4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2019-N-3723]

Watson Laboratories, Inc.; Withdrawal of Approval of an Abbreviated New Drug Application for Oxycodone Hydrochloride and Ibuprofen Tablets

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration's (FDA) Center for Drug Evaluation and Research (CDER) is withdrawing approval of an abbreviated new drug application (ANDA) for oxycodone hydrochloride and ibuprofen tablets. The basis for the withdrawal is that the holder of the ANDA has repeatedly failed to submit the required data to support a finding of bioequivalence for this ANDA. The holder of the ANDA 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DATES: Approval is withdrawn as of [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].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, 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:

FDA's Office of Generic Drugs (OGD) approved ANDA 078394, held by Watson Laboratories, Inc. (Watson),[1] for a generic version of oxycodone hydrochloride and ibuprofen tablets, 5 milligrams (mg)/400 mg, under the requirements of section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(j)) and FDA's implementing regulations. The OGD approved ANDA 078394 on November 26, 2007. In a notice of opportunity for a hearing (NOOH) published in the *Federal Register* of October 28, 2019 (84 FR 57739), CDER notified Watson of CDER's proposal to issue an order, under section 505(e) of the FD&C Act and § 314.150 (21 CFR 314.150), withdrawing approval of ANDA 078394 and all amendments and supplements to it on the grounds that Watson has failed to submit the required bioequivalence data necessary to demonstrate the bioequivalence of its drug product.

As noted in the October 28, 2019, NOOH, FDA issued a letter to Watson on August 9, 2011, regarding ANDA 078394 because this drug product application was supported by bioequivalence studies with the bioanalytical analysis conducted by Cetero Research at the Houston, TX, site between April 1, 2005, and June 15, 2010. As FDA noted in its August 9, 2011 correspondence, inspection findings regarding Cetero Research's bioequivalence studies raised significant concerns about the validity of the reported results of the analytical studies conducted between April 2005 and June 2010 in support of drug applications. Accordingly, FDA informed Watson that ANDA 078394 needed to be supplemented by conducting new bioequivalence studies or re-assaying the samples from the original bioequivalence study. FDA recommended to Watson that the results of the requested bioequivalence studies or re-assays be submitted to ANDA 078394 within 6 months of the date of the August 9, 2011, letter.

[1] In correspondence dated February 23, 2017, Watson notified FDA that Watson is an indirect, wholly-owned subsidiary of Teva Pharmaceuticals USA, Inc.

In its October 28, 2019, notice of opportunity for a hearing, CDER provided Watson with an opportunity to request a hearing to show why approval of ANDA 078394 should not be withdrawn. No request for a hearing on this matter was received following publication of the notice for an opportunity for a hearing in the *Federal Register*. Failure to file a written notice of participation and request for a hearing as required by § 314.200 (21 CFR 314.200) constitutes an election by Watson not to make use of the opportunity for a hearing concerning the proposal to withdraw approval of ANDA 078394 and a waiver of any contentions concerning the legal status of the drug product. We note that in correspondence dated November 1, 2019, Watson requested withdrawal of the approval of ANDA 078394 under § 314.150(c) (21 CFR 314.150(c)). Because this application withdrawal is effectuated through the notice-of-opportunity-for-a-hearing process (see 84 FR 57739), Watson's request to withdraw approval under § 314.150(c) is moot.

FDA finds that Watson has repeatedly failed to submit the required data to support a finding of bioequivalence for ANDA 078394. In addition, under § 314.200, FDA finds that Watson has waived any contentions concerning the legal status of the drug product. Therefore, under section 505(e) of the FD&C Act, approval of ANDA 078394, and all amendments and supplements thereto, is withdrawn (see DATES). Introduction or delivery for introduction of this drug product into 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), 331(d))).

Dated: July 28, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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