DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring MD 20993

NDA 20-697/S-016

Valeant Pharmaceuticals International
Attention: Susan T. Hall, Ph.D., Senior Vice President
Global Regulatory Sciences and Compliance
One Enterprise
AlisoViejo, CA 92656

Dear Ms. Hall:

Please refer to your supplemental new drug application dated December 24, 2008, received December 31, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Tasmar® (tolcapone) Tablets, 100 mg.

This "Changes Being Effected in 30 days" supplemental new drug application provides for the following changes:

- a change in the manufacturing site from Hoffman-La Roche Inc. (Nutley, New Jersey) to Legacy Pharmaceuticals Puerto Rico LLC (Humacao, Puerto Rico)
- a change in physical appearance of the drug product logo (imprint to deboss)
- updated label/labeling to reflect the physical appearance and manufacturing site change
- alternate testing site for the Specific Surface Area Test for the drug substance
- an alternate testing site for the Assay test for the excipient, (b) (4)
- a change in the number of units for the physician samples packaging configuration from 15-ct to 21-ct tablets
- a 36 month expiry for drug product manufactured by Legacy Pharmaceuticals Puerto Rico LLC

We completed our review of this supplemental new drug application. This supplement is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that should incorporate changes made in S-013 and S-015 into S-016. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission, "**SPL for approved NDA20-697/S-016**."

CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed carton and container labels that are identical to the enclosed carton and immediate container labels as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (October 2005)*. Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Final Printed Carton and Container Labels for approved NDA 20-697/S-016**." Approval of this submission by FDA is not required before the labeling is used.

Marketing the product(s) with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Teshara Bouie, Regulatory Project Manager, at (301) 796-1649.

Sincerely,

{See appended electronic signature page}

James D. Vidra, Ph.D.
Branch Chief
Branch VII, Division of Post-Marketing Evaluation
Office of New Drug Quality Assessment
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/

Jim Vidra

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