DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 050680/S-011
NDA 050767/S-012

SUPPLEMENT APPROVAL

Pharmacia & Upjohn
A subsidiary of 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 February 4, 2015, received February 4, 2015, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for CLEOCIN (clindamycin phosphate, USP) Vaginal Cream (NDA 050680) and CLEOCIN (clindamycin phosphate vaginal suppositories) Vaginal Ovules (NDA 050767).

We acknowledge receipt of your amendment dated June 12, 2015.

These Prior Approval supplemental new drug applications propose the addition of Pseudomembranous Colitis to the list of ADVERSE REACTIONS in the United States Prescribing Information (USPI) and addition of clarifying information to the Drug Interactions section of the USPI.

APPROVAL & LABELING

We have completed our review of these supplemental applications, as amended. 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 (text for the package insert), 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 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 numbers and annual report dates.

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 Jane A. Dean, RN, MSN, Regulatory Health Project Manager, at (301) 796-1202.

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(S):
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
07/13/2015