DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 50-162/S-085 **SUPPLEMENT APPROVAL**

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

Dear Ms. Curran:

Please refer to your supplemental new drug application dated August 31, 2007, received August 31, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for CLEOCIN HCL® (clindamycin hydrochloride capsules, USP).

This "Changes Being Effected" supplemental new drug application provides for changes to the **BOXED WARNING, WARNING** and **PRECAUTIONS** sections of the package insert with regard to *Clostridium difficile* associated disease. These changes were requested by the Agency in a letter to you dated March 15, 2007.

We have completed our review of this application, and it is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed upon labeling text, which is identical to the content of labeling [21 CFR 314.50(l)(1)(i)] in structured product labeling (SPL) format submitted on August 31, 2007.

If you 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 an electronic copy of the letter to both this NDA and to the following address:

MedWatch
Food and Drug Administration
5600 Fishers Lane, Room 12B05
Rockville, MD 20857

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}

Katherine A. Laessig, MD
Deputy Director
Division of Anti-Infective and Ophthalmology Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

Enclosure: Content of Labeling

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-50162	SUPPL-85	PHARMACIA AND UPJOHN CO	CLEOCIN HCL

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

/s/

KATHERINE A LAESSIG
11/20/2009