DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 50-537 S013
NDA 50-600 S002
NDA 50-615 S003

Pharmacia
Attention: Rebecca Tong, Senior Regulatory Manager
7000 Portage Road
Kalamazoo, MI 49001

Dear Ms. Tong:

Please refer to the following supplemental new drug applications dated March 18, 1993 and received March 24, 1993: NDA 50-537/S013, NDA 50-600/S002 and NDA 50-615/S003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Cleocin T (clindamycin phosphate) Topical Solution, Cleocin T (clindamycin phosphate) Gel, and Cleocin T (clindamycin phosphate) Topical Lotion respectively.

We also acknowledge receipt of the following correspondence to your supplemental NDAs:

NDA 50-537/S013:	NDA 50-600/S002:	NDA 50-615/S003:
October 11, 1993	October 11, 1993	October 11, 1993
April 25, 1994	April 25, 1994	April 25, 1994
May 27, 1994	May 27, 1994	May 27, 1994
June 7, 1994	June 7, 1994	June 7, 1994

These supplemental new drug applications provide for revisions in the WARNINGS and ADVERSE REACTIONS section of the label.

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 agreed upon enclosed labeling text. Accordingly, these supplemental applications are approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the enclosed labeling text. Please submit the copies of final printed labeling (FPL) electronically according to the guidance for industry titled *Provide 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, these submission should be designated "FPL for approved supplements NDA 50-537/S013, NDA 50-600/S002 and NDA 50-615/S003." Approval of these submissions by the FDA is not required before the labeling is used.

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 Frank Cross, Project Manager, at (301) 827-2020.

Sincerely,

{See appended electronic signature page}

Jonathan K. Wilkin, M.D.
Director
Division of Dermatologic and Dental Drug Products,
Office of Drug Evaluation V
Center for Drug Evaluation and Research

Enclosure

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

/s/

Jonathan Wilkin
7/14/02 04:02:44 PM