NDA 20-992/S-011

Barr Laboratories, Inc.
Attention: John R. Rapoza, M.S., R.Ph.
Sr. Vice President, Regulatory Affairs
5040 Lester Road
Cincinnati, OH 45213

Dear Mr. Rapoza:

Please refer to your supplemental new drug application dated October 20, 2000, received October 23, 2000, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Cenestin® (synthetic conjugated estrogens, A) 0.625 mg, 0.9 mg and 1.25 mg Tablets.

This "Changes Being Effected in 30 days" supplemental new drug application provides for a revision of the **WARNNINGS** and **PRECAUTIONS** Sections of the package insert as well as a revision of the **DANGERS OF ESTROGENS** Section of the package insert as requested by the Division in a letter dated August 16, 2000.

We have completed the review of this supplemental application 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 final printed labeling submitted October 20, 2000. Accordingly, this supplemental application is approved effective on the date of this letter.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" 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

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, call Diane Moore, BS, Regulatory Project Manager, at (301) 827-4260.

Sincerely,

{See appended electronic signature page}

Daniel Shames, M.D.
Acting Director
Division of Reproductive and Urologic Drug Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research