



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville, MD 20857

NDA 20-697 /S010

VALEANT Pharmaceuticals International  
Attention: Arthur L. Rosenthal  
Vice President, Regulatory Affairs  
3300 Hyland Avenue  
Costa Mesa, CA 92626

Dear Mr. Rosenthal:

Please refer to your supplemental new drug application dated May 19, 2005, received May 20, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Tasmart (tolcapone) 100mg and 200 mg Tablets.

We acknowledge receipt of your draft labeling provided in a February 16, 2006, email communication to Dr. John Feeney.

This supplemental new drug application provides for labeling revisions throughout regarding changes to liver function testing.

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

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 submission "**FPL for approved supplement NDA 20-697/S-010.**" 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  
WO 22, Room 4447  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002

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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 question, call CDR Teresa Wheelous, Sr. Regulatory Project Manager, at (301) 796-2250.

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

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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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Russell Katz  
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