



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-0252]

Watson 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 (ER) Tablets, 300 Milligrams (mg) (Bupropion HCl ER Tablets, 300 mg), under abbreviated new drug application (ANDA) 77-715, held by Watson Laboratories, Inc. (Watson), 4955 Orange Dr., Fort Lauderdale, FL 33314. Watson has voluntarily requested that approval for this product be withdrawn and waived its opportunity for a hearing.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: Carolina M. Wirth, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6282, Silver Spring, MD 20993-0002, 301-796-3602.

SUPPLEMENTARY INFORMATION: FDA approved ANDA 77-715 for Bupropion HCl ER Tablets, 300 mg on June 13, 2007, under section 505(j) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 355(j)). Bupropion HCl ER Tablets, 300 mg was indicated for the treatment of major depressive disorder. On September 24, 2013, FDA requested that Watson voluntarily withdraw its Bupropion HCl ER Tablets, 300 mg from the market after results of a

bioequivalence study conducted by Watson showed that the firm's Bupropion HCl ER Tablets, 300 mg are not therapeutically equivalent to the 300-mg strength of the reference listed drug. In a letter dated September 30, 2013, Watson requested that FDA withdraw approval of the 300-mg strength of Bupropion HCl ER Tablets, approved under ANDA 77-715, under § 314.150(d) (21 CFR 314.150(d)). In that letter, Watson also waived its opportunity for a hearing. The Agency acknowledged Watson's requests in a letter dated October 4, 2013.

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Evaluation and Research, approval of the 300-mg strength of Bupropion HCl Extended-Release Tablets under ANDA 77-715 is withdrawn (see DATES).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: April 3, 2014.

Leslie Kux,

Assistant Commissioner for Policy.