DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 50-441/S-071
NDA 50-639/S-031

SUPPLEMENT APPROVALS

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

Dear Mr. Abarshalin:

Please refer to your Supplemental New Drug Applications (sNDAs) dated November 12, 2015, received November 12, 2015 and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for the following:

- **NDA 50-441/S-071:** Cleocin Phosphate (clindamycin injection, USP)
- **NDA 50-639/S-031:** Cleocin Phosphate IV (clindamycin injection in 5% dextrose) Solution in GALAXY plastic containers

These "Prior Approval" supplemental new drug applications provide for revisions to the **Microbiology** subsection and the **REFERENCES** section of the package insert, submitted in response to our September 9, 2015, supplement request letter. In addition, a statement regarding unpleasant or metallic taste has been added to the **ADVERSE REACTIONS** section.

APPROVAL & LABELING

We have completed our review of these supplemental applications. 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 includes 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 MS Word format, that includes the changes approved in these supplemental applications, as well as annual reportable changes and annotate each change. To facilitate the review of your submissions, provide highlighted or 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 approved NDAs (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/

JOSEPH G TOERNER
03/24/2016