DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 50-441/S-081
NDA 50-639/S-040

SUPPLEMENT APPROVALS

Pharmacia & Upjohn, a subsidiary of Pfizer, Inc.
Attention: Mikhail Abarshalin
Senior Manager, Pfizer Global Regulatory Affairs
235 East 42nd Street
New York, NY 10017-7555

Dear Mr. Abarshalin:

Please refer to your Supplemental New Drug Applications (sNDAs) dated September 11, 2018, received September 11, 2018, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for the following:

- **NDA 50-441/S-081:** Cleocin Phosphate (clindamycin injection, USP)
- **NDA 50-639/S-040:** Cleocin Phosphate (clindamycin injection in 5% dextrose) Solution in GALAXY plastic containers

These "Changes Being Effected" supplemental new drug applications provide for revised language in the **PRECAUTIONS** section, **Nursing Mothers** subsection of the package insert to provide accurate information as it relates to concentration of clindamycin excreted in human breast milk after systemic administration.

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.

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, 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 include labeling changes for these NDAs, 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 Microsoft Word format, that includes the changes approved in these supplemental applications, as well as annual reportable changes. To facilitate review of your submission(s), provide a highlighted marked-up copies that show all changes, as well as clean Microsoft Word versions. The marked-up copies 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}

Dmitri Iarikov, MD, PhD
Deputy 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. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

DMITRI IARIKOV
06/19/2019 10:46:52 AM