



NDA 21-169/S 017
NDA 21-224/S-015
NDA 21-615/S-009

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 and received May 27, 2008, 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 editorial changes and for the addition of terms identified as ADRs to the Post Marketing Experiences section of labeling. The added ADRs are:

Gastrointestinal System Disorders: upper and lower GI bleeding, stomach discomfort, abdominal discomfort

Nervous System Disorders: lethargy, dysgeusia, hypersomnia

Eye Disorders: vision blurred

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.

We note that your May 27, 2008, submission includes final printed labeling (FPL) for your package insert. We have not reviewed this FPL. You are responsible for assuring that the wording in this printed labeling is identical to that of the approved content of labeling in the structured product labeling (SPL) format.

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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 G. Katz, MD
Director,
Division of Neurology Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

ENCLOSURE:
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