DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 17-892/S-038

Pharmacia & Upjohn Company
235 East 42nd Street
New York, NY 10017

Attention: Carol J. Haley, Ph.D.
Director, Worldwide Regulatory Affairs

Dear Dr. Haley:

Please refer to the supplemental new drug application **S-038** 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 submissions dated May 31, 2007, October 19, 2007, January 8, 2008, and January 31, 2008.

We note that the "Changes Being Effected" supplemental new drug application **S-038** provides for changes to the package insert and was submitted in response to the Agency's February 14, 2006 letter requesting a class labeling change for the sedative-hypnotic drug group, and a subsequent letter dated March 2, 2007 which requested a Medication Guide.

We have completed our review of the supplemental application **S-038** and it is approved, effective on the date of this letter, for use as recommended in the enclosed agreed upon labeling text submitted on January 31, 2008.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert, and medication guide) submitted on January 31, 2008.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA.* Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate the submission "**FPL for approved supplement NDA 17-892/S-038**."

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division/ the Division of Neurology Products and two copies of both the promotional materials and the package insert directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

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 the reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Cathleen Michaloski, MPH, Regulatory Project Manager, at (301)-796-1123.

Sincerely,

{See appended electronic signature page}

Russell Katz, M.D.
Director, Division of Neurology Products
Office of Drug Evaluation 1
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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