DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-169/S-010, 012, 013, 014
NDA 21-224/S-008, 010, 011, 012
NDA 21-615/S-001, 003, 004, 005

Johnson & Johnson Pharmaceutical Research & Development, LLC
Attention: Susan Merchant
1125 Trenton Harbourton Road
P.O. Box 200
Titusville, NJ 08560-0200

Dear Ms. Merchant:

Please refer to your supplemental new drug application submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Razadyne Tablets, Oral Solution and Extended-Release Capsules.

We acknowledge receipt of your submissions dated February 11, 2005, April 28, 2005, June 17, 2005 and August 16, 2005 and February 14, 2006.

These supplemental new drug applications provide for the following changes to product labeling:

NDA 21-169/S-010; NDA 21-224/S-008; NDA 21-615/S-001

DESCRIPTION: A change was made in the term used for an inactive ingredient ("hypromellose," previously termed "hydroxypropyl methylcellulose") in the tablet formulation for this drug.

CLINICAL TRIALS: A clarification was added that the CIBIC-Plus, a primary efficacy measure used in clinical trials in Alzheimer's Disease, required the use of caregiver information.

WARNINGS: A statement that bradycardia was rarely severe in randomized controlled trials was added.

ADVERSE REACTIONS/Other Adverse Reactions Observed During Clinical Trials: New adverse event terms were included.

ADVERSE REACTIONS/Post-Marketing Experience: The heading "Central and Peripheral Nervous System Disorders" was changed to "Psychiatric Disorders" to meet current system organ class naming conventions.

OVERDOSAGE: Two additional cases of accidental overdose with galantamine were reported in this section.

NDA 21-169/S-012; 21-224/S- 010; NDA 21-615/S-003

ALL SECTIONS: The proprietary name Razadyne™ has been substituted for Reminyl®.

HOW SUPPLIED: Changes in NDC code for the tablet and oral solution formulations; change in name and logo for marketing company.

NDA 21-169/S-013; NDA 21-224/S-011: NDA 21-615/S-004

These supplements provide for the following changes:

New labeling regarding drug-drug interaction of memantime and Razadyne within the Clinical Pharmacology and Precautions, Drug-Drug Interactions sections.

Revision of the dosing guidance for hepatically impaired patients with in the Dosage and Administration section.

NDA 21-169/S-014; NDA 21-224/S-012; NDA 21-615/S-005

A combined package insert for all 3 Razadyne formulations (IR, ER, and oral solution).

We completed our review of these supplemental new drug applications, as amended. They are approved, effective on the date of this letter, for use as recommended in the labeling text submitted on February 14, 2006.

The final printed labeling (FPL) must be identical to the submitted labeling (package insert submitted February 14, 2006).

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Approval of this submission by FDA is not required before the labeling is used.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Melina Griffis, R.Ph., Sr. Regulatory Project Manager, at (301) 796-1078.

Sincerely,

{See appended electronic signature page}

Russell Katz, M.D.
Director
Division of Neurology Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

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

/s/

Russell Katz

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