DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-346 / S-025
NDA 21-346 / S-028

Heddie Martynowicz, M.S.
Senior Director, Regulatory Affairs
Johnson & Johnson Pharmaceutical Research & Development LLC
1125 Trenton-Harbourton Road, PO Box 200
Titusville, NJ 08560-0200

Dear Ms. Martynowicz:

Please refer to your supplemental new drug application 21-346 S-025, dated April 8, 2008, received April 9, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Risperdal® CONSTA® Long-Acting Injection.

Please also refer to your supplemental new drug application 21-346 S-028, dated and received July 21, 2008, for the above referenced drug product.

We also acknowledge receipt of your submissions dated:

21-346 S-025:	March 26, 2009		
21-346 S-028:	August 1, 2008	September 16, 2008	October 10, 2008
	November 19, 2008	December 15, 2008	March 27, 2009

Your March 26, 2009 submission to NDA 21-346 S-025 constituted a complete response to our February 9, 2009 action letter for this supplemental NDA.

These supplemental new drug applications provide for:

S-025: use of Risperdal CONSTA as adjunctive therapy with lithium or valproate for the maintenance treatment of bipolar I disorder.

S-028: use of Risperdal CONSTA as monotherapy for the maintenance treatment of bipolar I disorder.

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

Final Printed Labeling. The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert). As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l) in Structured Product Labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to the enclosed labeling

(text for the package insert). Upon receipt, we will transmit this version to the National Library of Medicine for public dissemination. For administrative purposes, please clearly label this submission as **"SPL for Approved NDA 21-346 S-025 and 21-346 S-028".**

Pediatric Research Equity Act (PREA) Requirements: Phase 4 Commitments. Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

We are waiving the pediatric study requirement for ages 0 to 9 years because:

A) necessary studies are impossible or highly impracticable.

Bipolar disorder cannot be reliably diagnosed in this age group, and therefore appropriate studies cannot be developed and carried out.

We are waiving the pediatric study requirement for ages 10 to 17 years because:

E) this product does not represent a meaningful therapeutic benefit over existing therapies for pediatric patients and is not likely to be used in a substantial number of pediatric patients.

Postmarketing Commitments; Postmarketing Requirements. There are no postmarketing commitments or requirements associated with the approval of either NDA 21-346 S-025 or NDA 21-346 S-028.

Introductory Promotional Materials. In addition, submit three copies of the introductory promotional materials that you propose to use for these new indications. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division and two copies of both the promotional materials and the package insert(s) directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

Letters to Health Care Professionals. 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
Food and Drug Administration
Suite 12B05
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 Doris J. Bates, Ph.D., Senior Regulatory Health Project Manager, at (301) 796-2260.

Sincerely,

{See appended electronic signature page}

Thomas P. Laughren, M.D.
Director
Division of Psychiatry Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

Enclosure: Approved Agreed-Upon 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

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