DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 11-839/S-068

Pharmacia & Upjohn
Attention: Donald R. Gieseker, Pharm. D.
Associate Director, Regulatory Affairs
7000 Portage Road
Kalamazoo, MI 49001-0199

AUG 04 1998

Dear Dr. Gieseker:

Please refer to your supplemental new drug application dated July 31, 1997, received August 4, 1997, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Provera (medroxyprogesterone acetate) 5mg and 10mg tablets.

We acknowledge receipt of your submissions dated September 2, 1997, and January 8, June 29, July 22 and August 3, 1998. The user fee goal date for this application is August 4, 1998.

This supplemental new drug application provides for the use of Provera® for the reduction of endometrial hyperplasia in postmenopausal women receiving 0.625mg conjugated estrogens for 12 to 14 consecutive days per month, either beginning on the 1st day of the cycle or the 16th day of the cycle.

We have completed the review of this supplemental application, as amended, 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. Accordingly, the supplemental application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the submitted draft labeling (package insert and container and carton labels dated August 3, 1998). 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 supplement NDA 11-839/S-068." Approval of this submission by FDA is not required before the labeling is used.

If additional information relating to the safety or effectiveness of this drug becomes available before we receive the final printed labeling, revision of that labeling may be required.

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

If a letter communicating important information about this drug product (i.e., a "Dear Healthcare Practitioner" 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

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, contact John C. Markow, Project Manager, at (301) 827-4260.

Sincerely,

8/4/97

Lisa D. Rarick, M.D.
Director
Division of Reproductive and Urologic Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research