DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 50-441/S-059

SUPPLEMENT APPROVAL

Pharmacia and Upjohn Company
Attention: Beatrice Curran
Associate Director
Worldwide Regulatory Strategy
235 East 42nd Street
New York, NY 10017

Dear Ms. Curran:

Please refer to your Supplemental New Drug Application (sNDA) dated July 23, 2010, received, July 23, 2010, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Cleocin Phosphate (clindamycin injection, USP) Sterile Solution.

We acknowledge receipt of your amendment dated September 30, 2010.

This "Changes Being Effected" supplemental new drug application provides for revisions to the the presentation of strength and concentration on the container label and carton labeling for Cleocin Phosphate (clindamycin injection, USP) Sterile Solution.

We have completed our review of this supplemental application, as amended and it is approved, effective on the date of this letter.

CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed carton and container labels that are identical to the carton and immediate container labels submitted on September 30, 2010, as soon as they are available but no more than 30 days after they are printed.

LETTERS TO HEALTH CARE PROFESSIONALS

If you decide to issue a letter communicating important safety-related information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit, at least 24 hours prior to issuing the letter, an electronic copy of the letter to this NDA to the following address:

MedWatch Program
Office of Special Health Issues
Food and Drug Administration
10903 New Hampshire Ave
Building 32, Mail Stop 5353
Silver Spring, MD 20993

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call J. Christopher Davi, MS, Senior Regulatory Project Manager, at (301) 796-0702.

Sincerely,

{See appended electronic signature page}

Sumathi Nambiar, MD, MPH
Deputy Director for Safety
Division of Anti-Infective and Ophthalmology Products
Office of Antimicrobial Products
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/

SUMATHI NAMBIAR
10/15/2010