4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-N-3966]

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

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 ZALEPLON Capsules, 5 milligrams (mg) and 10 mg, 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 Upsher-Smith has voluntarily requested that approval of this application be withdrawn, and has waived its opportunity for a hearing.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: Effective **[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 June 6, 2008, FDA approved ANDA 078706 for ZALEPLON Capsules, 5 mg and 10 mg, submitted by Upsher-Smith. According to annual reports Upsher-Smith filed with the Agency, Upsher-Smith stopped distributing these products by April 6, 2010. In a letter dated August 9, 2011, FDA informed Upsher-Smith that it had concerns about the validity of bioequivalence data submitted with ANDA 078706 from studies

conducted by a certain contract research organization, establishing bioequivalence of Upsher-Smith's product to the reference listed drug, SONATA (ZALEPLON) Capsules, 5 mg and 10 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 did not respond to this letter. FDA then sent another letter to Upsher-Smith on August 19, 2016, requesting that Upsher-Smith provide the requested bioequivalence data within 30 calendar days or voluntarily seek withdrawal of ANDA 078706 under section 314.150(d) (21 CFR 314.150(d)).

In a letter dated September 15, 2016, Upsher-Smith informed FDA that it did not intend to submit the requested bioequivalence data and requested that the Agency withdraw approval of ANDA 078706 for ZALEPLON Capsules under section 314.150(d). In that letter, Upsher-Smith also waived any opportunity for a hearing otherwise provided under section 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), approval of ANDA 078706, 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 11, 2017.

Anna K. Abram,

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

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