FDA Approves First Generic Bupropion Hydrochloride Extended-Release Tablets

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[摘要] December 14, 2006. The U. S. Food and Drug Administeration (FDA) today approved the first generic version of Wellbutrin XL (Bupropion hydrochloride) Extended-Release Tablets, which are indicated for the treatment of major depressive disorder (MDD). The approval is an important step in the agency's effort to increase the availability of lower-cost generic medications. In 2005, Wellbutrin XL was the 21st highest-selling brand-name drug in the United States, with sales totaling $1,326,323,000 as reported in the online magazine Drug Topics.
[关键词] Hydrochloride;Generic;Tablets

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"This approval is another example of our agency's efforts to increase access to safe and effective generic alternatives as soon as the law permits," said Gary J. Buehler, Director, Office of Generic Drugs. "Bupropion hydrochloride is a widely used antidepressant, and its generic version can bring significant savings to the millions of Americans with depression."

The economic benefits of FDA's generic drug approval program are significant because generic drug products, which are used to fill over 50 percent of all prescriptions, frequently cost a fraction of the price of the brand-name drugs. The Office of Generic Drugs reviews and takes action on generic drug applications, and the same thorough and rigorously scientific review standards of safety, efficacy and quality are applied to generic drug applications as are applied to new drug application. Consumers and health professionals can be assured that an approved generic drug is bioequivalent to a brand name drug and is its equal in dosage form,

FDA received a citizen petition (a formal request for FDA action) that asked FDA to consider several issues for bupropion hydrochloride extended-release tablets, including how similarly the drug is absorbed into the bloodstream. After reviewing the issues raised in the petition, FDA determined that its standards for approval of the generic drug application for bupropion are appropriate.

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