4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0233]

Impax Laboratories, Inc.; Withdrawal of Approval of Bupropion Hydrochloride Extended-Release Tablets, 300 Milligrams

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of Bupropion Hydrochloride (HCl) Extended-Release Tablets, 300 Milligrams (mg) (Bupropion HCl Extended-Release Tablets 300 mg), under Abbreviated New Drug Application (ANDA) 77-415, held by Impax Laboratories, Inc. (Impax), 30831 Huntwood Ave., Hayward, CA 94544, and marketed under the name BUDEPRION XL. Impax has voluntarily requested that approval for this product be withdrawn and waived its opportunity for a hearing.

DATES: Effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER.]

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION: FDA approved ANDA 77-415 for Bupropion HCl Extended-Release Tablets 300 mg (marketed under the name BUDEPRION XL) on December 15, 2006 pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(j)). Bupropion HCl Extended-Release Tablets 300 mg was indicated for the treatment of major depressive disorder. On September 27, 2012, FDA requested that Impax voluntarily withdraw its Bupropion HCl Extended-Release Tablets 300 mg from the market after results of an FDA-sponsored bioequivalence study showed that Impax's Bupropion HCl Extended-Release Tablets 300 mg are not therapeutically equivalent to the 300-mg strength of the reference listed drug. In a letter dated September 30, 2012, Impax requested that FDA withdraw approval of the 300-mg strength of Bupropion HCl Extended Release Tablets, approved under ANDA 77-415, pursuant to § 314.150(d) (21 CFR 314.150(d)). In that letter, Impax also waived its opportunity for a hearing. The Agency acknowledged Impax's requests in a letter dated November 2, 2012.

Therefore, under section 505(e) of the FD&C Act (21 U.S.C. 355(e)) and § 314.150(d), and under authority delegated by the Commissioner to the Director, Center for Drug Evaluation and Research, approval of the 300-mg strength of Bupropion HCl Extended-Release Tablets under ANDA 77-415 is withdrawn (see DATES).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: March 12, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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