DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-444/S-012

Johnson & Johnson Pharmaceutical Research & Development, L.L.C.
Attention: Jacqueline Brown, R.Ph.
Manager, Regulatory Affairs
1125 Trenton-Harbourton Road, P.O. Box 200
Titusville, NJ 08560

Dear Ms. Brown:

We acknowledge receipt of your supplemental new drug application dated and received September 3, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for RISPERDAL M-TAB (risperidone) 0.5 mg, 1 mg, 2 mg, 3 mg, and 4 mg Orally Disintegrating Tablets.

We additionally acknowledge receipt of your amendment dated December 9, 2004.

This supplemental new drug application provides for reformulation of the existing 2 mg tablet strength and for the addition of 3 mg and 4 mg tablet strengths of RISPERDAL M-TAB (risperidone) Orally Disintegrating Tablets.

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 submitted labeling text (copy attached).

The final printed labeling (FPL) must be identical, to the submitted labeling (package insert submitted September 3, 2004).

Please submit the FPL electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDA. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 21-444/S-012." Approval of this submission by FDA is not required before the labeling is used.

The following is the dissolution specification for all strengths of RISPERDAL M-TAB (risperidone) Orally Disintegrating Tablets:

(b)(4)

A 24-month expiry is granted for the 2 mg, 3 mg, and 4 mg strengths of RISPERDAL M-TAB (risperidone) Orally Disintegrating Tablets in (b)(4) blister packaging.

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, 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

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/

Russell Katz

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