DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-346/S-021, S-022, S-023, S-026

Ortho-McNeil-Janssen Pharmaceutical, Inc.
C/O Johnson and Johnson Pharmaceutical Research and Development, L.L.C.
Attention: Heddie Martynowicz, M.S., Senior Director, Regulatory Affairs
1125 Trenton-Harbourton Road
P.O. Box 200
Titusville, NJ 08560-0200

Dear Ms. Martynowicz:

Please refer to your supplemental new drug applications dated May 25, 2007 (S-021), November 16, 2007 (S-022), February 14, 2008 (S-023), and June 6, 2008 (S-026), submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Risperdal (risperidone) Consta Intramuscular Injection.

These supplemental new drug applications provide for the following changes:

S-021

- Provides for the conversion of labeling to the PLR format.

S-022

- Provides for the additional site of administration of the deltoid muscle.

S-023

- Provides language regarding dystonia as requested by the FDA on January 16, 2008, as well as other adverse event information.

S-026

- Provides for new information on instructions for use.

We 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 (enclosed).

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert, text for the patient package insert).

Within 21 days of the date of this letter, submit 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 in content to the enclosed labeling text. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission **"SPL for approved supplement NDA 21-346/S-021, S-022, S-023, S-026."**

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 and two copies of both the promotional materials and the package insert 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

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 Keith Kiedrow, Pharm.D., Senior Regulatory Project Manager, at (301) 796-1924.

Sincerely,

{See appended electronic signature page}

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

Enclosure

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
10/8/2008 04:06:35 PM