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

mg, and 1.25 mg, were not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for these products, if all other legal and regulatory requirements are met.

**FOR FURTHER INFORMATION CONTACT:** Bronwen Blass, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave. Bldg. 51, Rm. 6228, Silver Spring, MD 20993–0002, 301–796–5092.

**SUPPLEMENTARY INFORMATION:** In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the ''listed drug,'' which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is known generally as the ''Orange Book.'' Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

CENESTIN (estrogens, conjugated synthetic A) Tablets, 0.3 mg, 0.45 mg, 0.625 mg, 0.9 mg, and 1.25 mg, is the subject of NDA 020992, held by Teva Branded Pharmaceutical Products R&D, Inc. (Teva), and was initially approved on March 24, 1999. CENESTIN is indicated for treatment of moderate to severe vasomotor symptoms due to menopause and treatment of moderate to severe symptoms of vulvar and vaginal atrophy due to menopause.

In 2016, Teva notified FDA that CENESTIN (estrogens, conjugated synthetic A) Tablets, 0.3 mg, 0.45 mg, 0.625 mg, 0.9 mg, and 1.25 mg, were being discontinued, and FDA moved the drug product to the ''Discontinued Drug Product List'' section of the Orange Book.

Foley & Lardner submitted a citizen petition dated March 8, 2017 (Docket No. FDA–2017–P–1461), under 21 CFR 10.30, requesting that the Agency determine whether CENESTIN (estrogens, conjugated synthetic A) Tablets, 0.3 mg, 0.45 mg, 0.625 mg, 0.9 mg, and 1.25 mg, were withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that CENESTIN (estrogens, conjugated synthetic A) Tablets, 0.3 mg, 0.45 mg, 0.625 mg, 0.9 mg, and 1.25 mg, were not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that these products were withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of these products from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have found no information that would indicate that these drug products were withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list CENESTIN (estrogens, conjugated synthetic A) Tablets, 0.3 mg, 0.45 mg, 0.625 mg, 0.9 mg, and 1.25 mg, in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to CENESTIN (estrogens, conjugated synthetic A) Tablets, 0.3 mg, 0.45 mg, 0.625 mg, 0.9 mg, and 1.25 mg, may be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: August 24, 2017.

**Anna K. Abram,**

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

[FR Doc. 2017–18376 Filed 8–29–17; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket Nos. FDA–2016–E–1283; FDA–2016–E–1291]**

### Determination of Regulatory Review Period for Purposes of Patent Extension; KENGREAL

**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 KENGREAL 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 (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: