DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 078965

Barr Laboratories, Inc.
Attention: Robert Vincent
Senior Director, Regulatory Affairs
400 Chestnut Ridge
Woodcliff Lake, NJ 07677

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated April 26, 2007, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Norethindrone and Ethinyl Estradiol Tablets USP (Chewable), 0.4 mg/0.035 mg and Ferrous Fumarate Tablets USP (Chewable), 75 mg (28-Day Regimen).

Reference is also made to your amendments dated June 30, 2008; January 16, April 22, August 17, October 22, and November 9, 2009; and March 29, 2010. We also acknowledge receipt of your correspondence dated August 24, and October 26, 2009; and May 21, 2010, pertaining to the patent issues associated with this ANDA.

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 and Ethinyl Estradiol Tablets USP (Chewable), 0.4 mg/0.035 mg and Ferrous Fumarate Tablets USP (Chewable), 75 mg (28-Day Regimen) to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Femcon Fe Chewable Tablets, 0.4 mg/0.035 mg and Ferrous Fumarate Tablets, 75 mg (28-Day Regimen) of Warner Chilcott, Inc. (Warner Chilcott). 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, Warner Chilcott's Femcon Fe Chewable Tablets, is 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. 6,667,050 (the '050 patent), is scheduled to expire on April 6, 2019.

Your ANDA contains a paragraph IV certification under section 505(j)(2)(A)(vii)(IV) of the Act stating that the '050 patent is invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Norethindrone and Ethinyl Estradiol Tablets USP (Chewable), 0.4 mg/0.035 mg and Ferrous Fumarate Tablets USP (Chewable), 75 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 the listed '050 patent. 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 '050 patent was brought against Barr within the statutory 45-day period in the United States District Court for the District of New Jersey [Warner Chilcott Company, Inc. v. Barr Laboratories, Inc., Civil Action No. 07-cv-04560]. You have also notified the agency that the case was dismissed; therefore, under section 505(j)(5)(B)(iii) your ANDA is eligible for approval.

With respect to 180-day generic drug exclusivity, the agency has determined that Barr was the first ANDA applicant to submit a substantially complete ANDA with a paragraph IV certification to the '050 patent. Therefore, with this approval, Barr is eligible for 180 days of generic drug exclusivity for Norethindrone and Ethinyl Estradiol Tablets USP (Chewable), 0.4 mg/0.035 mg and Ferrous Fumarate Tablets USP (Chewable), 75 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.

Please 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.

As soon as possible, but no later than 14 days from the date of this letter, please submit, using the FDA automated drug registration and listing system (eLIST), the 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 (including the package insert, and any patient package insert and/or Medication Guide that may be required). Information on submitting SPL files using eLIST may be found in the guidance for industry titled “SPL Standard for Content of Labeling – Technical Qs and As” at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/U_CM72392.pdf

The SPL will be accessible via publicly available labeling repositories.

Sincerely yours,

{See appended electronic signature page}

Keith Webber, Ph.D.
Deputy Director
Office of Pharmaceutical Science
Center for Drug Evaluation and Research