CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: 17-892/S-034

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 17-892/S-034

Pharmacia & UpJohn
Attention: Marcia J. Rogers
Regulatory Manager, Regulatory Affairs
7000 Portage Road
Kalamazoo, MI 49001-0199

Dear Ms. Rogers:

Please refer to your supplemental new drug application dated August 20, received August 24, 1998, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Halcion (triazolam) 0.125 mg and 0.25 mg Tablets.

We acknowledge receipt of your submission dated January 21, 2003. Your submission of January 21, 2003, constituted a complete response to our October 22, 2002 action letter.

This "Prior Approval" supplemental new drug application proposes revisions to the **CLINICAL PHARMACOLOGY** section and the addition of a new section under **PRECAUTIONS** entitled **Geriatric Use** to add additional information on geriatric use and to comply with a Federal Register notice dated August 27, 1997.

Additionally, we note that you have incorporated our requested revisions to labeling, as communicated in our October 22, 2002 action letter, verbatim.

We have completed the review of this supplemental application, 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 (labeling submitted January 21, 2003/Label Code 0812110831), which incorporates the revisions listed. Accordingly, this supplemental application is approved effective on the date of this letter.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Practitioner" 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 regarding this letter, call Mr. Paul David, R.Ph., Senior Regulatory Project Manager, at (301) 594-5530.

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

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

/s/

Russell Katz
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