DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 50-537/S-026
NDA 50-600/S-007
NDA 50-615/S-005

Pharmacia & Upjohn
Attention: Rebecca K. Tong, M.S.
Senior Regulatory Manager
7000 Portage Road
Kalamazoo, MI 49001-0199

Dear Ms. Tong:

Please refer to your supplemental new drug applications, dated March 20, 2003, received March 21, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for CLEOCIN T (clindamycin phosphate) Topical Solution, USP, CLEOCIN T (clindamycin phosphate) Gel, and CLEOCIN T (clindamycin phosphate) Topical Lotion.

We acknowledge receipt of your submissions dated April 18, and May 8, 2003.

Your supplements provide for Geriatric Use labeling in accordance with 21CFR 201.57)(f)(10).

We have completed the review of these supplemental applications, and have concluded that the information presented is adequate. Accordingly, the supplements are approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the enclosed draft labeling (text for the package insert).

Please submit the copies of final printed labeling (FPL) electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). 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. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, the submission should be designated "FPL for approved supplement", citing the appropriate NDA/Supplement number. Approval of this submission by FDA is not required before the labeling is used.

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, please call Frank H. Cross, Jr., M.A., CDR, Senior Regulatory Management Officer, at (301) 827-2020.

Sincerely,

{See appended electronic signature page}

Jonathan K. Wilkin, M.D.
Director
Division of Dermatologic & Dental Drug Products
Office of Drug Evaluation V
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/

John Kelsey
5/30/03 03:17:08 PM
for Dr. Wilkin