



NDA 50-162/S-098 & S-099

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 February 13, 2017 (S-098), and March 3, 2017 (S-099), received February 13, 2017, and March 3, 2017, respectively, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Cleocin HCl (clindamycin hydrochloride, USP) Capsules.

The “Changes Being Effected” (S-098) and Prior Approval (S-099) supplemental new drug applications provided for the following:

- **S-098:** Updates to the **CLINICAL PHARMACOLOGY, Metabolism** subsection and the **PRECAUTIONS, Drug Interactions** subsection, to add new text related to the drug interaction between clindamycin and cytochrome P450 (CYP) 3A4 inducers. Additionally, the **DOSAGE AND ADMINISTRATION, Pediatric Patients** subsection, was revised to add a clarification statement on the administration of clindamycin capsules to children who are unable to swallow them whole.
- **S-099:** Updates to the **PRECAUTIONS, Pregnancy** and **Nursing Mothers** subsections of the package insert to include the removal of Pregnancy category B and revisions necessary to align product labeling with current Pregnancy and Lactation Labeling final rule requirements, as requested in the Agency’s December 8, 2016, Prior Approval Supplement request letter.

APPROVAL & LABELING

We have completed our review of these supplemental applications 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, submitted on April 28, 2017, with the addition of any labeling changes in pending “Changes Being Effectuated” (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 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
05/02/2017