



NDA 022108/S-002

**SUPPLEMENTAL APPROVAL
RELEASE REMS REQUIREMENT**

Valeant International (Barbados) SRL
c/o John B. Dubeck, U.S. Agent
Keller and Heckman
1001 G Street, NW, Suite 500 West
Washington, DC 20001

Dear Mr. Dubeck:

Please refer to your Supplemental New Drug Application (sNDA) dated December 8 2009, received December 9, 2009, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Aplenzin (bupropion hydrobromide) Extended-Release Tablets 174mg, 348mg, and 522mg.

We acknowledge receipt of your amendments dated July 2, 2010, September 1, 2010, April 8, 2011, and April 21, 2011.

This supplemental new drug application proposes to eliminate the requirement for the approved Aplenzin risk evaluation and mitigation strategy (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

The REMS for Aplenzin (bupropion hydrobromide) was originally approved on April 23, 2008. The REMS consists of a Medication Guide and a timetable for submission of assessments of the REMS.

You propose that FDA no longer require a REMS for Aplenzin (bupropion hydrobromide).

We have determined that it is no longer necessary to include the Medication Guide as an element of the approved REMS, and that a REMS is no longer necessary to ensure that the benefits of Aplenzin (bupropion hydrobromide) outweigh its risks. Therefore, we agree with your proposal and a REMS is no longer required.

We remind you that the Medication Guide will continue to be part of the approved labeling in accordance with 21 CFR 208.

If you have any questions, email Juliette Touré, PharmD, Senior Regulatory Project Manager, at 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

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

THOMAS P LAUGHREN
04/29/2011