CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

20-992/S-016

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-992/S-016

APPROVAL LETTER

Barr Laboratories
Attention: John R. Rapoza
Senoir Vice President, Regulatory Affairs
5040 Duramed Drive
Cincinatti Ohio, 45213

Dear Mr. Rapoza:

Please refer to your supplemental new drug application dated August 16, 2001, received August 17, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Cenestin (synthetic conjugated estrogens, A) tablets.

We acknowledge receipt of your submissions dated August 29 and November 1, 2001, February 21, March 22, May 16, June 3, 6, 10, 17, and 18, 2002.

This supplemental new drug application proposes the use of Cenestin 0.3 mg strength tablet for the treatment of vulvar and vaginal atrophy associated with the menopause.

We have completed the review of this application, as amended, and have concluded that adequate information has been presented to demonstrate that this drug product is safe and effective for use as recommended in the agreed upon labeling text. Accordingly, this 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 submitted June 18, 2002, patient package insert submitted June 18, 2002, immediate container and carton labels submitted August 16, 2001).

Please submit the FPL electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). Alternatively, you may submit 20 paper 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 20-992/S016." Approval of this submission by FDA is not required before the labeling is used.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens must contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred (21 CFR 314.55).

Based on the information submitted, we conclude the following:

For vulvar and vaginal atrophy associated with the menopause, we are waiving the pediatric study requirement for this action for this application for patients in the pediatric population.

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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 Dornette Spell-LeSane, NP-C, Regulatory Project Manager, at (301) 827-4260.

Sincerely,

{See appended electronic signature page}

Daniel Shames
Director
Division of Reproductive and Urologic Drug Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

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This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Daniel A. Shames
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