# CENTER FOR DRUG EVALUATION AND RESEARCH

*APPLICATION NUMBER:*

**21-228/S-003**

# APPROVAL LETTER

**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 21-228/S-003

Pharmacia & Upjohn
Attention: James Balun
Regulatory Manager
7000 Portage Road
Kalamazoo, MI 49001-0199

Dear Mr. Balum:

Please refer to your supplemental new drug application dated November 7, 2001, received November 13, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Detrol LA Capsules.

We acknowledge receipt of your submission dated November 7, 2001.

This "Changes Being Effected in 30 days" supplemental new drug application provides for addition of the ——— facility as an alternate site for performance of primary packaging and labeling of the drug product.

We have completed the review of this supplemental application, and it is approved.

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 Evelyn R. Farinas, R.Ph., M.G.A., Regulatory Project Manager, at (301) 827-4260.

Sincerely,

*{See appended electronic signature page}*

Moo-Jhong Rhee, Ph.D.
Chemistry Team Leader,
for the Division of Reproductive and Urologic Drug Products,
(HFD-580)
DNDC II, Office of New Drug Chemistry
Center for Drug Evaluation and Research

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/s/

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David T. Lin
12/17/01 12:34:31 PM
I concur for Moo-Jhong Rhee.

APPEARS THIS WAY
ON ORIGINAL