



NDA 15-923 / S-081  
NDA 18-701 / S-056

Johnson & Johnson Pharmaceutical Research & Development, LLC  
Attention: Joseph Fisher  
1125 Trenton-Harbourton Road  
POB 200  
Titusville, NJ 08560

Dear Mr. Fisher:

Please refer to your supplemental new drug applications dated and received February 14, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Haldol (haloperidol) Injection and Haldol Decanoate (haloperidol) IM Injection.

These "Changes Being Effected" supplemental new drug applications provide for class-labeling changes under **ADVERSE REACTIONS**, Extrapyramidal Symptoms. The following subsection has been added:

**Dystonia**

*Class Effect:* Symptoms of dystonia, prolonged abnormal contractions of muscle groups, may occur in susceptible individuals during the first few days of treatment. Dystonic symptoms include: spasm of the neck muscles, sometimes progressing to tightness of the throat, swallowing difficulty, difficulty breathing, and/or protrusion of the tongue. While these symptoms can occur at low doses, they occur more frequently and with greater severity with high potency and at higher doses of first generation antipsychotic drugs. An elevated risk of acute dystonia is observed in males and younger age groups.

We have completed our review of these supplemental new drug applications and they are approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on February 14, 2008 (copy attached).

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

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We remind you that you must comply with the requirements for an approved NDA set forth under 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](mailto:Steven.Hardeman@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

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**This is a representation of an electronic record that was signed electronically and  
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/s/

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Thomas Laughren  
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