DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 21169 / S-024
NDA 21224 / S-022
NDA 21615 / S-016

SUPPLEMENT APPROVAL

Janssen Pharmaceuticals, Inc.
Attention: Tamara Mazza
Associate Director, Global Regulatory Affairs
1125 Trenton Harbourton Road
Titusville, NJ 08560

Dear Ms. Mazza:

Please refer to your Supplemental New Drug Application (sNDA) dated June 29, 2010, received June 30, 2010, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Razadyne (galantamine hydrobromide) Tablet, Razadyne (galantamine hydrobromide) Oral Solution, Razadyne ER (galantamine hydrobromide) Extended Release Capsules.

We acknowledge receipt of your amendments dated June 25, 2013.

These Prior Approval supplemental new drug applications provide labeling that implements the requirements of the Physician's Labeling Rule (PLR) specifications, and a waiver request for the half page HIGHLIGHTS section.

These supplemental new drug applications provide revisions to the labeling for Razadyne (galantamine hydrobromide) Tablet, Razadyne (galantamine hydrobromide) Oral Solution, and Razadyne ER (galantamine hydrobromide) Extended Release Capsules.

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.

WAIVER OF HIGHLIGHTS SECTION

We acknowledge your request to waive the requirements of 21 CFR 201.57(d)(8) regarding the length of Highlights of prescribing information. As previously discussed with you, we are denying your request.

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).

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, Regulatory Project Manager at (301) 796-1161.

Sincerely,

{See appended electronic signature page}

Russell G. Katz, MD
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/

RUSSELL G KATZ
06/28/2013