

## Medication Safety Alert

**MEDICATIONS:** Zyban<sup>®</sup> and Wellbutrin<sup>®</sup>

**DOSAGE FORMS:** Tablets

**ISSUE:** On July 1, 2009, GlaxoSmithKline<sup>®</sup>, the manufacturer of Zyban (bupropion hydrochloride) and Wellbutrin (bupropion hydrochloride), made revisions to the black-box warnings in the prescribing information for these products. These revisions warn of the risk of serious neuropsychiatric symptoms, which include changes in behavior, hostility, agitation, depressed mood, suicidal thoughts and behavior and attempted suicide.

The added warnings are based on the continued review of post-marketing adverse event reports received by the FDA. These reports include those with a temporal relationship between the use of Zyban and suicidal events and the occurrence of suicidal ideation and suicidal behavior in patients with no history of psychiatric disease.

Health care professionals should advise patients to stop taking Zyban or Wellbutrin and contact a health care provider immediately if they experience agitation, depressed mood or any changes in behavior that are not typical of nicotine withdrawal, or if they experience suicidal thoughts or behavior. The verbiage that was added to the black-box warning suggests doctors take the following action:

Advise patients and caregivers that the patient should stop taking bupropion hydrochloride and contact a health care provider immediately if agitation, hostility, depressed mood or changes in thinking or behavior that are not typical for the patient are observed, or if the patient develops suicidal ideation or suicidal behavior.

More information regarding this issue is available at:  
[www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm170090.htm](http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm170090.htm)