



NDA 20-272 / SLR-035  
NDA 20-588 / SLR-023  
NDA 21-444 / SLR-007

Janssen Pharmaceutica Products, L.P.  
Attention: Susan Merchant  
Manager, Regulatory Affairs  
1125 Trenton-Harbourton Road  
Titusville, NJ 08560-020

Dear Ms. Merchant:

Please refer to your supplemental new drug applications dated November 6, 2003 received November 7, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Risperdal (risperidone) Tablets and Oral Solution, and Risperdal M-TAB (risperidone) Orally Disintegrating Tablets.

These "Changes Being Effected" supplemental new drug applications incorporate the hyperglycemia text from the Risperdal Consta labeling (NDA 21-346 - approved October 29, 2003) into the Oral Risperdal labeling under WARNINGS. Under DESCRIPTION, hydroxypropyl methylcellulose has been changed to hypromellose.

The changes approved on October 29, 2003, with the deletion of labeling relative to proarrhythmic effects in WARNINGS and PRECAUTIONS; the revision of the ECG Changes subsection under ADVERSE REACTIONS; and the revision of OVERDOSAGE to separate the pre-marketing and post-marketing information and add the terms "extrapyramidal symptoms" and "torsades de pointes" to the post-marketing information have been incorporated into this label.

We have completed our review of these applications and they are approved, effective on the date of this letter, for use as recommended in the submitted labeling text.

The final printed labeling (FPL) must be identical to the submitted labeling (text for the package insert - submitted November 6, 2003).

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 supplement NDA 20-272 / SLR-035, NDA 20-588 / SLR-023, and NDA 21-444 / SLR-007." Approval of these submissions by FDA is not required before the labeling is used.

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We believe the safe use of the Risperdal drug products can be enhanced by informing prescribers and patients of the addition of "Hyperglycemia and Diabetes Mellitus" labeling information under WARNINGS and request that you issue a letter communicating this important information (i.e., a "Dear Health Care Professional" letter). Please 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

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

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/s/

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Russell Katz  
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