DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-697/S-012

Valeant Pharmaceuticals International
Attention: Arthur Rosenthal
Sr. Director, Corporate Regulatory Affairs
One Enterprise
Aliso Viejo, CA 92656

Dear Mr. Rosenthal:

Please refer to your new drug application submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Tasmar (tolcapone) 100 mg and 200 mg Tablets.

We also refer to your supplemental application dated September 14, 2006, received September 15, 2006, and your amendment dated December 7, 2006, received December 11, 2006.

This supplemental application provides for changing the current patient consent form to a patient acknowledgement of risks form, and provides for associated revisions to labeling.

We have completed our review of S-012, as amended. This supplement, S-012, is approved effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert) which was submitted December 7, 2006.

Please submit an electronic version of the FPL according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format - NDA. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this/these submission "FPL for approved supplement NDA 20-697/S-012" Approval of this submission by FDA is not required before the labeling is used.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH
Food and Drug Administration
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

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 CDR Teresa Wheelous, Sr. Regulatory Project Manager, at (301) 796-1161.

Sincerely,

{See appended electronic signature page}

Russell Katz, M.D.
Director
Division of Neurology Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

Enclosure

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

/s/

Russell Katz

1/24/2007 01:02:27 PM