DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 17830/S-014, S-016, S-017, S-018, S-019 and S-030

**SUPPLEMENT APPROVAL**

Valeant Pharmaceuticals North America, LLC
Attention: Elizabeth L. Tan, Ph.D.
Director, Regulatory Affairs
700 US Rt. 202/206 North
Bridgewater, NJ 08807

Dear Dr. Tan:

Please refer to your following Supplemental New Drug Applications (sNDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Lodosyn (carbidopa) Tablets:

| SUPPLEMENT TYPE/ NUMBER | DATE OF SUBMISSION | DATE OF RECEIPT | PROVISIONS |
|---|---|---|---|
| Changes Being Effected S-014 | November 5, 2003 | November 12, 2003 | Response to 12/18/02, Approvable letter. Editorial changes to PRECAUTIONS & ADVERSE REACTIONS sections. Adds malignant melanoma to ADVERSE REACTIONS |
| Changes Being Effected S-016 | November 5, 2003 | November 12, 2003 | Response to 12/18/02, Approvable letter. Extensive changes to achieve consistency with Sinemet & Sinemet CR label. |

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| Changes Being Effected S-017 | November 5, 2003 | November 12, 2003 | Response to 12/18/02, Approvable letter. Changes to the DESCRIPTION, CONTRAINDICATIONS, PRECAUTIONS, ADVERSE REACTIONS, and HOW SUPPLIED sections of labeling. |
| Changes Being Effected S-018 | November 5, 2003 | November 12, 2003 | Response to 12/18/02, Approvable letter. Changes to the following sections of labeling CLINICAL PHARMACOLOGY, CONTRAINDICATIONS, WARNINGS, PRECAUTIONS, ADVERSE REACTIONS, DOSAGE AND ADMINISTRATION, and change in logo. |
| Changes Being Effected S-019 | November 5, 2003 | November 12, 2003 | Response to 12/18/02, Approvable letter. Changes to strengthen the ADVERSE REACTIONS section of labeling (adding bullous lesions and increased libido as adverse reactions). |
| Changes Being Effected S-030 | January 5, 2007 | January 8, 2007 | Changes to PRECAUTIONS: Nursing Mothers |

## APPROVAL & LABELING

We have completed our review of this supplemental application. 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 that includes labeling changes 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).

## PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit the following, in triplicate, (1) a cover letter requesting advisory comments, (2) the proposed materials in draft or mock-up form with annotated references, and (3) the package insert(s) to:

Food and Drug Administration
Center for Drug Evaluation and Research
Office of Prescription Drug Promotion (OPDP)
5901-B Ammendale Road
Beltsville, MD 20705-1266

You must submit final promotional materials and package insert(s), accompanied by a Form FDA 2253, at the time of initial dissemination or publication [21 CFR 314.81(b)(3)(i)]. Form FDA 2253 is available at http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf. Information and Instructions for completing the form can be found at http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf. For more information about submission of promotional materials to the Office of Prescription Drug Promotion (OPDP), see http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm.

All promotional materials that include representations about your drug product must be promptly revised to be consistent with the labeling changes approved in this supplement, including any new safety information [21 CFR 314.70(a)(4)]. The revisions in your promotional materials should include prominent disclosure of the important new safety information that appears in the revised package labeling. Within 7 days of receipt of this letter, submit your statement of intent to comply with 21 CFR 314.70(a)(4) to the address above or by fax to 301-847-8444.

**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 Stacy Metz, PharmD, Regulatory Project Manager, at (301) 796-2139.

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

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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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ERIC P BASTINGS
02/21/2014