DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-346 / S-013

Johnson & Johnson Pharmaceutical Research & Development, LLC
Attention: Harindra R. Abeysinghe, Ph.D.
1125 Trenton-Harbourton Road
Titusville, NJ 08560

Dear Dr. Abeysinghe:

Please refer to your supplemental new drug application dated May 18, 2006, received May 22, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Risperdal Consta (risperidone) Long-Acting Injection.

This "Changes Being Effected" supplemental new drug application provides for changes in the following sections of labeling:

- **CLINICAL PHARMACOLOGY**, **Pharmacokinetics**, Metabolism and Drug Interactions
- **PRECAUTIONS**, **Drug Interactions**
- **PRECAUTIONS**, **Geriatric Use**, Concomitant use with Furosemide in Elderly Patients with Dementia-Related Psychosis

We have completed our review of this supplemental new drug application and it is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on May 18, 2006.

If you have any questions, call LCDR Keith Kiedrow, Pharm.D., Regulatory Project Manager, at (301) 796-1924.

Sincerely,

{See appended electronic signature page}

Thomas Laughren, M.D.
Director
Division of Psychiatry 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/

Thomas Laughren

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