice

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Request for public comment on Draft Health Center Program Scope of Project and Telehealth Policy Information Notice.

SUMMARY: HRSA is inviting public comment on the Draft Health Center Program Scope of Project and Telehealth Policy Information Notice (Telehealth PIN). The purpose of the Telehealth PIN is to establish policy for health centers that provide services via telehealth within the HRSA-approved scope of project. The Telehealth PIN also describes considerations and criteria health centers must meet for providing services via telehealth within the Health Center Program scope of project.

The Health Center Program is authorized by section 330 of the Public Health Service Act, 42 U.S.C. 254b. HRSA provides federal award funding to health centers to deliver required primary care and additional health services to medically underserved areas and populations. HRSA also certifies entities that it has determined to meet section 330 requirements as Health Center Program look-alikes. Health centers provide required primary care and additional health services to residents of the area served by the health center.

Each health center is responsible for maintaining its operations, including developing and implementing its own operating procedures for providing health services through telehealth, in compliance with all Health Center Program requirements and all other applicable federal, state, and local laws and regulations.[1]

Health centers are increasingly using telehealth as a means of delivering required and additional services to health center patients. Providing health care via telehealth [2] can increase patient access and improve clinical outcomes, quality of care, continuity of care, and reduce the need for hospitalization. Within the context of the Health Center Program scope of project, telehealth is not a service or a service delivery method requiring specific HRSA approval; rather, telehealth is a mechanism or means for delivering a health service(s) to health center patients using telecommunications technology or equipment.

DATES: Submit comments no later than November 14, 2022.

ADDRESSES: The PIN is available at the Scope of Project and Telehealth PIN Public Comments web page. Written comments should be submitted through the HRSA Bureau of Primary Health Care Contact Form (*https://hrsa.force.com/feedback/s/policy-information-notice*), by November 14, 2022.

FOR FURTHER INFORMATION CONTACT: Jennifer Joseph, Director, Office of Policy and Program Development, Bureau of Primary Health Care, HRSA, 5600 Fishers Lane, Rockville, Maryland 20857; email: *jjoseph@hrsa.gov;* telephone: 301–594–4300; fax: 301–594–4997.

SUPPLEMENTARY INFORMATION: HRSA provides grants to eligible applicants under section 330 of the PHS Act, as amended (42 U.S.C. 254b), to support the delivery of preventive and primary care services to the nation's underserved individuals and families. HRSA also certifies eligible applicants under the Health Center Look-Alike Program (see sections 1861(aa)(4)(B) and 1905(l)(2)(B) of the Social Security Act). Look-alikes do not receive Health Center Program funding but must meet the Health Center Program statutory and regulatory requirements. Nearly 1,400 Health Center Program-funded health centers and approximately 100 Health Center Program look-alike organizations collectively operate over 14,000 service delivery sites that provide care to over 30 million patients in every U.S. state, the District of Columbia, Puerto Rico, the U.S. Virgin Islands, and the Pacific Basin. Note that for the purposes of this document, the term ''health center'' refers to entities that receive a federal award under section 330 of the PHS Act, as amended, as well as subrecipients and organizations designated as look-alikes, unless otherwise stated.

Section A of the Telehealth PIN includes considerations for health centers delivering services via telehealth within the HRSA-approved scope of project. Each health center is responsible for maintaining its operations, including developing and implementing its own operating procedures for telehealth, in compliance with all Health Center Program

[1] 42 CFR 51c.304(d)(3)(v).

[2] HRSA defines telehealth as the use of electronic information and telecommunication technologies to support long-distance clinical health care, patient and professional health-related education, health administration, and public health.