DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 50-162/S-082
NDA 50-441/S-045
NDA 50-639/S-013

Pfizer, Inc
Attention: Pritpal Nijjar
Regulatory Manager
235 East 42nd Street
New York, NY 10017

Dear Ms. Nijjar:

Please refer to your supplemental new drug applications submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for:

a. Cleocin HCl® (clindamycin hydrochloride, USP) Capsules
(NDA 50-162/S-082), dated December 8, 1998, received December 10, 1998.

b. Cleocin Phosphate® (clindamycin injection, USP) Sterile Solution
(NDA 50-441/S-045), dated November 25, 1998, received November 30, 1998, and

c. Cleocin Phosphate® (clindamycin injection in 5% dextrose) IV Sterile Solution
(NDA 50-639/S-013), dated November 25, 1998, received November 30, 1998.

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

We acknowledge receipt of your submissions dated June 5, 2002 (NDA 50-162), December 19, 2002 (NDA 50-162, NDA 50-441, and NDA 50-639), January 22, 2004 (NDA 50-162, NDA 50-441, and NDA 50-639) and September 7, 2004 (NDA 50-441 and NDA 50-639).

Your submissions of January 22, 2004 constituted a complete response to our June 20, 2003 action letter.

These supplemental new drug applications provide for changes to the **Microbiology** subsection in response to the Agency's January 26, 1993 letter to "All NDA Holders", revisions to the **SUSCEPTIBILITY TESTING METHODS** section, and an updated **REFERENCES** section.

Additionally, these supplements provide for the following editorial revisions:

1. In the **CLINICAL PHARMACOLOGY** section, **Microbiology** subsection, the last sentence of the third paragraph has been revised to read "…established in adequate and well controlled clinical trials".

2. In the **SUSCEPTIBILITY TESTING METHODS**, **Dilution Techniques** subsection the reference for anaerobic testing methods has been added to the sentence that begin "Standardized procedures are based on…."

3. In the INDICATIONS AND USAGE section, the In Vitro Susceptibility Testing subsection has been removed and the contents placed under **SUSCEPTIBILITY TESTING METHODS**.

4. Additionally, minor punctuation revisions have been made in the **REFERENCES** section and the footnotes in **Tables 1**, **2**, and **3** have been revised for consistency.

We completed our review of these supplemental new drug applications, as amended, They are approved, effective on the date of this letter, for use as recommended in the final printed labelings (FPL's) submitted on January 22, 2004.

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 J. Christopher Davi, Regulatory Project Manager, at (301) 827-2125.

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

Enclosures:
Attachment 1: FPL 50-162/S-082
Attachment 2: FPL 50-441/S-045
Attachment 3: FPL 50-639/S-013

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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