

SPINE SAFETY CAUTIONARY NOTICE:

**Information for Healthcare Professionals:
Drug Safety Labeling Changes -
Wellbutrin (bupropion hydrochloride) Tablets and Sustained-Release Tablets**

According to MedWatch, FDA notified healthcare professionals that BOXED WARNINGS, WARNINGS, PRECAUTIONS and MEDICATION GUIDE text for Wellbutrin (bupropion hydrochloride) tablets and sustained-release tablets have been updated to address neuropsychiatric symptoms and suicide risk in smoking cessation treatment.

The revised BOXED WARNING indicates the following:

- All patients being treated with bupropion for smoking cessation treatment should be observed for neuropsychiatric symptoms including changes in behavior, hostility, agitation, depressed mood, and suicide-related events, including ideation, behavior, and attempted suicide. These symptoms, as well as worsening of pre-existing psychiatric illness and completed suicide have been reported in some patients attempting to quit smoking while taking Zyban in the postmarketing experience. When symptoms were reported, most were during treatment with Zyban, but some were following discontinuation of treatment with Zyban.
- In many postmarketing cases, resolution of symptoms after discontinuation of Zyban was reported, although in some cases the symptoms persisted; therefore, ongoing monitoring and supportive care should be provided until symptoms resolve.

Read the complete summary of MedWatch safety labeling changes at:

<http://www.fda.gov/Safety/MedWatch/SafetyInformation/ucm176817.htm>

The North American Spine Society is committed to quality patient care through promotion of patient safety and prevention of medical errors. NASS monitors a variety of government and other resources for patient safety related notices that may be useful to our members. Information from these notices is also archived on the NASS website at <http://www.spine.org/Pages/PracticePolicy/ClinicalCare/SpineSafetyAlerts/Default.aspx>. This information is provided as a service for information and education only.