must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 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, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Patricia Stewart, Office of Operations, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993; 301–796–4735, *patricia.stewart@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is holding a public meeting to share high-level findings from a recently-completed interim assessment of FDA's hiring process, conducted by a qualified, independent contractor with expertise in assessing transformation of human resources operations. FDA recognizes that the critical work to protect public health is made possible in part by the Agency's ability to attract and retain a talented, diverse, and dedicated workforce. As FDA continues to fulfil its strategic mission, it is imperative that the Agency identify and leverage the talent, skills, and diversity within—and outside of—the Agency.

These priorities are reflected in FDA's plan to enhance its hiring and retention programs; recruit qualified candidates with diverse backgrounds, experiences, and talents; provide internal development opportunities; and further enhance the Agency's ability to nurture a supportive and fair work environment. The public meeting will provide an update on FDA's progress toward PDUFA (Prescription Drug User Fee Act) and BsUFA (Biosimilar User Fee Act) user fee hiring and retention commitments and solicit input on actions with regards to the hiring process. To view the evaluation assessment report, please visit here: *https://www.fda.gov/industry/prescription-drug-user-fee-amendments/fda-interim-hiring-and-retention-assessment-report.*

This public meeting is intended to meet performance commitments included in PDUFA VI and BsUFA II. These user fee programs were reauthorized as part of the FDA Reauthorization Act of 2017 (FDARA) (Pub. L. 115–52) signed by the President on August 18, 2017. The complete set of performance goals for each program are available at:

- PDUFA VI program: *https://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM511438.pdf* and
- BsUFA II program: *https://www.fda.gov/downloads/forindustry/userfees/biosimilaruserfeeactbsufa/ucm521121.pdf.*

II. Topics for Discussion at the Public Meeting

This public meeting will provide FDA the opportunity to update interested public stakeholders on topics related to the FDA hiring and retention programs. Booz Allen Hamilton will present their findings and recommendations that are outlined in the Interim Hiring and Retention Assessment report and FDA will provide an update on the Agency's progress in addressing the findings from the independent third-party evaluation that was published June 5, 2020. To view the evaluation assessment report, please visit here: *https://www.fda.gov/industry/prescription-drug-user-fee-amendments/fda-interim-hiring-and-retention-assessment-report*

III. Participating in the Public Meeting

Registration: To register for the public meeting, please visit the following website to register: *https://www.eventbrite.com/e/fda-hiring-and-retention-interim-assessment-public-meeting-registration-106125275556.* Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone.

Persons interested in attending this public meeting must register by July 28, 2020, 11:59 p.m. Eastern Time.

If you need special accommodations due to a disability (*e.g.* Closed Captioning), please contact Patricia Stewart (see **FOR FURTHER INFORMATION CONTACT**) no later than July 22, 2020.

Requests for Oral Presentations: During online registration you may indicate if you wish to present during a public comment session, and which topic(s) you wish to address. We will do our best to accommodate requests to make public comments. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations and request time for a joint presentation. Following the close of registration, we will determine the amount of time allotted to each presenter and the approximate time each oral presentation is to begin, and will select and notify participants by July 27, 2020. All requests to make oral presentations must be received by July 22, 2020, 11:59 p.m. Eastern Time. If selected for presentation, any presentation materials must be emailed to Patricia Stewart (see **FOR FURTHER INFORMATION CONTACT**) no later than July 28, 2020. No commercial or promotional material will be permitted to be presented at the public meeting.

Streaming Webcast of the Public Meeting: The webcast for this public meeting is at *https://collaboration.fda.gov/fdapublicmeeting073020/.*

If you have never attended a Connect Pro event before, test your connection at *https://collaboration.fda.gov/common/help/en/support/meeting_test.htm.* To get a quick overview of the Connect Pro program, visit *https://www.adobe.com/go/connectpro_overview.* FDA has verified the website addresses in this document, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

Transcripts: Please be advised that as soon as a transcript of the public meeting is available, it will be accessible at *https://www.regulations.gov.* It may be viewed at the Dockets Management Staff (see A**DDRESSES**).

Dated: July 7, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–14980 Filed 7–10–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–E–4463]

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

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 XEPI 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 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–4463 for ''Determination of Regulatory Review Period for Purposes of Patent Extension; XEPI.'' 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, XEPI (ozenoxacin). XEPI is indicated for topical treatment of impetigo due to *Staphylococcus aureus* or *Streptococcus pyogenes* in adult and pediatric patients 2 months of age and older. Subsequent to this approval, the USPTO received a patent term restoration application for XEPI (U.S. Patent No. 6,335,447) from Toyama Chemical Co., Ltd., and the USPTO requested FDA's assistance in determining the patent's eligibility for patent term restoration. In a letter dated

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]

BILLING CODE 4164–01–P

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,