DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-272 / S-042
NDA 20-588 / S-030
NDA 21-444 / S-016
NDA 21-346 / S-010

Johnson & Johnson Pharmaceutical Research & Development, L.L.C.
Attention: Manisha Padhye, Ph.D.
1125 Tenton-Harbourton Road
PO Box 200
Titusville, NJ 08560

Dear Dr. Padhye:

Please refer to your supplemental new drug applications dated April 29, 2005, received May 2, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Risperdal (risperidone) Tablets, Oral Solution, Risperdal M-Tab Orally Disintegrating Tablets, and Risperdal Consta Injection.

These "Changes Being Effected" supplemental new drug applications provide for revised labeling regarding mortality in elderly patients with dementia-related psychosis.

We completed our review of these supplemental new drug applications and they are approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on April 29, 2005 (attached).

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 CAPT Steven D. Hardeman, R.Ph., Acting Chief, Project Management Staff, at (301) 594-5525.

Sincerely,

{See appended electronic signature page}

Thomas Laughren, M.D.
Acting Director
Division of Psychiatry Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

2 attachments

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

/s/

Thomas Laughren
8/17/2005 02:11:34 PM