DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-272 / SLR-024
NDA 20-588 / SLR-015

Johnson & Johnson Pharmaceutical Research & Development, L.L.C.
Attention: Susan J. Merchant
125 Trenton-Harbourton Road
Titusville, NJ 08560-0200

Dear Ms. Merchant:

Please refer to your supplemental new drug applications dated April 12, 2002, received April 16, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Risperdal (risperidone) tablets and oral solution.

We acknowledge receipt of your submissions dated April 18 and October 11, 2002.

These "Changes Being Effected" supplemental new drug applications provide for the addition of "hyperglycemia" to the **ADVERSE REACTIONS: Postintroduction Reports** section of the package insert for Risperdal (risperidone) tablets and oral solution.

We have 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 October 11, 2002.

However, additional labeling changes related to this topic might be required if supported by the results of future studies.

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 Steven D. Hardeman, R.Ph., Senior Regulatory Project Manager, at (301) 594-5525.

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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