

FDA Approves First Generic Venlafaxine

The Food and Drug Administration today approved the first generic version of Effexor (venlafaxine), an important step in the agency's effort to increase the availability of lower-cost generic medications. Venlafaxine is indicated for the treatment of major depressive disorder (MDD).

"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. "Venlafaxine is a widely used antidepressant, and its generic version can bring significant savings to the millions of Americans diagnosed with MDD."

The economic benefits of FDA's generic drug approval program are significant because generic drug products are used to fill over 50 percent of all prescriptions and can cost a fraction of the price of the brand name drugs. Competition from generic drugs that are safe and effective alternatives may quickly lead to reductions in spending. The savings would likely increase as more competitors enter the market. (See http://www.fda.gov/cder/ogd/generic_competition.htm).

Venlafaxine Tablets 25 mg, 37.5 mg, 50 mg, 75 mg and 100 mg are manufactured by TEVA Pharmaceuticals USA (TEVA) in North Wales, PA. This product will carry the same labeling including the black box warning as the originator drug. TEVA is eligible for 180 days of generic drug exclusivity. The FDA may approve other applications after the exclusivity period has expired.

The Office of Generic Drugs continues working expeditiously to review and take action on generic drug applications as quickly as possible. For more information on other first generic versions, please see <http://www.fda.gov/cder/ogd/approvals/1stgen0506.htm>

For additional information related to FDA's Office of Generic Drugs, please go to: http://www.fda.gov/cder/consumerinfo/generic_equivalence.htm