DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 78-515

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

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated September 28, 2006, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Drospirenone and Ethinyl Estradiol Tablets, 3.0 mg/0.02 mg (28-Day Regimen).

Reference is also made to your amendments dated February 13, 2007; February 26, March 12, March 19, June 16, July 9, and October 31, 2008; and February 10, and March 25, 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 Drospirenone and Ethinyl Estradiol Tablets, 3.0 mg/0.02 mg (28-day regimen) to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Yaz Tablets, 3.0 mg/0.02 mg (28-day regimen) of Bayer Healthcare Pharmaceuticals, Inc. (Bayer). 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 ANDA, Bayer's Yaz Tablets, 3.0 mg/0.02 mg, is subject to periods of patent protection. The following patents with their expiration dates are currently listed in the agency's publication titled Approved

Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book") for this drug product:

U.S. Patent Number	Expiration Date
5,569,652 (the '652 patent)	October 29, 2013
5,798,338 (the '338 patent)	July 10, 2015
6,787,531 (the '531 patent)	August 31, 2020
6,933,395 (the '395 patent)	August 11, 2017
6,958,326 (the '326 patent)	December 20, 2021
6,987,101 (the '101 patent)	December 22, 2017
7,163,931 (the '931 patent)	December 20, 2021
RE37564 (the '564 patent)	June 30, 2014
RE37838 (the '838 patent)	June 30, 2014
RE38253 (the '253 patent)	June 30, 2014

With respect to each of these patents, your ANDA contains paragraph IV certifications under section 505(j)(2)(A)(vii)(IV) of the Act stating that each patent is invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Drospirenone and Ethinyl Estradiol Tablets, 3.0 mg/0.02 mg (28-day regimen), under this ANDA. You have notified the agency that Barr Laboratories, Inc. (Barr) complied with the requirements of section 505(j)(2)(B) of the Act, and that no action for infringement was brought against Barr within the statutory 45-day period, which action would have resulted in a 30-month stay of approval under section 505(j)(5)(B)(iii).

With respect to 180-day generic drug exclusivity, the agency has concluded that that Barr was the first ANDA applicant to submit a substantially complete ANDA with a paragraph IV certification to the '652, '338, '531, '395, '326, '101, '931, '564, '838, and '253 patents. Therefore, with this approval, Barr is eligible for 180 days of generic drug exclusivity for Drospirenone and Ethinyl Estradiol Tablets, 3.0 mg/0.02 mg (28-day regimen). This exclusivity, which is provided for under section 505(j)(5)(B)(iv) of the Act, will begin to run from the date of the commercial marketing identified in section 505(j)(5)(B)(iv). Please submit correspondence to this ANDA informing the agency of the date the exclusivity begins to run.

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/oc/datacouncil/spl.html, 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 78-515".***

Sincerely yours,

{See appended electronic signature page}

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

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
3/30/2009 03:15:22 PM
Deputy Director, for Gary Buehler