DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 021894/S-012

SUPPLEMENT APPROVAL

Valeant International Bermuda
C/O Valeant Pharmaceuticals North America LLC
Attention: Isabelle Lefebvre
Director, Branded Rx & Gx Products Portfolio
US Regulatory Affairs
400 Somerset Corporate Blvd.
Bridgewater, New Jersey 08807

Dear Ms. Lefebvre:

Please refer to your Supplemental New Drug Application (sNDA) dated and received August 24, 2015, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Xenazine (tetrabenazine) tablets, 12.5 mg and 25 mg.

This prior approval sNDA proposes to eliminate the requirement for the approved risk evaluation and mitigation strategy (REMS) for Xenazine. This supplement is in response to our August 21, 2015, REMS Modification Notification letter.

We have completed our review of this supplemental application and it is approved, effective on the date of this letter.

RISK EVALUATION AND MITIGATION STRATEGY REQUIREMENTS

The REMS for Xenazine (tetrabenazine) was originally approved on August 15, 2008, and the most recent REMS modification was approved on August 2, 2013. The approved REMS consists of a communication plan and a timetable for submission of assessments of the REMS.

In order to minimize burden on the healthcare delivery system of complying with the REMS, we determined that you were required to make the following REMS modification: propose to eliminate the requirement for the REMS. Because the communication plan has been completed and the most recent assessment, submitted to the Agency on November 13, 2014, demonstrates that the communication plan has met its goals, we have determined that it is no longer necessary to include it as an element of the approved REMS to ensure that the benefits of the drug outweigh the risks.

Therefore, because the communication plan is no longer necessary to ensure the benefits of the drug outweigh the risks, a REMS is no longer required for Xenazine (tetrabenazine).

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, Regulatory Project Manager, at (301) 796-2139.

Sincerely,

{See appended electronic signature page}

Alice Hughes, MD
Deputy Director for Safety
Division of Neurology 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/

ALICE HUGHES
08/25/2015