DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 21-169/S 016
NDA 21-224/S-014
NDA 21-615/S-008

SUPPLEMENT APPROVAL

Janssen Pharmaceuticals, Inc.
Attention: Mary Mulligan
Manager, Global Regulatory Affairs
920 Route U.S. Highway 202, Box 300
Raritan, NJ 08869-0602

Dear Ms. Mulligan:

Please refer to your Supplemental New Drug Applications (sNDA) dated May 02, 2007, received May 03, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for New Drug Application (NDA) 21-169 for RAZADYNE® (galantamine hydrobromide) Tablets, NDA 21-224 RAZADYNE® (galantamine HBr) Oral Solution, and NDA 21-615 RAZADYNE® ER (galantamine HBr) Extended-Release Capsules.

These "Changes Being Effected" supplements provide for adding adverse events to the Post-Marketing Experience section of labeling. Specifically, the following adverse events were added:

Hepatobiliary Disorders: elevated liver enzymes, hepatitis

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.

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

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If you have any questions, call Teresa Wheelous, Sr. 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
03/01/2012