

- *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*Instructions:* All submissions received must include the Docket No. FDA-2007-D-0369 for “Draft Guidance on Digoxin.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” will be publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff office between 9 a.m. and 4 p.m., Monday through Friday.

- *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 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.gpo.gov/fdsys/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 office, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of the draft revised guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft revised guidance document.

**FOR FURTHER INFORMATION CONTACT:**

Xiaoqiu Tang, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 4730, Silver Spring, MD 20993-0002, 301-796-5850.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

In the **Federal Register** of June 11, 2010 (75 FR 33311), FDA announced the availability of a guidance for industry entitled “Bioequivalence Recommendations for Specific Products,” which explained the process that would be used to make product-specific guidances available to the public on FDA’s Web site at <https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>.

As described in that guidance, FDA adopted this process to develop and disseminate product-specific guidances and to provide a meaningful opportunity for the public to consider and comment on the guidances. This notice announces the availability of a draft revised product-specific guidance for generic digoxin tablets.

FDA initially approved new drug application (NDA) 020405 for LANOXIN (digoxin tablets) in September 1997. In May 2008, we issued a final guidance for industry on generic digoxin tablets. We are now issuing a draft revised guidance for industry on generic digoxin tablets (“Draft Guidance on Digoxin”).

In December 2015, Concordia Pharmaceuticals submitted a citizen petition requesting, among other things, that FDA amend the guidance for industry on BE recommendations for generic digoxin tablets issued in 2008. FDA has reviewed the issues raised in the citizen petition and is responding to the citizen petition (Docket No. FDA-2015-P-4566, available at <https://www.regulations.gov>).

This draft revised guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft revised guidance, when finalized, will represent the current thinking of FDA on the design of BE studies to support ANDAs for digoxin tablets. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

**II. Electronic Access**

Persons with access to the internet may obtain the draft revised guidance at either <https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <https://www.regulations.gov>.

Dated: August 24, 2017.

**Anna K. Abram,**

*Deputy Commissioner for Policy, Planning, Legislation, and Analysis.*

[FR Doc. 2017-18386 Filed 8-29-17; 8:45 am]

**BILLING CODE 4164-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2016-E-0624]

**Determination of Regulatory Review Period for Purposes of Patent Extension; XTORO**

**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 XTORO 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 (in the **SUPPLEMENTARY INFORMATION** section) are incorrect may submit either electronic or written comments and ask for a redetermination by October 30, 2017. 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 26, 2018. 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 October 30, 2017. The <https://www.regulations.gov> electronic filing system will accept comments until midnight Eastern Time at the end of October 30, 2017.

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-2016-E-0624 for "Determination of Regulatory Review Period for Purposes of Patent Extension; XTORO." 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 Office between 9 a.m. and 4 p.m., Monday through Friday.

- **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 Office. 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 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.gpo.gov/fdsys/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.

**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 XTORO (finaxofacin). XTORO is indicated for treatment of acute otitis externa caused by susceptible strains of *Pseudomonas aeruginosa* and *Staphylococcus aureus*. Subsequent to this approval, the USPTO received a patent term restoration application for XTORO (U.S. Patent No. 6,133,260) from Alcon Pharmaceuticals Ltd. for Bayer Intellectual Property GmbH, and the USPTO requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated May 2, 2016, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of XTORO 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 XTORO is 1,880 days. Of this time, 1,643 days occurred during the testing phase of the regulatory review period, while 237 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 (the FD&C Act) (21 U.S.C. 355(i)) became effective:* October 26, 2009. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on October 26, 2009.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the FD&C Act:* April 25, 2014. FDA has verified the applicant's claim that the new drug application (NDA) for XTORO (NDA 206307) was initially submitted on April 25, 2014.

3. *The date the application was approved:* December 17, 2014. FDA has verified the applicant's claim that NDA 206307 was approved on December 17, 2014.

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 1,058 days of patent term extension.

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 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 21 CFR 60.30, including but not limited to: Must be timely (see **DATES**), must be filed in accordance with 21 CFR 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 24, 2017.

**Anna K. Abram,**  
*Deputy Commissioner for Policy, Planning, Legislation, and Analysis.*

[FR Doc. 2017–18379 Filed 8–29–17; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2017–N–0002]

#### Upsher-Smith Laboratories, Inc.; Withdrawal of Approval of an Abbreviated New Drug Application for PROPRANOLOL HYDROCHLORIDE

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or the Agency) is withdrawing approval of an abbreviated new drug application (ANDA) for PROPRANOLOL HYDROCHLORIDE Extended-Release Capsules, held by Upsher-Smith Laboratories, Inc. (Upsher-Smith), 6701 Evenstad Dr., Maple Grove, MN 55369. Upsher-Smith has voluntarily requested that approval of this application be withdrawn and has waived its opportunity for a hearing. **DATES:** August 30, 2017.

**FOR FURTHER INFORMATION CONTACT:** Stefanie Kraus, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6215, Silver Spring, MD 20993–0002, 301–796–9585.

**SUPPLEMENTARY INFORMATION:** On March 6, 2009, FDA approved abbreviated new drug application (ANDA) 078311 for PROPRANOLOL HYDROCHLORIDE Extended-Release Capsules, USP, 60 milligrams (mg), 80 mg, 120 mg, and 160 mg. In a letter dated August 9, 2011, FDA informed Upsher-Smith that it had concerns about the validity of bioequivalence data submitted with ANDA 078311 from studies conducted by a certain contract research organization, establishing bioequivalence of Upsher-Smith's product to the reference listed drug (RLD), INDERAL LA (propranolol hydrochloride) Extended Release Capsules, 60 mg, 80 mg, 120 mg, and 160 mg. In that letter, FDA directed Upsher-Smith to supplement its ANDA with either: (1) New bioequivalence studies or (2) re-assays of the samples from the original bioequivalence studies. Upsher-Smith submitted new fasted and fed bioequivalence studies to

supplement ANDA 078311 in paper format on August 29, 2013, and in electronic format on May 9, 2014.

On April 14, 2016, FDA informed Upsher-Smith that the applicant's fed bioequivalence study failed to meet FDA's bioequivalence criteria and, therefore, requested that Upsher-Smith voluntarily seek withdrawal of ANDA 078311 under § 314.150(d) (21 CFR 314.150(d)).

In a letter dated May 13, 2016, Upsher-Smith requested that FDA withdraw approval of ANDA 078311 for PROPRANOLOL HYDROCHLORIDE Extended-Release Capsules under § 314.150(d) because the new bioequivalence data did not demonstrate therapeutic equivalence of its product to the RLD, INDERAL LA. In that letter, Upsher-Smith also waived any opportunity for a hearing otherwise provided under § 314.150(a).

Therefore, under section 505(e) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(e)) and § 314.150(d), and under authority delegated by the Commissioner of Food and Drugs to the Director, Center for Drug Evaluation and Research, approval of ANDA 078311, and all amendments and supplements thereto, is withdrawn (see **DATES**). Distribution of this product in 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) and 331(d)).

Dated: August 24, 2017.

**Anna K. Abram,**  
*Deputy Commissioner for Policy, Planning, Legislation, and Analysis.*

[FR Doc. 2017–18375 Filed 8–29–17; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2017–P–1461]

#### Determination That CENESTIN (Estrogens, Conjugated Synthetic A) Tablets, 0.3 Milligrams, 0.45 Milligrams, 0.625 Milligrams, 0.9 Milligrams, and 1.25 Milligrams, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) has determined that CENESTIN (estrogens, conjugated synthetic A) Tablets, 0.3 milligrams (mg), 0.45 mg, 0.625 mg, 0.9