AUG 13 1999

NDA 50-767

Pharmacia & Upjohn
Attention: Carl M. DeJuliis, M.S., R.Ph.
Regulatory Manager
7000 Portage Road
Kalamazoo, MI 49001-0199

Dear Mr. DeJuliis:

Please refer to your new drug application dated October 13, 1998, received October 14, 1998, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act, for Cleocin® Vaginal Ovules (clindamycin phosphate vaginal suppositories), 100 mg. We note that this application is subject to the exemption provisions contained in section 125(d)(2) of Title I of the FDA Modernization Act of 1997.

We acknowledge receipt of your submissions and amendments dated:

January 21, 1999	July 13, 1999	July 26, 1999 (2)	August 6, 1999
March 22, 1999	July 20, 1999	July 27, 1999	August 10, 1999
May 12, 1999	July 21, 1999	August 5, 1999	August 13, 1999
July 8, 1999			

This new drug application provides for the use of Cleocin® Vaginal Ovules (clindamycin phosphate vaginal suppositories), 100 mg, for the treatment of bacterial vaginosis.

We have completed the review of this application, as amended, and we 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. (See attached.) Accordingly, the application is approved, effective on the date of this letter.

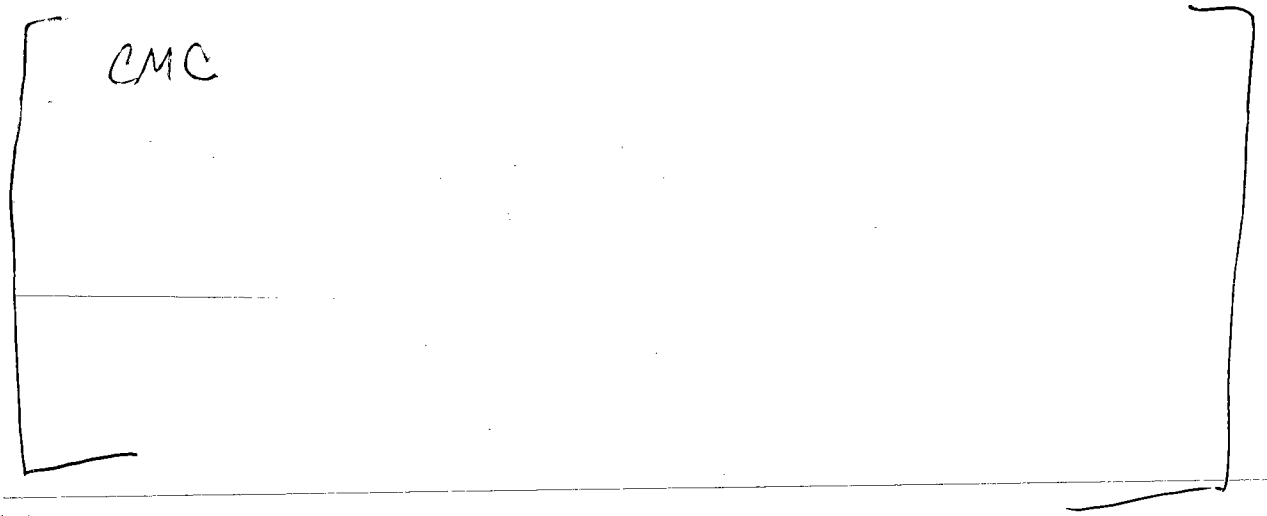
The final printed labeling (FPL) must be identical to the submitted draft labeling (text for the package insert, text for the patient instruction, the immediate container of the ovule, and carton labels submitted August 13, 1999). Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Please submit 20 copies of the FPL as soon as it is 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 "FPL for approved NDA 50-767." 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 become available, revision of that labeling may be required.

We remind you of your Phase 4 commitments specified in your submissions dated August 6, and August 10, 1999. These commitments, along with any completion date agreed upon, are listed below:

1. Pharmacia and Upjohn (PNU) will study the effects of clindamycin phosphate on embryofetal development in rats, and rabbits (if feasible), with protocols that comply with Good Laboratory Practices (GLP). Results from preliminary dose-range (non-GLP) studies, as well as protocols for the definitive (GLP) studies, will be submitted to the CDER reviewing Division for concurrence on issues of dose-selection and general scientific content. PNU commits to completion and submission of study reports from the definitive (GLP) studies to FDA by October 1, 2000.



Validation of the regulatory methods has not been completed. At the present time, it is the policy of the Center not to withhold approval because the methods are being validated. Nevertheless, we expect your continued cooperation to resolve any problems that may be identified.

Be advised that, as of April 1, 1999, all applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred (63 FR 66632). We are waiving the pediatric study requirement for this application, because the Agency believes adult clinical trial data can be extrapolated to demonstrate safety and effectiveness in postmenarchal girls, and it is unlikely that premenarchal girls would need to use this medication.

In addition, please submit three copies of the introductory promotional materials 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 this Division and two copies of both the promotional materials and the package insert directly to:

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

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. In addition, we remind you of 21 CFR 201.56 (b) which states that labeling shall not be promotional in tone.

If you have any questions, please contact:

Christina H. Chi, Ph.D.,
Regulatory Project Manager,
at (301) 827-2127.

Sincerely yours,

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

Enclosure: 8 pages (labeling).