DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 020697/S-004

SUPPLEMENT APPROVAL

Valeant Pharmaceuticals North America LLC
Attention: Elizabeth L. Tan, PhD
Director, Regulatory Affairs
700 Route 202/206 North
Bridgewater, New Jersey 08807

Dear Ms. Tan:

Please refer to your Supplemental New Drug Application (sNDA) dated August 20, 1999, received August 23, 1999, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Tasmar (tolcapone) 100 mg Tablets.

We acknowledge receipt of your amendments dated April 11, 2006, and April 23, 2012. The April 11, 2006, submission constituted a complete response to our December 19, 2002, action letter.

This "Prior Approval" supplemental new drug application provides for a new labeling subsection, Geriatric Use, as stated in the August 27, 1997, Federal Register final rule. In addition, we note that drugs that have an effect on central dopaminergic activity may lead to certain side effects, which warrant a detailed description in the Prescribing Information. Therefore, to be consistent and thorough, class language has been added to the Tasmar labeling which includes the following: Warnings-Patients Falling Asleep During Activities of Daily Living and Precautions-Hallucinations/Psychotic Like Behavior and Impulse Control/ Compulsive Behaviors. Furthermore, because the manufacture of the 200 mg strength tablet has been discontinued, reference to the 200 mg tablet has been removed from the Prescribing Information.

We have completed our review of this supplemental application, as amended. 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), 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 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).

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, call Tracy Peters, Regulatory Project Manager, at (301) 796-2953.

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
05/11/2013