DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDAs 15923/S-089, 18701/S-065

SUPPLEMENT APPROVAL

Johnson & Johnson Pharmaceutical Research & Development, LLC
Attn: Mary Mulligan, Manager Regulatory Affairs
920 US Highway 202
Raritan, NJ 08869

Dear Ms. Mulligan:

Please refer to your Supplemental New Drug Applications (sNDAs) dated and received on November 18, 2011, submitted under section 505(b) of the Federal Food Drug, and Cosmetic Act (FDCA) for Haldol (haloperidol) 5 mg/mL Injection (NDA 15923) and Haldol Decanoate (haloperidol) 50 mg/mL and 100 mg/mL IM Injection (NDA 18701).

We acknowledge receipt of your amendments dated July 16, 2012, August 13, 2012, December 13, 2012, and February 22, 2013.

These "Prior Approval" labeling supplemental new drug applications provide for revisions to the carton and blister labeling for Haldol (haloperidol) Injection and Haldol Decanoate (haloperidol) IM Injection as well as the authorized generic of each product (Haldol Injection and Haldol Decanoate Injection).

We have completed our review of these supplemental applications. They are approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon carton/container labeling.

In addition, we have the following comments regarding the haloperidol injection (authorized generic) label.

1) To improve the readability and prominence of the established name on the label use title case font for the word "Injection" and ensure the entire established name "Haloperidol Injection" has the same font and font size.

2) Ensure the established name is the most prominent information on the label.

Please submit these labels electronically according to the guidance for industry titled "Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (June 2008)." Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Product Correspondence – Final Printed Carton and Container Labels for approved NDA 15923/S-089 and NDA 18701/S-065**." Approval of this submission by FDA is not required before the labeling is used.

REPORTING REQUIREMENTS

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 Sonny Saini, Pharm.D., MBA, Regulatory Project Manager, at (301) 796-0532.

Sincerely,

{See appended electronic signature page}

Mitchell V. Mathis, M.D.
CAPT, USPHS
Director (acting)
Division of Psychiatry Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

ENCLOSURE:
Content of Carton/Container Labeling

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

MITCHELL V Mathis
05/06/2013