DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 076221

Barr Laboratories, Inc.
Attention: Nicholas Tantillo
Senior Director, Regulatory Affairs
400 Chestnut Ridge Road
Woodcliff Lake, NJ 07677

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated August 13, 2001, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Norethindrone Acetate and Ethinyl Estradiol Tablets USP, 1 mg/0.005 mg.

Reference is also made to the tentative approval letter issued by this office on October 5, 2004, and to your amendments dated April 16, and June 21, 2007; and February 27, July 17, October 9, October 20, and October 30, 2009.

We have completed the review of this ANDA and have concluded that adequate information has been presented to demonstrate that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly the ANDA is approved, effective on the date of this letter. The Division of Bioequivalence has determined your Norethindrone Acetate and Ethinyl Estradiol Tablets USP, 1 mg/0.005 mg, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Femhrt Tablets, 1 mg/0.005 mg, of Warner Chilcott, Inc. Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your ANDA.

The RLD upon which you have based your application, Warner Chilcott's Femhrt, is currently subject to a period of patent protection. As noted in the agency's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book"), U.S. Patent No. 5,208,225 (the '225 patent), is scheduled to expire on May 4, 2010.

Your ANDA contains a paragraph IV certification to the '225 patent under section 505(j)(2)(A)(vii)(IV) of the Act stating that the patent is invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Norethindrone Acetate and Ethinyl Estradiol Tablets USP, 1 mg/0.005 mg, under this ANDA. Section 505(j)(5)(B)(iii) of the Act provides that approval of an ANDA shall be made effective immediately, unless an action is brought against Barr Laboratories, Inc. (Barr) for infringement of the listed '225 patent.

In your September 7, 2004 amendment, you notified the Agency that on May 17, 2004, a settlement agreement was reached between Galen Chemicals Limited (Galen) and Barr in Civil Action No. 01-CV-11214 (CLB) (Pfizer Inc. and Warner-Lambert Company v. Barr Laboratories, Inc.) effectively terminating the patent litigation. As part of the settlement, effective November 4, 2009, Barr was granted a non-exclusive license under the '225 patent. This license permits the agency to approve this ANDA prior to expiration of the '225 patent.

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

We note that if FDA requires a Risk Evaluation & Mitigation Strategy (REMS) for a listed drug, an ANDA citing that listed drug also will be required to have a REMS. See section 505-1(i) of the Act.

Postmarketing reporting requirements for this ANDA 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 directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705

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 with a completed Form FDA 2253 at the time of their initial use.

Within 14 days of the date of this letter, submit updated content of labeling [21 CFR 314.50(1)] in structured product labeling (SPL) format, as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm, that is identical in content to the approved labeling. Upon receipt and verification, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission as ***"Miscellaneous Correspondence – SPL for Approved ANDA 076221".***

Sincerely yours,

{See appended electronic signature page}

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

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
ANDA-76221	ORIG-1	BARR LABORATORIES INC	NORETHINDRONE ACETATE;ETHINYL ESTRADIOL

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

/s/

ROBERT L WEST
11/06/2009
Deputy Director, for Gary Buehler