NDA 15-923 / S-084
NDA 18-701 / S-059

Johnson & Johnson Pharmaceutical R & D, L.L.C.
Attention: Harindra Abeysinghe, Ph.D.
Director, Regulatory Affairs
1125 Trenton-Harbourton Road, POB 200
Titusville, NJ 08560
Dear Dr. Abeysinghe:

Please refer to your supplemental new drug applications dated May 4, 2009 and received on May 1, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for HALDOL (haloperidol) Injection, 5 mg base / mL [NDA 15-923] and HALDOL Decanoate (haloperidol) IM Injection, 50 mg base / mL and 100 mg base / mL [NDA 18-701].

We acknowledge receipt of your submissions dated June 22, 2009, to each of the supplements referenced above.

Reference is made to our letter dated April 5, 2009, notifying you, under Section 505(o)(4) of the FDCA, of new safety information that we believe should be included in the labeling for the entire class of antipsychotic drugs. This information pertains to the risk of leukopenia, neutropenia, and agranulocytosis.

We also refer you to the letter we sent on June 2, 2009, informing you that we determined that a 30-day extension of the discussion period was warranted to allow us to complete our review and reach agreement on the content of the labeling. We also refer to modified labeling language that we sent to you via email on June 9, 2009.

The supplemental new drug applications, as amended, provide for the addition of the subsection PRECAUTIONS/ Leukopenia, Neutropenia and Agranulocytosis to the labeling for HALDOL (haloperidol).

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

CONTENT OF LABELING

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 that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission, **"SPL for approved supplements NDA 15-923 / S-084 and NDA 18-701 / S-059 ."**

In addition, within 21 days of the date of this letter, amend any pending applications for these NDAs with content of labeling in structured product labeling (SPL) format to include the changes approved in these applications.

Failure to make these changes within the specified period of time could make your product misbranded under 21 USC 321(n) and 352(a).

We request that the revised labeling approved today be available on your website within 10 days of receipt of this letter.

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 these NDAs and a copy to the following address:

>   MEDWATCH
>   Food and Drug Administration
>   5515 Security Lane
>   HFD-001, Suite 5100
>   Rockville, MD 20852

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, please contact Doris J. Bates, Ph.D., Safety Regulatory 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: Package Insert labeling

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Mitchell Mathis
7/19/2009 07:50:11 AM
For Dr. Laughren
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