

May 13, 2019, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of XEPI 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 XEPI is 2,819 days. Of this time, 2,282 days occurred during the testing phase of the regulatory review period, while 537 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:* March 26, 2010. FDA has verified the applicant's claim that the date the investigational new drug application became effective was March 26, 2010.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the FD&C Act:* June 23, 2016. FDA has verified the applicant's claim that the new drug application (NDA) for XEPI (NDA 208945) was initially submitted on June 23, 2016.

3. *The date the application was approved:* December 11, 2017. FDA has verified the applicant's claim that NDA 208945 was approved on December 11, 2017.

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 1,678 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 7, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020-15013 Filed 7-10-20; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2019-N-3708]

InvaGen Pharmaceuticals, Inc.; Withdrawal of Approval of an Abbreviated New Drug Application for Trandolapril Tablets

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration's (FDA or Agency) Center for Drug Evaluation and Research (CDER) is withdrawing approval of an abbreviated new drug application (ANDA) for trandolapril tablets. The basis for the withdrawal is that the holder of the ANDA has repeatedly failed to submit the required data to support a finding of bioequivalence for this ANDA. The holder of the ANDA has waived its opportunity for a hearing.

DATES: Withdrawal of approval is applicable July 13, 2020.

FOR FURTHER INFORMATION CONTACT:

Jennifer Forde, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6228, Silver Spring, MD 20993-0002, 301-348-3035.

SUPPLEMENTARY INFORMATION: FDA's Office of Generic Drugs (OGD) approved ANDA 078320, held by InvaGen Pharmaceuticals, Inc. (InvaGen), for a generic version of trandolapril tablets, 1 milligram (mg), 2 mg, and 4 mg, under the requirements of section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(j)) and FDA's implementing regulations. OGD

approved ANDA 078320 on June 12, 2007. In a notice published in the **Federal Register** of October 28, 2019 (84 FR 57736), CDER notified InvaGen of CDER's proposal to issue an order, under section 505(e) of the FD&C Act and § 314.150 (21 CFR 314.150), withdrawing approval of ANDA 078320 and all amendments and supplements to it on the grounds that InvaGen has failed to submit the required bioequivalence data necessary to demonstrate the bioequivalence of its drug product. In its October 28, 2019, notice of opportunity for a hearing (NOOH), CDER provided InvaGen with an opportunity to request a hearing to show why approval of ANDA 078320 should not be withdrawn.

As noted in the October 28, 2019, NOOH, FDA issued a letter to InvaGen on August 9, 2011, regarding ANDA 078320 because this drug product application was supported by bioequivalence studies with the bioanalytical analysis conducted by Cetero Research at the Houston, TX, site between April 1, 2005, and June 15, 2010. As FDA noted in its August 9, 2011, correspondence, inspection findings regarding Cetero Research's bioequivalence studies raised significant concerns about the validity of the reported results of the analytical studies conducted between April 2005 and June 2010 in support of drug applications, and as such, steps needed to be taken to demonstrate the bioequivalence of InvaGen's drug product approved under ANDA 078320. FDA informed InvaGen that ANDA 078320 needed to be supplemented by conducting new bioequivalence studies or re-assaying the samples from the original bioequivalence study. FDA recommended to InvaGen that the results of the requested bioequivalence studies or re-assays be submitted to ANDA 078320 within 6 months of the date of the August 9, 2011, letter.

Although the October 28, 2019, NOOH states that FDA did not receive a response from InvaGen to the August 9, 2011, letter from FDA, upon further review, additional correspondence between InvaGen and FDA has been identified. In a letter to FDA dated August 12, 2011, InvaGen requested a 6-month extension for submitting bioequivalence study data for ANDA 078320. On September 21, 2011, FDA issued a letter to InvaGen acknowledging InvaGen's August 12, 2011, request for an extension. In a letter to FDA dated September 6, 2012, InvaGen requested an additional 6-month extension to submit bioequivalence study data; and in a letter to FDA dated October 4, 2012,

InvaGen requested that FDA consider and grant InvaGen's request for an extension. On October 23, 2012, FDA issued a letter to InvaGen granting InvaGen an extension until March 2013 to submit bioequivalence study data. InvaGen has not submitted the bioequivalence study data.

The additional correspondence noted above that was not identified in the October 28, 2019, NOOH does not alter the underlying basis of the October 28, 2019, NOOH. In the absence of information showing bioequivalence between the generic drug at issue and the reference listed drug (RLD), there is no basis for concluding that the Agency's finding of safety and efficacy supporting approval of the RLD can be used as a basis to support approval of the generic drug. Section 505(e) of the FD&C Act provides FDA the authority to withdraw approval of an ANDA in these circumstances.

In correspondence dated November 7, 2019, InvaGen requested withdrawal of the approval of ANDA 078320 under § 314.150(d). Because this application withdrawal is effectuated through the NOOH process (see 84 FR 57736), InvaGen's request to withdraw approval under § 314.150(d) is moot. In the November 7, 2019, correspondence, InvaGen also waived its opportunity for a hearing under § 314.150(a).

FDA finds that InvaGen has repeatedly failed to submit the required data to support a finding of bioequivalence for ANDA 078320. In addition, under 21 CFR 314.200, FDA finds that InvaGen has waived any contentions concerning the legal status of the drug product. Therefore, under section 505(e) of the FD&C Act, approval of ANDA 078320, and all amendments and supplements thereto, is withdrawn (see **DATES**). Introduction or delivery for introduction of this drug product into interstate commerce without an approved application is illegal and subject to regulatory action (see sections 505(a) and 301(d) of the FD&C Act (21 U.S.C. 355(a), 331(d))).

Dated: July 7, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020-14981 Filed 7-10-20; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-E-4404]

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

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 CARTIVA 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 medical device.

DATES: Anyone with knowledge that any of the dates as published (in **SUPPLEMENTARY INFORMATION**) are incorrect may submit either electronic or written comments and ask for a redetermination by September 11, 2020. 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 January 11, 2021. 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 September 11, 2020. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of September 11, 2020. 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 No. FDA-2018-E-4404 for "Determination of Regulatory Review Period for Purposes of Patent Extension; CARTIVA." 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