DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 050680/S-013
NDA 050767/S-014

SUPPLEMENT APPROVAL

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

Dear Mr. Abarshalin:

Please refer to your supplemental New Drug Applications (sNDAs) dated and received July 6, 2017, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for the following:

NDA NUMBER	PRODUCT NAME
NDA 050680/S-013	Cleocin T (clindamycin phosphate, USP) Vaginal Cream, 2%
NDA 050767/S-014	Cleocin T (clindamycin phosphate vaginal suppositories) Vaginal Ovules, 100 mg

These supplemental applications, submitted as a "Changes Being Effected" supplements, provide for 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.

We have completed our review of these applications. They are approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

LABELING

Submit final printed labeling as soon as they are available, but no more than 30 days after they are printed. The final printed labeling (FPL) must be identical to the enclosed labeling (package insert) and submitted labeling (package insert submitted July 6, 2017), and must be in the "Drug Facts" format (21 CFR 201.66), where applicable.

The final printed labeling should be submitted electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (May 2015, Revision 3).* For administrative purposes, designate this submission "**Final Printed Labeling for approved NDA 050680/S-013 and NDA 050767/S-014.**" Approval of this submission by FDA is not required before the labeling is used.

DRUG REGISTRATION AND LISTING

All drug establishment registration and drug listing information is to be submitted to FDA electronically, via the FDA automated system for processing structured product labeling (SPL) files (eLIST). At the time that you submit your final printed labeling (FPL), the content of labeling (Drug Facts) should be submitted in SPL format as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. 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/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf. In addition, representative container or carton labeling, whichever includes Drug Facts, (where differences exist only in the quantity of contents statement) should be submitted as a JPG file.

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}

Dmitri Iarikov, MD, PhD
Acting 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 and this page is the manifestation of the electronic signature.

/s/

DMITRI IARIKOV
09/08/2017