DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-272/S-026, S-027
NDA 20-588/S-017, S-018
NDA 21-444/S-002, S-003

Johnson & Johnson Research & Development, L.L.C
Attention: Megan L. Zoschg, Pharm.D.
Associate Director, Regulatory Affairs
1125 Trenton Harbourton Road
P.O. Box 200
Titusville, NJ 08560-0200

Dear Dr. Zoschg:

Please refer to your supplemental new drug applications submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following:

Application	Drug Name	Submission Date	Receipt Date	Provides For:
NDA 20-272/S-026	Risperdal (risperidone) Tablets	December 13, 2002	December 13, 2002	Monotherapy – for short term treatment of acute manic or mixed episodes associated with Bipolar I Disorder
NDA 20-588/S-017	Risperdal (risperidone) Oral Solution			
NDA 21-444/S-002	Risperdal (risperidone) Orally Disintegrating Tablets	August 13, 2003	August 13, 2003	
NDA 20-272/S-027	Risperdal (risperidone) Tablets	December 13, 2002	December 13, 2002	Adjunctive Therapy - for short term treatment of acute manic or mixed episodes associated with Bipolar I Disorder
NDA 20-588/S-018	Risperdal (risperidone) Oral Solution			
NDA 21-444/S-003	Risperdal (risperidone) Orally Disintegrating Tablets	August 13, 2003	August 13, 2003	

We also acknowledge receipt of your additional submissions dated October 31, 2003.

Your submissions on October 31, 2003 constituted a complete response to our October 14, 2003 action letter.

We have completed our review of these applications, as amended. These applications are approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

Labeling
The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert). Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

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, these submissions should be designated "FPL for approved supplements NDA 20-272/S-026, S-027; NDA 20-588/S-017, S-018; NDA 21-444/S-002, S-003." Approval of these submissions by FDA is not required before the labeling is used.

Post-Marketing Study Commitments
We remind you of your post-marketing study commitment in your submission dated October 31, 2003. Details of this commitment are as follows:

1. A study exploring the question of longer-term efficacy of Risperdal in patients with either manic or mixed episodes who have responded during acute treatment.

Protocol Submission:	by February 2004
Study Start:	by August 2004
Final Report Submission:	by December 2007

Submit this clinical protocol to your IND for one of these products. Submit nonclinical and chemistry, manufacturing, and controls protocols and all study final reports to this NDA. In addition, under 21 CFR 314.81(b)(2)(vii) and 314.81(b)(2)(viii), you should include a status summary of this commitment in your annual report to these NDAs. The status summary should include expected summary completion and final report submission dates, any changes in plans since the last annual report, and, for clinical studies, number of patients entered into each study. All submissions, including supplements, relating to these post-marketing study commitments must be prominently labeled "Post-Marketing Study Protocol", "Post-Marketing Study Final Report", or "Post-Marketing Study Correspondence."

Promotional Materials
In addition, submit three copies of the introductory promotional materials that you propose to use for these products. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division/ the Division of Neuropharmacological Drug Products and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

MedWatch
If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

Other
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 Richardae C. Taylor, Pharm.D., Regulatory Project Manager, at (301) 594-2850.

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
-Package Insert

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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