DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-346 / S-011

Johnson & Johnson
Attention: Harindra R. Abeysinghe, Ph.D.
1125 Trenton-Harbourton Road
POB 200
Titusville, NJ 08560

Dear Dr. Abeysinghe:

Please refer to your supplemental new drug application dated October 25, 2005, received October 26, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Risperdal Consta (risperidone) Long-Acting Injection.

We acknowledge receipt of your submission of February 3, 2006.

This "Changes Being Effected" supplemental new drug application provides for labeling changes as follows (changes highlighted):

1. Under the **PRECAUTIONS** section, **Pregnancy** subsection, the following statement has been added --

   Placental transfer of risperidone occurs in rat pups. There are no adequate and well-controlled studies in pregnant women. However, there was one report of a case of agenesis of the corpus callosum in an infant exposed to risperidone *in utero*. The causal relationship to oral RISPERDAL® therapy is unknown. Reversible extrapyramidal symptoms in the neonate were observed following postmarketing use of risperidone during the last trimester of pregnancy.

   RISPERDAL® CONSTA® should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

2. Under the **ADVERSE REACTIONS** section, **Postintroduction Reports** subsection, the following event has been added –

   Adverse events reported since market introduction which were temporally (but not necessarily causally) related to oral RISPERDAL® therapy include the following: anaphylactic reaction, angioedema, apnea, atrial fibrillation, benign pituitary adenomas, cerebrovascular disorder, including cerebrovascular accident, diabetes mellitus aggravated, including diabetic ketoacidosis, hyperglycemia, intestinal obstruction, jaundice, mania, pancreatitis, Parkinson's disease aggravated, pulmonary embolism.

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 February 3, 2006.

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 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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