DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-860

JUL 13 1998

Berlex Laboratories
Attention: Ms. Nancy Velez
Manager, Drug Regulatory Affairs
340 Cambridge Road
P.O. Box 1000
Montville, NJ 07045-1000

Dear Ms. Velez:

Please refer to your new drug application (NDA) dated June 13, 1997, received June 13, 1997, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Levlite™ (levonorgestrel 0.100 mg and ethinyl estradiol 0.020 mg) Tablets.

We acknowledge receipt of your submissions dated August 15, October 9 and 31 (2), December 5, 12, and 23, 1997; March 4, April 2 and 28, May 6, 21 and 26, June 2, 17 and 29, and 30, and July 2, 6, 9, and 10, 1998. Your submission of May 26, 1998, extended the user fee goal date for this application to September 13, 1998.

This new drug application provides for the use of Levlite™ (levonorgestrel 0.100 mg and ethinyl estradiol 0.020 mg) Tablets for the prevention of pregnancy.

We have completed the review of this 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 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, patient package insert and brief patient insert dated June 30, 1998, and immediate container and carton labels dated July 10, 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 NDA 20-860." Approval of this submission by FDA is not required before the labeling is used.

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 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.

If you have any questions, contact Christina Kish, Project Manager, 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