DEPARTMENT OF HEALTH & HUMAN SERVICES

ANDA 76-785

Food and Drug Administration
Rockville MD 20857

MAY 23 2005

Barr Laboratories, Inc.
Attention: Nicholas Tantillo
Senior Director, Regulatory Affairs
2 Quaker Road
P.O. Box 2900
Pomona, NY 10970

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated June 30, 2003, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Kelnor® 1/35 Tablets (Ethynodiol Diacetate and Ethinyl Estradiol Tablets USP), 1 mg/35 mcg, packaged in 28-day regimens.

Reference is also made to your amendments dated February 2, April 16, August 11, October 12, and November 3, 2004; and January 14, February 11, and May 9, 2005.

We have completed the review of this abbreviated application and have concluded that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly the application is approved. The Division of Bioequivalence has determined your Kelnor® 1/35 Tablets (Ethynodiol Diacetate and Ethinyl Estradiol Tablets USP), 1 mg/35 mcg, to be bioequivalent and, therefore, therapeutically equivalent to the listed drug (Demulen® 1/35-28 Tablets of G.D. Searle, LLC.). Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your application.

Under Section 506A of the Act, certain changes in the conditions described in this abbreviated application require an approved supplemental application before the change may be made.

Post-marketing reporting requirements for this abbreviated application are set forth in 21 CFR 314.80-81 and 314.98. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

Promotional materials may be submitted to FDA for comment prior to publication or dissemination. Please note that these submissions are voluntary. If you desire comments on proposed launch promotional materials with respect to compliance with applicable regulatory requirements, we recommend you submit, in draft or mock-up form, two copies of both the promotional materials and package insert(s) directly to:

Food and Drug Administration
Division of Drug Marketing, Advertising, and Communications, HFD-42
5600 Fishers Lane
Rockville, MD 20857

We call your attention to 21 CFR 314.81(b)(3) which requires that all promotional materials be submitted to the Division of Drug Marketing, Advertising, and Communications (HFD-42) with a completed Form FDA 2253 at the time of their initial use.

Sincerely yours,

Gary Buehler
Director
Office of Generic Drugs
Center for Drug Evaluation and Research