US says Teva antidepressant is ineffective

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(AP)—Teva Pharmaceuticals has stopped shipping its generic version of a popular antidepressant off the market after a U.S. government analysis showed the pill does not work properly.

The Food and Drug Administration said Wednesday it asked Teva to withdraw Budeprion XL 300 after new testing showed the drug releases its key ingredient faster than the original drug Wellbutrin XL 300, made by GlaxoSmithKline.

A spokeswoman for Teva said the company stopped shipping the drug last Thursday.

The action contradicts the FDA's previous update on the issue in 2008, when regulators said the drugs are essentially the same. That review came after hundreds of patients complained that Teva's drug did not work as well or caused side effects like headaches, anxiety and insomnia.

In 2007, the website ConsumerLab published an analysis of the two drugs, indicating Budeprion XL released 34 percent of its active ingredient in just two hours, compared to 8 percent for the original drug. ConsumerLab is a small privately-held company that independently teswsts drugs and nutrition products.

"We're proud we were able to help uncover this problem, but it's unfortunate that it's taken the FDA five years to get the product removed," said Dr. Tod Cooperman, president of ConsumerLab. "I believe the majority of generics are fine but there are certainly situations

where some aren't equivalent."

Generic drugs approved by the FDA are required to be chemically equivalent to the original products, producing the same medical effects in patients.

The FDA said Wednesday that its initial, incorrect ruling was based on tests of the 150 milligram version of Budeprion, under the assumption those results would also apply to the 300 milligram version. The agency said that approach "is no longer appropriate."

"Based on the information we had available at that time we concluded that the 150 milligram strength was doing what it should, and that it was acceptable to extrapolate those findings to the 300 milligram strength" said Barbara Davit, director of bioequivalence for FDA's office of generic drugs. Agency officials said they decided to perform their own study after continuing to receive complaints about Budeprion XL 300.

The FDA said it completed its study of the two drugs in 24 adult patients in August, and notified Teva of the findings last month.

"The role of patients and health care professionals in sharing their experiences with generic versions of Wellbutrin XL 300 mg contributed to further studies, which led to this action," said Dr. Gregory Geba, the FDA's director for generic drug.

Wellbutrin, known chemically as buprion, is prescribed to treat depression, anxiety and symptoms of nicotine withdrawal.

The FDA approved the first generic versions of Wellbutrin XL in 2006. Most doctors switch patients from branded drugs to cheaper generic versions when they become available, since generic drugs can cost between 30 to 80 percent less.

Budeprion XL is a once-a-day pill made by U.S.-based Impax Laboratories Inc. and sold by Israel-based Teva Pharmaceutical Industries Ltd.

"FDA's guidance affects the bioequivalence rating of the product and does not reflect any safety issue," said Denise Bradley. "Teva's first priority is to our patients and providing them with quality medicines."

Four other generic drugmakers market 300 milligram versions of Wellbutrin: Anchen, Actavis, Watson and Mylan. The FDA has not tested the equivalence of those drugs, but said it has requested the drugmakers conduct their own studies and submit them to the agency by March 2013.

FDA officials said patients taking the 300 milligram dose of Budepion account for just 2 percent of the U.S. market for the drug.