CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

NDA 18-701/S-046

Name:	Haldol Injection (IM)
Generic Name:	haloperidol decanoate
Sponsor:	Ortho-McNeil Pharmaceutical, Inc.
Approval Date:	04/17/2002

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APPLICATION NUMBER:

NDA 18-701/S-046

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APPLICATION NUMBER:

NDA 18-701/S-046

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 15-921 / S-076
NDA 15-922 / S-066
NDA 15-923 / S-072
NDA 18-701 / S-046

The R.W. Johnson Pharmaceutical Research Institute
Attention: Susie Merchant
920 Route 202
POB 300
Raritan, NJ 08869-0602

Dear Ms. Merchant:

Please refer to your supplemental new drug applications dated December 6, 2001, received December 10, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Haldol (haloperidol) Tablets, Concentrate, Injection, and Haldol (haloperidol) Decanoate Injection

These "Changes Being Effected" supplemental new drug applications provide for labeling changes as requested in our letter of September 25, 2000, specifically modification of labeling text to more clearly state that these agents are indicated for the treatment of schizophrenia.

We have completed the review of these supplemental applications and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the submitted final printed labeling (package insert submitted December 6, 2001). Accordingly, these supplemental applications are approved effective on the date of this letter.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

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, call Steven D. Hardeman, R.Ph., Senior Regulatory Project Manager, at (301) 594-5525.

Sincerely,

{See appended electronic signature page}

Russell Katz, M.D.
Director
Division of Neuropharmacological Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

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