DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-346 / S-020

Johnson & Johnson
Attention: Harindra R. Abeysinghe, Ph.D.
1125 Trenton-Harbourton Road
Titusville, NJ 08560-0200

Dear Dr. Abeysinghe:

Please refer to your supplemental new drug application dated and received December 27, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Risperdal (risperidone) Consta Long Acting Injection.

This "Changes Being Effected" supplemental new drug application provides for changes under the PRECAUTIONS (General Administration) and ADVERSE REACTIONS (Postintroduction Reports) sections of the labeling. Additional revisions to align the Risperdal Consta labeling with the latest approved labeling for the Risperdal oral formulations have been made.

We have completed our review of this application and it is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text (email of 3/8/07).

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert).

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. For administrative purposes, designate this submission "**FPL for approved supplement NDA 21-346 / S-020**." Approval of this submission by FDA is not required before the labeling is used.

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, email Keith Kiedrow, Pharm.D., Regulatory Project Manager, at Kieth.Kiedrow@FDA.HHS.GOV.

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

Enclosure (labeling)

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
3/9/2007 01:14:52 PM