



NDA 021515/S-036  
NDA 022108/S-014

**SUPPLEMENT APPROVAL**

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

Dear Ms. Luce:

Please refer to your Supplemental New Drug Applications (sNDA) dated January 16, 2017, received January 17, 2017, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Wellbutrin XL (bupropion hydrochloride) extended-release tablets 150 mg and 300 mg (NDA 021515) and Aplenzin (bupropion hydrobromide) extended-release tablets 174 mg, 348 mg, 522 mg (NDA 022108).

We also refer to our letter dated December 16, 2016, requesting you to submit a Prior Approval Supplement with revisions to the Highlights, Boxed Warnings, Warnings and Precautions, Patient Counseling, and Medication Guide based upon the results of Post Marketing Requirement 1630-1.

These Prior Approval supplement new drug applications provide for revisions to the labeling for Wellbutrin XL and Aplenzin consistent with our December 16, 2016, supplement request letter.

**APPROVAL & LABELING**

We have completed our review of these supplemental applications. 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**

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, 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 include 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 these supplemental applications, 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).

### **REQUIRED PEDIATRIC ASSESSMENTS**

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because none of these criteria apply to your application, you are exempt from this requirement.

### **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 CAPT Kofi Ansah, Pharm.D., RAC, Senior Regulatory Project Manager, at (301)796-4158 or email: [Kofi.Ansah@fda.hhs.gov](mailto:Kofi.Ansah@fda.hhs.gov).

Sincerely,

*{See appended electronic signature page}*

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

ENCLOSURE:  
Content of Labeling

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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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MITCHELL V Mathis  
05/04/2017