**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 15-923 S-078
NDA 18-701 S-053

Johnson & Johnson
Attention: Harindra R. Abeysinghe, Ph.D.
Associate Director, Regulatory Affairs
1125 Trenton-Harbourton Road
Titusville, NJ 08560

Dear Dr. Abeysinghe:

Please refer to your supplemental new drug applications dated and received March 21, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Haldol (haloperidol) Injection and Haldol Decanoate (haloperidol) for IM Injection.

These "Changes Being Effected" supplemental new drug applications provide for the addition a statement under WARNINGS to inform prescribers that cases of sudden death and QT prolongation have been observed in patients taking Haldol.

We have completed our review of these applications, as amended, and they are approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text (email of 5/4/07).

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 15-923/S-078" or "SPL for approved supplement NDA 18-701/S-053."

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
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

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, email Felecia Curtis, RN, Regulatory Project Manager, at Felecia.Curtis@FDA.HHS.GOV.

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 (labeling)

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

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/s/

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Thomas Laughren

5/4/2007 04:38:11 PM