application under section 306(a) of the FD&C Act (21 U.S.C. 335a(a)). FDA based the debarment on a finding under section 306(a)(2) of the FD&C Act that Dr. Kalidindi had been convicted of a felony under Federal law for conduct relating to the development, or approval, of any drug product or otherwise relating to the regulation of a drug product.

Section 306(d)(4) of the FD&C Act provides that any individual debarred under section 306(a)(2) may apply to FDA for special termination of debarment. Pursuant to section 306(d)(4)(C)–(D), FDA may grant a request for special termination and limit the period of debarment to less than permanent but no less than 1 year if the Agency finds: (1) That the individual has provided substantial assistance in the investigations or prosecutions of offenses described in section 306(a) or (b) of the FD&C Act, or relating to any matter under the jurisdiction of FDA and (2) that doing so best serves the interest of justice and protects the integrity of the drug approval process.

On May 27, 1998, FDA denied a previous petition for special termination of debarment submitted by Dr. Kalidindi. On January 13, 2020, Dr. Kalidindi again petitioned for special termination of debarment under section 306(d)(4) of the FD&C Act. On April 10, 2020, FDA's Office of Regulatory Affairs proposed denying that petition and offered Dr. Kalidindi an opportunity to request a hearing on the proposal to deny the petition. On May 9, 2020, Dr. Kalidindi requested a hearing and, on June 8, 2020, submitted materials in support of his hearing request.

By a decision dated September 15, 2021, FDA's Chief Scientist granted Dr. Kalidindi's petition for special termination based on her conclusion that doing so best served the interest of justice and protected the integrity of the drug approval process. In so concluding, she found that there were no genuine and substantial issues of fact with respect to the level and scope of substantial assistance provided by Dr. Kalidindi in the investigation and prosecution of others for offenses described in section 306(a) or (b) of the FD&C Act, or otherwise relating to FDA's jurisdiction, and that the level and scope of such substantial assistance, among other considerations, justified special termination of his debarment after 28 years. The Chief Scientist's decision is available at *https://www.fda.gov/media/152270/download.* The decision is also available at *https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/fda-debarment-list-drug-product-applications/fda-expired-debarment-list-drug-product-applications.*

Dated: November 4, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021–24973 Filed 11–15–21; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2020–E–2167 and FDA–2020–E–2168]

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

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 QINLOCK and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of applications 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 the **SUPPLEMENTARY INFORMATION** section) are incorrect may submit either electronic or written comments and ask for a redetermination by January 18, 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 May 16, 2022. 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. Electronic comments must be submitted on or before January 18, 2022. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of January 18, 2022. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is 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–2020–E–2167 and FDA–2020–E–2168 for ''Determination of Regulatory Review Period for Purposes of Patent Extension; QINLOCK.'' 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 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 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, QINLOCK (ripretinib) indicated for the treatment of adult patients with advanced gastrointestinal stromal tumor who have received prior treatment with 3 or more kinase inhibitors, including imatinib. Subsequent to this approval, the USPTO received patent term restoration applications for QINLOCK (U.S. Patent Nos. 8,188,113 and 8,461,179) from Deciphera Pharmaceuticals LLC and the USPTO requested FDA's assistance in determining the patents' eligibility for patent term restoration. In a letter dated December 14, 2020, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of QINLOCK 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 QINLOCK is 1,741 days. Of this time, 1,586 days occurred during the testing phase of the regulatory review period, while 155 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:* August 11, 2015. FDA has verified the applicant's claims that the date the investigational new drug application became effective was on August 11, 2015.

2. *The date the application was initially submitted with respect to the human drug product under section 505 of the FD&C Act:* December 13, 2019. FDA has verified the applicant's claims that the new drug application (NDA) for QINLOCK (NDA 213973) was initially submitted on December 13, 2019.

3. *The date the application was approved:* May 15, 2020. FDA has verified the applicant's claims that NDA 213973 was approved on May 15, 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 applications for patent extension, this applicant seeks 707 days or 947 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: November 3, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021–24978 Filed 11–15–21; 8:45 am]

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