



NDA 21894/S-013

SUPPLEMENT APPROVAL

Valeant Pharmaceuticals North America, LLC
Attention: Jennifer S. Knicley, MS
Senior Manager, Regulatory Affairs
400 Somerset Corporate Blvd.
Bridgewater, New Jersey 08807

Dear Ms. Lefebvre:

Please refer to your Supplemental New Drug Application (sNDA) dated March 13, 2017, received March 13, 2017, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Xenazine (tetrabenazine) Tablets.

This Prior Approval supplemental new drug application addresses the June 5, 2014, Fulfillment of Postmarketing Requirements Letter regarding the assessment of the 9-desmethyl- β -DHTBZ metabolite (1790-1, 1790-2 and 1790-3). It also provides for the addition of results of the completed embryo-fetal development study (1790-8), requested by the Division in the May 12, 2015, Fulfillment of Postmarketing Requirement/Prior Approval Supplement Request Letter. In addition, this supplement includes changes related to other completed nonclinical studies which were conducted as postmarketing requirements and also proposes changes in compliance with the Agency's Pregnancy and Lactation Labeling Rule (PLLR).

APPROVAL & LABELING

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

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 Effectuated" (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 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, call Stacy Metz, PharmD, Senior Regulatory Project Manager, at (301) 796-2139.

Sincerely,

{See appended electronic signature page}

Eric Bastings, MD
Deputy Director
Division of Neurology 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/

ERIC P BASTINGS
09/13/2017