DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 50-441/S-055
50-639/S-016

Pfizer Global Pharmaceuticals
Attention: Beatrice A. Curran
Associate Director
World Wide Regulatory Strategy
235 East 42nd Street
New York, NY 10017

Dear Ms. Curran:

Please refer to your supplemental new drug applications dated November 14, 2007, received November 15, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Cleocin Phosphate (clindamycin injection) Sterile Solution, USP and Cleocin Phosphate (clindamycin injection in 5% dextrose) IV Sterile Solution.

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 the correction of minor typographical errors in the package inserts, as well as meta data corrections to the structured product labeling (SPL) for Cleocin Phosphate.

We completed our review of these applications, as amended. These applications are approved, effective on the date of this letter, for use as recommended in the content of labeling [21 CFR 314.50(1)] in structured product labeling (SPL) format submitted on January 19, 2007.

You are responsible for assuring that the wording in the final printed labeling (FPL) is identical to that of the approved content of labeling in the structured product labeling (SPL) format.

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

MEDWATCH
Food and Drug Administration
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

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, Regulatory Project Manager, at (301) 796-0702.

Sincerely,

{See appended electronic signature page}

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

Enclosure: Labeling submitted on November 14, 2007

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

/s/

Kathrine Laessig

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