DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug
Administration
Rockville MD 20857

NDA 21-169/S-003
NDA 21-224/S-003

Johnson & Johnson Pharmaceutical Research & Development, L.L.C.
Attention: Cynthia Chianese
1125 Trenton-Harbourton Road
Titusville, NJ 08560-0200

Dear Ms. Chianese:

Please refer to your supplemental new drug applications dated January 18, 2002 and March 6, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Reminyl (galantamine hydrobromide) Tablets & Oral Suspension.

These "Changes Being Effected in 30 days" supplemental new drug applications provide for the addition of the following paragraph to the Overdosage section of labeling:

> "In a post-marketing report, one patient who had been taking 4 mg of galantamine daily for a week inadvertently ingested eight 4 mg tablets (32 mg total) on a single day. Subsequently, she developed bradycardia, QT prolongation, ventricular tachycardia and torsades de pointes accompanied by a brief loss of consciousness for which she required hospital treatment."

We have completed the review of these supplemental applications and have concluded that adequate information has been presented to demonstrate that the drug products are safe and effective for use as recommended in the submitted final printed labeling. Accordingly, these supplemental applications are approved effective on the date of this letter.

Please note that the word "inadvertently" was misspelled and should be corrected at the next printing of FPL.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under

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21 CFR 314.80 and 314.81.

If you have any questions, call Melina Fanari, R.Ph., Senior Regulatory Management Officer, at (301) 594-5526.

Sincerely,

{See appended electronic signature page}

Russell Katz, M.D.
Director
Division of Neuropharmacological Drug 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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