DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 77-527

Barr Laboratories, Inc.
Attention: Nicholas Tantillo
Senior Director, Regulatory Affairs
225 Summit Avenue
Montvale, NJ 07645

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated January 6, 2005, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Drospirenone and Ethinyl Estradiol Tablets, 3 mg/0.03 mg, (28-Day Regimen).

Reference is also made to the tentative approval letter issued by this office on September 20, 2007, and to your amendments dated May 25, June 17, and December 22, 2005; April 6, and April 25, 2007; and March 4, March 13, and March 26, 2008.

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 mg/0.03 mg, (28-day regimen) to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Yasmin Tablets, 3 mg/0.03 mg of Bayer Healthcare Pharmaceuticals, 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 ANDA, Bayer's Yasmin Tablets, 3 mg/0.03 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
6,787,531 (the '531 patent)	August 31, 2020
6,933,395 (the '395 patent)	August 11, 2017

Your ANDA contains paragraph IV patent certifications under section 505(j)(2)(A)(vii)(IV) of the Act stating that each of these listed patents is invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Drospirenone and Ethinyl Estradiol Tablets, 3 mg/0.03 mg, (28-day regimen), 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 was brought against Barr Laboratories, Inc. (Barr) for infringement of one or more of these patents that were the subjects of the paragraph IV certifications. You have notified the agency that Barr complied with the requirements of section 505(j)(2)(B) of the Act, and that litigation for infringement of the '531 patent was brought against Barr within the statutory 45-day period in the United States District Court for the District Court of New Jersey [Schering AG and Berlex Inc. v. Barr Laboratories, Inc., Civil Action No. 05-CV-02308-JLL-BJH]. You have also notified the agency that the court declared the asserted claims of the '531 patent invalid. No litigation for infringement was brought against Barr within the 45-day period for the '652 or '395 patents.

With respect to 180-day generic drug exclusivity for Drospirenone and Ethinyl Estradiol Tablets, 3 mg/0.03 mg, (28-day regimen), the agency has concluded that Barr was the first ANDA applicant to submit a substantially complete ANDA for Drospirenone and Ethinyl Estradiol Tablets, 3 mg/0.03 mg, (28-day regimen), with a paragraph IV certification to the three patents listed above. Therefore, with this approval, Barr may be eligible for 180 days of generic drug exclusivity for Drospirenone and Ethinyl Estradiol Tablets, 3 mg/0.03 mg, (28-day regimen). Generic drug exclusivity, which is provided for under section 505(j)(5)(B)(iv) of the Act, begins to run from the date of commercial marketing identified in section 505(j)(5)(B)(iv). Please submit correspondence to this ANDA informing the agency of the date commercial marketing begins. The agency notes that Barr failed to obtain tentative approval of this ANDA within 30-months after the date on which the ANDA was filed. See section 505(j)(5)(D)(i)(IV) of the Act. However, the agency is not making a formal determination at this time of Barr's eligibility for 180-day generic drug exclusivity.

It will do so only if another applicant becomes eligible for approval of the same drug product within 180 days after Barr begins commercial marketing of Drospirenone and Ethinyl Estradiol Tablets, 3 mg/0.03 mg, (28-day regimen).

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.

Sincerely yours,

{See appended electronic signature page}

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