DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 20823/S-009/S-027/S-028/S-029
NDA 21025/S-018/S-019/S-0020

SUPPLEMENT APPROVAL

Novartis Pharmaceuticals Corporation
Attention: Peter McArdle, Director, DRA
One Health Plaza
East Hanover, New Jersey 07936-1080

Dear Dr. McArdle:

Please refer to your Supplemental New Drug Applications (sNDA) dated and received January 10, 2003, June 2, 2011, February 10, 2012 and August 10, 2012, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Exelon (rivastigmine tartrate) Capsules 0.5 mg, 1.0 mg, & 1.5 mg Exelon (rivastigmine tartrate) Oral Solution 2 mg/ml.

These" Prior Approval" supplemental new drug applications provide the following:

NDA 20823/S-009 January 13, 2003
Inclusion in the prescribing information the pharmacological property to inhibit butyrylcholinesterase (BuChE).

We also reference the NDA 20823/S-009 amendments dated:

February 27, 2008	August 30, 2006
September 3, 2004	October 27, 2003

NDA 20823/S-027 & NDA 21025/S-018 June 02, 2011
Several revisions including labeling conversion to Physician's Labeling Rule format, and updates to text and tables in the ADR section.

NDA 20823/S028 & NDA 21025/S-019 February 10, 2012
Division of Neurology requested changes to labeling to reflect labeling changes approved in the Exelon Patch product labeling.

NDA 20823/S-029 & NDA 21025/S-020 August 10, 2012
Revisions to the prescribing information to reflect the recent updates to the CDS. Including proposed revisions to the Contraindications, Warnings & Precautions and Adverse Reactions sections of the prescribing information to address post-marketing reports of allergic contact

dermatitis with the Exelon patch, and isolated reports of generalized hypersensitivity reactions of the skin reported with either the transdermal or oral formulations of rivastigmine.

APPROVAL & LABELING

We have completed our review of these supplemental applications. They are 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, text for the patient 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).

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the

product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because none of these criteria apply to your application, you are exempt from this requirement.

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}

Eric Bastings, MD
Acting Director
Division of Neurology Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

ENCLOSURE(S):
Content of Labeling

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
10/01/2013