# CENTER FOR DRUG EVALUATION AND RESEARCH

**Approval Package for:**

**Application Number: 050680/S002**

**Trade Name: CLEOCIN 3 VAGINAL CREAM**

**Generic Name: CLINDAMYCIN PHOSPHATE VAGINAL CREAM, USP (2%)**

**Sponsor: PHARMACIA & UPJOHN**

**Approval Date: 3/2/98**

**Indication(s): TREATMENT OF BACTERIAL VAGINOSIS**

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## APPLICATION:

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| | Included | Pending Completion | Not Prepared | Not Required |
|---|---|---|---|---|
| Approval Letter | X | | | |
| Tenative Approval Letter | | | | X |
| Approvable Letter | | | | X |
| Final Printed Labeling | | X | | |
| Medical Review(s) | X | | | |
| Chemistry Review(s) | | | | X |
| EA/FONSI | | | | X |
| Pharmacology Review(s) | X | | | |
| Statistical Review(s) | X | | | |
| Microbiology Review(s) | X | | | |
| Clinical Pharmacology/ Biopharmaceutics Review(s) | X | | | |
| Bioequivalence Review(s) | | | | X |
| Administrative Document(s)/ Correspondence | X | | | |

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**Application Number: 050680/S002**

# APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

MAR 2 1998

NDA 50-680/S-002

Pharmacia & Upjohn
7000 Portage Road
Kalamazoo, MI 49001-0199

Attention: Donald R. Gieseker, Pharm.D.
Associate Director
U.S. Regulatory Affairs

Dear Dr. Gieseker:

We acknowledge your supplemental new drug application dated August 28, 1997, received September 2, 1997, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Cleocin$^{R}$ 3 Vaginal Cream, clindamycin phosphate vaginal cream, USP (2%). We note that this application is subject to the exemption provisions contained in section 125 (d)(2) of Title 1 of the FDA Modernization Act of 1997.

We also acknowledge receipt of your amendments and correspondences dated December 17, 1997, January 30, February 5, and February 27, 1998, as well as your fascimile dated March 2, 1998.

This supplemental application provides for a 3-day dosing regimen of 2% clindamycin phosphate vaginal cream in the treatment of bacterial vaginosis.

We have completed the review of this supplemental application including the submitted draft labeling, 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 draft labeling dated March 2, 1998. Accordingly, the supplemental application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the faxed draft labeling dated March 2, 1998.

Please submit 20 copies of the FPL as soon as they are available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FINAL PRINTED LABELING" for approved supplemental NDA 50-680/S-002. Approval of this submission by FDA is not required before the labeling is used.

Should additional information relating to the safety and effectiveness of the drug product become available, revision of the labeling may be required.

In addition, please submit three copies of the introductory promotional material that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to the Division of Special Pathogen and Immunologic Drug Products and two copies of both the promotional material and the package insert directly to:

Food and Drug Administration
Division of Drug Marketing, Advertising and Communications, HFD-40
5600 Fishers Lane
Rockville, Maryland 20857

Should a letter communicating important information about this drug product (i.e., a "Dear Doctor" letter) be 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 20852-9787

Please submit one market package of the drug product when it is available.

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 contact:
Christina H. Chi, Ph.D.,
Project Manager,
at (301) 827-2125.

Sincerely yours,

/S/

Mark J. Goldberger, M.D., M.P.H.
Director
Division of Special Pathogen and Immunologic Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research