



NDA 021515/S-028

**SUPPLEMENTAL APPROVAL  
RELEASE REMS REQUIREMENT**

Valeant Pharmaceuticals North America  
Madhu Anant, M.Sc., Ph.D., RAC  
Senior Director, Regulatory Affairs  
700 US Rt. 202/206 N  
Bridgewater, NJ 08807

Dear Dr. Madhu:

Please refer to your Supplemental New Drug Application (sNDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Wellbutrin XL (bupropion hydrochloride) 150 mg and 300 mg Extended-Release Tablets (S-028), dated and received September 1, 2011.

This supplemental new drug application provides for your risk evaluation and mitigations strategy (REMS) assessment as well as proposes to eliminate the requirement for the approved Wellbutrin XL REMS.

We have completed our review of this supplemental application. It is approved, effective on the date of this letter.

**RISK EVALUATION AND MITIGATION STRATEGY REQUIREMENTS**

This supplemental new drug application proposes to eliminate the requirement for the approved Wellbutrin XL risk evaluation and mitigation strategy (REMS). The REMS for Wellbutrin XL was originally approved on February 26, 2010. The REMS consists of a Medication Guide and a timetable for submission of assessments of the REMS.

We have determined that maintaining the Medication Guide as part of the approved labeling is adequate to address the serious and significant public health concern and meets the standard in 21 CFR 208.1. Therefore, it is no longer necessary to include the Medication Guide as an element of the approved REMS to ensure that the benefits of Wellbutrin XL outweigh its risks.

If you have any questions, email Juliette Touré, PharmD, Senior Regulatory Project Manager, at [Juliette.Toure@fda.hhs.gov](mailto:Juliette.Toure@fda.hhs.gov).

Sincerely,

*{See appended electronic signature page}*

Thomas Laughren, M.D.  
Director  
Division of Psychiatry Products  
Office of Drug Evaluation I  
Center for Drug Evaluation and Research

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**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**  
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/s/  
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THOMAS P LAUGHREN  
08/02/2012