DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 50-639/S-027
NDA 50-639/S-028
NDA 50-639/S-029

SUPPLEMENT APPROVALS

Pharmacia and Upjohn Company
c/o Pfizer, Inc.
Attention: Mikhail Abarshalin
Senior Manager, Worldwide Safety & Regulatory
235 East 42nd Street
New York, NY 10017

Dear Mr. Abarshalin:

Please refer to your Supplemental New Drug Applications (sNDAs) dated October 14 (S-027), December 6 (S-028) and 18 (S-029), 2013, received October 15, December 6 and 18, respectively, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for CLEOCIN PHOSPHATE (clindamycin phosphate in 5% dextrose) Sterile Solution, 300 mg/50 mL, 600 mg/50 mL and 900 mg/50 mL.

We also acknowledge receipt of your amendments dated November 12, 2013 (S-027), and February 6 (S-027, S-028 and S-029), and April 16, 2014 (S-027).

These "Changes Being Effected" supplemental new drug applications provide for the following:

- **S-027:** Revisions to the **PRECAUTIONS** section, **Pregnancy** subsection, **ADVERSE REACTIONS** section, **Hypersensitivity Reactions and Immune System** subsections, as well as revisions to the **DOSAGE AND ADMINISTRATION** section, to include clarifying language on diluted use for IV administration.

- **S-028:** Revisions to the **ADVERSE REACTIONS** section regarding toxic epidermal necrolysis, esophageal ulcer, and injection site irritation.

- **S-029:** The addition of Benzyl Alcohol excipient language in the **WARNINGS** section.

In addition, a new warning regarding severe skin reactions has been added to the **WARNINGS** section.

APPROVAL & LABELING

We have completed our review of these supplemental applications, as amended, and they are approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text and with the following editorial revisions/updates (underlined) to the **REFERENCES** Section:

1. Smith RB, Phillips JP: Evaluation of CLEOCIN HCl and CLEOCIN Phosphate in an Aged Population. Upjohn TR 8147-82-9122-021, December 1982.
2. CLSI. *Performance Standards for Antimicrobial Susceptibility Testing: Twenty-fourth Informational Supplement*. CLSI document M 100-S24. Wayne, PA: Clinical and Laboratory Standards Institute; 2014.
3. CLSI. *Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria that Grow Aerobically; Approved Standard* – Ninth Edition. CLSI document M07-A9. Wayne, PA: Clinical and Laboratory Standards Institute; 2012.
4. CLSI. *Performance Standards for Antimicrobial Disk Susceptibility Tests*; *Approved Standard - Eleventh Edition*. CLSI document M02-A11. Wayne, PA: Clinical and Laboratory Standards Institute; 2012.
5. CLSI. *Methods for Antimicrobial Susceptibility Testing of Anaerobic Bacteria; Approved Standard-Eighth Edition*. CLSI document M11-A8. Wayne, PA: Clinical and Laboratory Standards Institute; 2012.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at:

http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm.

Content of labeling must be identical to the enclosed labeling, including the minor revisions listed above, with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eList may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As at:

http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that includes labeling changes for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

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
Director
Division of Anti-Infective Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

ENCLOSURE: Content of Labeling

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
06/25/2014