DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 15-923 / S-080
NDA 18-701 / S-055

Johnson & Johnson
Attention: Harindra R. Abeysinghe, Ph.D.
1125 Trenton-Harbourton Road
Titusville, NJ 08560-0200

Dear Dr. Abeysinghe:

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

These "Changes Being Effected" supplemental new drug applications provide for labeling changes under WARNINGS, Cardiovascular Effects, regarding cases of sudden death, QT prolongation and Torsades de Pointes

We have completed our review of these applications and they are approved, effective on the date of this letter, for use as recommended in the labeling submitted on August 28, 2007.

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 CAPT Steven D. Hardeman, R.Ph., Chief, Project Management Staff, at Steven.Hardeman@FDA.HHS.GOV.

Sincerely,

{See appended electronic signature page}

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

Enclosure (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
9/19/2007 09:24:26 AM