

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