DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 76-784

Barr Laboratories, Inc.
Attention: Nicholas C. 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 Tri Lo Sprintec Tablets (Norgestimate and Ethinyl Estradiol Tablets, USP), 0.180 mg/0.025 mg, 0.215 mg/0.025 mg and 0.250 mg/0.025 mg (28 day).

Reference is also made to your amendments dated March 9, April 30, and June 11, 2004; November 17, and December 6, 2005; August 1, 2006; April 10, and April 27, 2007; November 14, 2008; and January 5, May 22, June 5, and June 29, 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 Norgestimate and Ethinyl Estradiol Tablets USP, 0.180 mg/0.025 mg, 0.215 mg/0.025 mg and 0.250 mg/0.025 mg (28 day) to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Ortho Tri-Cyclen Lo (Norgestimate and Ethinyl Estradiol) Tablets USP, 0.180 mg/0.025 mg, 0.215 mg/0.025 mg and 0.250 mg/0.025 mg (28 day) of Ortho-McNeil Janssen Pharmaceuticals, Inc. (Ortho-McNeil). 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, Ortho-McNeil's Ortho Tri-Cyclen Lo (Norgestimate and Ethinyl Estradiol) Tablets USP, 0.180 mg/0.025 mg, 0.215 mg/0.025 mg and 0.250 mg/0.025 mg (28 day), 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. 6,214,815 (the '815 patent) is scheduled to expire on December 9, 2019 (with pediatric exclusivity added).

Your ANDA contains a paragraph IV certification under section 505(j)(2)(A)(vii)(IV) of the Act stating that the '815 patent is invalid, unenforceable, or will not be infringed by your manufacture, use or sale of Norgestimate and Ethinyl Estradiol Tablets USP, 0.180 mg/0.025 mg, 0.215 mg/0.025 mg and 0.250 mg/0.025 mg (28 day) 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 '815 patent. You have notified the agency that Barr complied with the requirements of section 505(j)(5)(B) of the Act and that litigation for infringement of the '815 patent was brought against Barr within the statutory 45-day period in the United States District Court for the District of New Jersey [Ortho McNeil Pharmaceutical Inc. and Johnson and Johnson Pharmaceutical Research and Development, LLC v. Barr Laboratories, Inc., Civil Action No. 03-CV-4678-C]. Although this litigation remains ongoing, the 30-month period identified in section 505(j)(5)(B)(iii) of the Act, during which time FDA was precluded from approving your ANDA, has expired.

With respect to 180-day generic drug exclusivity, we note that Barr was the first ANDA applicant to submit a substantially complete ANDA with a paragraph IV certification to the '815 patent. Therefore, with this approval, Barr is eligible for 180 days of generic drug exclusivity for Norgestimate and Ethinyl Estradiol Tablets USP, 0.180 mg/0.025 mg, 0.215 mg/0.025 mg and 0.250 mg/0.025 mg (28 day). This exclusivity, which is provided for under section 505(j)(5)(B)(iv) of the Act, will begin to run from the earlier of the court decision or commercial marketing dates identified in section 505(j)(5)(B)(iv).[1] 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.

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[1] Because your ANDA was filed before the date of enactment of the Medicare Prescription Drug, Improvement and Modernization Act (MMA) (Public Law 108-173) on December 8, 2003, this reference to the 180-day exclusivity provision is to the section of the Act as in effect prior to December 8, 2003. See MMA § 1102(B)(1).

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 76-784".***

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/

Gary Buehler

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