



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 Upsher-Smith has voluntarily requested that approval of this application be withdrawn and has waived its opportunity for a hearing.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: [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

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.

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