DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-479/S-003
NDA 21-479/S-004

**PRIOR APPROVAL SUPPLEMENT**

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

Dear Mr. Rosenthal:

Please refer to your New Drug Application (NDA) as well as your supplemental new drug application dated May 17, 2007, and received February 1, 2008 (supplement 4), submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Zelapar® (selegiline hydrochloride) Orally Disintegrating Tablets.

Supplement 3 provides for the addition of information regarding intense urges to gamble, increased sexual urges, and other intense urges in patients using medications to treat Parkinson's disease. Supplement 4 provides for the addition of information regarding melanoma to the PRECAUTIONS section of the package insert.

We also refer to the letter dated January 30, 2008, to the Division of Neurology Products, in which you agreed to add the following text to the Information for Patients subsection of the PRECAUTIONS section:

> "There have been reports of patients experiencing intense urges to gamble, increased sexual urges, and other intense urges and the inability to control these urges while taking one or more of the medications that increase central dopaminergic tone, that are generally used for the treatment of Parkinson's disease, including Zelapar. Although it is not proven that the medications caused these events, these urges were reported to have stopped in some cases when the dose was reduced or the medication was stopped. Prescribers should ask patients about the development of new or increased gambling urges, sexual urges or other urges while being treated with Zelapar. Patients should inform their physician if they experience new or increased gambling urges, increased sexual urges or other intense urges while taking Zelapar. Physicians should consider dose reduction or stopping the medication if a patient develops such urges while taking Zelapar."

We completed our review of these applications and they are 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 submissions "**FPL for approved supplement NDA 21-479/S-003 and S-004**." 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 Beverly Conner, PharmD, Regulatory Project Manager, at (301) 796-1171.

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: labeling

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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

12/31/2008 08:18:08 AM