DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 021515/S-029/S-030
NDA 022108/ S-009

SUPPLEMENT APPROVAL

Valeant Pharmaceuticals North America, LLC
Isabelle B. Lefebvre, MSc. RA, RAC
Director, Branded Rx & Gx Products Portfolio
US Regulatory Affairs
400 Somerset Corporate Blvd
Bridgewater, NJ 08807

Dear Ms. Lefebvre:

Please refer to the following "Prior Approval" labeling Supplemental New Drug Applications (sNDA), submitted under section 505(b) and 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA):

- NDA 021515/S-029 – dated and received, August 1, 2012, Wellbutrin XL (bupropion Hydrochloride Extended-Release) 150 mg and 300 mg Tablets, that provides for labeling revisions to the CONTRAINDICATIONS, WARNINGS, DOSAGE AND ADMINISTRATION, describing the increased risk of hypertensive reactions when bupropion is used concomitantly with other drugs that inhibit the reuptake of dopamine or norepinephrine or inhibit their metabolism (e.g., MAOIs).

- NDA 021515/S-030 – dated and received February 12, 2013, Wellbutrin XL (bupropion Hydrochloride Extended-Release) 150 mg and 300 mg Tablets, that provides for the conversion of labeling to the Physician Labeling Rule (PLR) format, and

- NDA 022108/S-009 – dated and received July 31, 2012, Aplenzin (bupropion Hydrobromide Extended-Release) 174 mg, 348 mg, and 522 mg Tablets, that provides for labeling revisions to the CONTRAINDICATIONS, WARNINGS, DOSAGE AND ADMINISTRATION, describing the increased risk of hypertensive reactions when bupropion is used concomitantly with other drugs that inhibit the reuptake of dopamine or norepinephrine or inhibit their metabolism (e.g., MAOIs).

We acknowledge receipt of your amendments dated August 24, 2012, February 27, 2013, March 24, 2014, April 14, 2014, and May 29, 2014.

For NDA 21515 / S-029 / S-030, the March 24, 2014 submission constituted a complete response to our December 24, 2013, action letter.

For NDA 22108 / S-009, the April 14, 2014 submission constituted a complete response to our December 24, 2013, action letter.

APPROVAL & LABELING

We have completed our review of these supplemental applications, as amended. They are approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

WAIVER OF HIGHLIGHTS SECTION – NDA 21515/S-029/S-030

We are waiving the requirements of 21 CFR 201.57(d)(8) regarding the length of Highlights of prescribing information. This waiver applies to all future supplements containing revised labeling unless we notify you otherwise.

WAIVER OF HIGHLIGHTS SECTION – NDA 22108/S-009

Please note that we have previously granted a waiver of the requirements of 21 CFR 201.57(d)(8) regarding the length of Highlights of prescribing information.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling (text for the package insert and Medication Guide), with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eList may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that includes labeling changes for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy

should provide appropriate annotations, including supplement number(s) and annual report date(s).

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, contact CDR Kofi Ansah, Pharm.D., Senior Regulatory Project Manager, at (301)796-4158 or email: Kofi.Ansah@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

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

ENCLOSURE:
Content of Labeling (Full Prescribing Information and Medication Guide)

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

/s/

MITCHELL V Mathis
12/30/2014