CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number: NDA 20-756

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-756

MAY 13 1997

Columbia Research Laboratories, Inc.
Attention: Howard Levine, Pharm. D.
Vice President
100 N. Village Avenue
Rockville Centre, NY 11570

Dear Dr. Levine:

Please refer to your new drug application dated November 13, 1996, received November 13, 1996, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Crinone® (progesterone gel).

The User Fee goal date for this application is May 13, 1997.

This new drug application provides for progesterone supplementation or replacement as part of an Assisted Reproductive Technology (ART) treatment for infertile women with progesterone deficiency.

We further refer to your amendments dated April 14, May 3, 5, 6(2), 7, 9, 12(3), and May 13, 1997.

We have completed the review of this 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 in the submissions dated May 6 (carton and container labels), May 12 (Patient Package Insert), and May 13 (Physician Package Insert), 1997. Accordingly, the application is approved effective on the date of this letter.

Please submit 20 copies of the FPL as soon as it is available, and 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 NDA 20-756. 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 commitment to submit the final study report from your treatment IND, as specified in your submission dated May 13, 1997.

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.

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, and not in final print form.

Please submit one copy to this Division 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

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 Diane Moore, Consumer Safety Officer, at (301) 827-4260.

Sincerely,

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