ANDA 078515

**ANDA APPROVAL**

Barr Laboratories, Inc. (an indirect, wholly owned subsidiary of Teva Pharmaceuticals USA)
2945 West Corporate Lakes Blvd Suite B
Weston, NJ 33331
Attention: Janet Vaughn
Vice President, Regulatory Affairs

Dear Madam:

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 the approval letter issued on March 30, 2009. This corrected letter is being issued because we recently discovered that the March 30, 2009 approval letter incorrectly stated that Barr Laboratories, Inc. (Barr) was eligible for 180-day exclusivity. We note that you did not obtain approval or tentative approval within 30 months after the date on which the ANDA was filed. See section 505(j)(5)(D)(i)(IV) of the Act. FDA had not made a determination at the time of the March 30, 2009 letter regarding whether you had forfeited eligibility for 180-day exclusivity or retained it. However, commercial marketing of this drug commenced on June 1, 2010, and more than 180 days have elapsed since the first commercial marketing date. During that time, FDA did not have occasion to consider whether a forfeiture of eligibility for 180-day exclusivity may have occurred. If you retained eligibility for 180-day exclusivity, that period has run. This letter supersedes our March 30, 2009 approval letter. The action date for the approval letter remains unchanged as March 30, 2009, and the remainder of this letter addresses the topics as they should have been addressed in the approval letter dated March 30, 2009.

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 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 for Drospirenone and Ethinyl Estradiol Tablets, 3.0 mg/0.02 mg (28-Day Regimen), Barr was the first ANDA applicant to submit a substantially complete ANDA for Drospirenone and Ethinyl Estradiol Tablets, 3.0 mg/0.02 mg (28-Day Regimen), with a paragraph IV certification to the '652, '338, '531, '395, '326, '101, '931, '564, '838, and '253 patents. Therefore, with this approval, Barr may be eligible for 180 days of generic drug exclusivity for Drospirenone and Ethinyl Estradiol Tablets, 3.0 mg/0.02 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 within 180 days after Barr begins commercial marketing of Drospirenone and Ethinyl Estradiol Tablets, 3.0 mg/0.02 mg (28-Day Regimen).

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}*

For Edward M. Sherwood
Director
Office of Regulatory Operations
Office of Generic Drugs
Center for Drug Evaluation and Research

U.S. Food & Drug Administration
Silver Spring, MD 20993
www.fda.gov

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**This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.**

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/s/

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