

Product Withdrawals

Generic Name (Trade Name—Company)

October 5, 2012

Bupropion extended-release

(Budeprion XL—Impax Laboratories, Teva)

Product fails to demonstrate therapeutic equivalence

Uses/Notes

[FDA has released an update](#) reporting that Budeprion XL 300 mg is not therapeutically equivalent to GlaxoSmithKline's [Wellbutrin XL](#) 300 mg. This update is based on data from an agency-sponsored study which concluded that Budeprion XL 300 mg tablets failed to release bupropion into the blood at the same rate and to the same extent as the branded product. FDA conducted this study in response to numerous reports that patients who switched from Wellbutrin XL 300 mg to the generic product were experiencing reduced efficacy.

Based on these data, Impax has requested that the FDA withdraw approval of Budeprion XL 300 mg extended-release tablets and has stopped shipping the product. In addition, it has issued detailed information to patients about this product withdrawal. This update does not apply to the 150-mg dose of Budeprion XL or to the other four generic bupropion extended-release products made by other manufacturers.

FDA noted that it has not conducted bioequivalence studies of the other four generic versions of Wellbutrin XL 300 mg, but has recently asked each of the other manufacturers—Anchen, Actavis, Watson, and Mylan—to conduct their own studies to assess the bioequivalence of their 300-mg extended-release bupropion tablets to Wellbutrin XL 300 mg. Data from these studies are to be submitted to the agency no later than March 2013.

Patients taking Budeprion XL 300 mg as a substitute for Wellbutrin XL 300 mg should talk with their health provider if they have questions about taking this medication, the agency advised.

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