DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 50-162/S-084
NDA 50-441/S-048
NDA 50-639/S-014

Pharmacia and Upjohn Company
A subsidiary of Pfizer, Inc.
Attention: Marcia J. Rogers
Regulatory Manager
7000 Portage Road
Kalamazoo, MI 49001

Dear Ms. Rogers:

Please refer to the following supplemental new drug applications:

Name	NDA number	Supplement Number	Letter date	Received on
Cleocin HCl® (clindamycin hydrochloride capsules, USP)	50-162	084	November 11, 2003	November 13, 2003
Cleocin Phosphate® Sterile Solution (clindamycin injection, USP)	50-441	048	November 6, 2003	November 7, 2003
Cleocin Phosphate® IV Sterile Solution (clindamycin injection, in 5% dextrose)	50-639	014	November 6, 2003	November 7, 2003

These applications are subject to the exemption provisions contained in section 125(d)(2) of Title I of the FDA Modernization Act of 1997.

These "Changes Being Effected" supplemental new drug applications provide for revised labeling to comply with the Final Rule entitled " Labeling Requirements for Systemic Antimicrobial Drug Products Intended for Human Use" (68FR 6062, February 6, 2003).

We have completed our review of these applications and they are approved effective on the date of this letter.

If you issue a letter communicating important information about these drug products (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to these NDAs and a copy to the following address:

MEDWATCH, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

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 Judit Milstein, Regulatory Project Manager, at (301) 827-2207.

Sincerely,

{See appended electronic signature page}

Janice M. Soreth, MD
Director
Division of Anti-Infective Drug Products
Office of Drug Evaluation IV
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/

Janice Soreth

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