DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 22083/S-008

SUPPLEMENT APPROVAL

Novartis Pharmaceuticals Corporation
Attention: Peter McArdle, Director, Drug Reg. Affairs
One Health Plaza
East Hanover, NJ 07936-1080

Dear Mr. McArdle:

Please refer to your Supplemental New Drug Application (sNDA) dated and received 23-Dec-2009, , submitted under section 505(b)/ of the Federal Food, Drug, and Cosmetic Act (FDCA) for Exelon® Patch (rivastigmine transdermal system).

This Prior Approval" supplemental new drug application provides the following:

1. The incorporation of several stylistic changes to the formatting of the prescribing information and patient counseling information for Exelon® Patch.
2. Informational changes to Section 2 Dosage and Administration, Section 6 Adverse Reactions, Section 10 Overdosage and Section 17 Patient Counseling Information and the FDA Approved Patient Information.

We acknowledge receipt of your August 6, 2010, supplemental amendment, which provides the following:

1. Introduce a new sub-section under Section 5 Warnings and Precautions concerning medication errors with the heading of 5.1 Medication Errors Resulting in Overdose.
2. Incorporate additional FDA requested revisions to the Highlights Section, Section 2 Dosage and Administration, Section 5.2 Gastrointestinal Adverse Reactions, Section 6.4 Additional Adverse Reactions Reported, Section 10 Overdosage, Section 17.2 Importance of Correct Usage and Section 17.7 Missed Doses.
3. Additionally, the entire Patient Information section has been completely reformatted following guidance and input received from FDA. Most notably, a new illustration (Figure A) has been introduced to clarify instructions on the proper techniques for the application of Exelon Patch, emphasizing the proper placement of the patch and that only one patch should be worn at any given time.

We have completed our review of this supplemental application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

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.

LETTERS TO HEALTH CARE PROFESSIONALS

If you decide to issue a letter communicating important safety-related information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit, at least 24 hours prior to issuing the letter, an electronic copy of the letter to this NDA, to CDERMedWatchSafetyAlerts@fda.hhs.gov, and to the following address:

MedWatch Program
Office of Special Health Issues
Food and Drug Administration
10903 New Hampshire Ave
Building 32, Mail Stop 5353
Silver Spring, MD 20993

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 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 1
Center for Drug Evaluation and Research

ENCLOSURE(S):
Content of Labeling

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-22083	SUPPL-8	NOVARTIS PHARMACEUTICALS CORP	EXELON PATCH

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

/s/

ERIC P BASTINGS on behalf of RUSSELL G KATZ
08/27/2010