DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 22108/S-012

SUPPLEMENT APPROVAL

Valeant Pharmaceuticals North America LLC
Attention: Libette Luce, MA
Director, Regulatory Affairs
400 Somerset Corporate Center
Bridgewater, NJ 08807

Dear Ms. Luce:

Please refer to your Supplemental New Drug Application (sNDA) dated and received, August 12, 2016 submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Aplenzin (bupropion hydrobromide) Extended Release Tablets.

This "Changes Being Effected" supplemental new drug application provides for the addition of the following statement in Section 9.2 Abuse – Humans:

Bupropion hydrobromide extended-release tablets are intended for oral use only. The inhalation of crushed tablets or injection of dissolved bupropion has been reported. Seizures and/or cases of death have been reported when bupropion has been administered intranasally or by parenteral injection.

We have completed our review of this supplemental application, and it is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, email Steven D. Hardeman, R.Ph., Chief, Project Management Staff, at Steven.Hardeman@FDA.GOV.

Sincerely,

{See appended electronic signature page}

Mitchell V. Mathis, M.D.
Director
Division of Psychiatry Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

ENCLOSURE(S):
Content of Labeling

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

/s/

STEVEN D HARDEMAN
08/30/2016

MITCHELL V Mathis
08/30/2016