4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2019-N-3839]

Impax Laboratories, LLC; Withdrawal of Approval of an Abbreviated New Drug Application for Ursodiol Capsules USP, 300 Milligrams

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing the approval of abbreviated new drug application (ANDA) 077895 for Ursodiol Capsules USP, 300 milligrams (mg), held by Impax Laboratories, LLC (Impax). Impax requested withdrawal of this application and has waived its opportunity for a hearing.

DATES: Approval is withdrawn as of **[INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

FOR FURTHER INFORMATION CONTACT: Jennifer Forde, Office of Regulatory Policy, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6228, Silver Spring, MD 20993-0002, 301-348-3035.

SUPPLEMENTARY INFORMATION: On July 27, 2006, FDA approved ANDA 077895 for Ursodiol Capsules USP, 300 mg, submitted by CorePharma, LLC (CorePharma). According to annual reports filed with the Agency, this product has not been commercially manufactured since February 2010.

In a letter dated August 9, 2011, FDA informed CorePharma that it had concerns about the validity of bioequivalence data submitted with ANDA 077895 from studies conducted by a

certain contract research organization intended to establish bioequivalence of CorePharma's product to its reference listed drug (RLD), new drug application 019594, Actigall (Ursodiol) Capsules, 300 mg. In that letter, FDA directed CorePharma to supplement its ANDA with either: (1) new bioequivalence studies or (2) re-assays of the samples from the original bioequivalence studies. In a letter dated January 26, 2012, CorePharma submitted a request for an extension of time to submit new bioequivalence data in response to the Agency's August 9, 2011, letter. On February 10, 2012, the Agency granted CorePharma's request for an extension to submit new bioequivalence data by October 30, 2012.

FDA subsequently sent another letter to CorePharma on August 19, 2016, requesting that CorePharma provide the requested bioequivalence data within 30 calendar days or voluntarily seek withdrawal of ANDA 077895 under § 314.150(d) (21 CFR 314.150(d)). In response to the August 19, 2016, correspondence, FDA received a letter from CorePharma dated September 7, 2016, stating that CorePharma did not wish to request the withdrawal of approval of ANDA 077895 for Ursodiol Capsules. In February 2017, the Agency was notified that the ownership of ANDA 077895 was transferred from CorePharma to Impax.

On April 24, 2017, FDA issued a letter to Impax, noting that as of the date of the April 24, 2017, letter, FDA had not received the requested bioequivalence data. In the April 24, 2017, correspondence, FDA strongly suggested to Impax that it voluntarily seek withdrawal of ANDA 077895 under § 314.150(d) as a result of failing to provide data and information establishing bioequivalence to the RLD. In a letter dated February 25, 2019, Impax informed FDA that it would like to request the withdrawal of ANDA 077895 under § 314.150(d). Additionally, in a March 14, 2019, correspondence to FDA, Impax waived any opportunity for hearing provided under § 314.150(a).

In the *Federal Register* of February 5, 2019 (84 FR 1745), FDA erroneously included ANDA 077895 in a list of drug applications for which approval was being withdrawn under § 314.150(c). Elsewhere in this issue of the *Federal Register*, FDA is publishing a correction to that notice to remove ANDA 077895 from the list of applications whose approval was withdrawn under § 314.150(c). In addition, for the reasons discussed above, and because of Impax's request, FDA is withdrawing approval of ANDA 077895, and all amendments and supplements thereto, under § 314.150(d). Distribution of Ursodiol Capsules USP, 300 mg, in interstate commerce without an approved application is illegal and subject to regulatory action (see sections 505(a) and 301(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(a) and 331(d)).

Dated: September 6, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019-19908 Filed: 9/13/2019 8:45 am; Publication Date: 9/16/2019]