DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 50-680/S-004

Pharmacia & Upjohn Company
Attention: Robert S. Gremban
Regulatory Manager
7000 Portage Rd
Kalamazoo, MI 49001

Dear Mr. Gremban:

Please refer to your supplemental new drug application dated March 6, 2003, received March 7, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for CLEOCIN ® (clindamycin phosphate vaginal cream, USP).

We acknowledge the receipt of your submissions dated April 11, 2003.

This supplemental new drug application provides for the addition of a **Geriatric Use** subsection at the end of the **PRECAUTIONS** section of the package insert in accordance with the August 27, 1997 final rule and 21 CFR 201.57(f)(10). Additions are double underlined.

> **Geriatric Use**
> Clinical studies for CLEOCIN Vaginal Cream 2% did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients.

We have completed the review of this supplemental application and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon labeling text (enclosed). Accordingly, the supplemental application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the enclosed draft labeling (text for the package insert submitted April 11, 2003).

Please submit copies of the final printed labeling (FPL) electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). Please submit a Microsoft Word version of the FPL in the same submission with the PDF version. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Please individually mount ten of the copies on heavyweight paper or similar material. For administrative purposes, this submission should be

designated “FPL for approved supplement NDA 50-680/S-004." Approval of this submission by FDA is not required before the labeling is used.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, please call Christine Lincoln, RN, M.S., MBA, Labeling Reviewer, at (301) 827-2127.

Sincerely,

{See appended electronic signature page}

Renata Albrecht, M.D.
Director
Division of Special Pathogen and
Immunologic Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Steven Gitterman

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