CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

ANDA 078267Orig1s000

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 78-267

Watson Laboratories, Inc.
Attention: Janie M. Gwinn
Director, Regulatory Affairs
311 Bonnie Circle
Corona, CA 92880

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated April 14, 2006, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Norethindrone Acetate and Ethinyl Estradiol Tablets USP, 1 mg/0.02 mg and Ferrous Fumarate Tablets 75 mg (24-Day Regimen).

Reference is also made to your amendments dated February 28, March 3, April 30, June 30, August 15, September 26, October 1, October 9, and October 24, 2008; and February 2, April 3, and June 15, June 16, 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 Norethindrone Acetate and Ethinyl Estradiol Tablets USP, 1 mg/0.02 mg and Ferrous Fumarate Tablets 75 mg (24-day regimen) to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Loestrin 24 Fe Tablets, 1 mg/0.02 mg, of Warner Chilcott, Inc. Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your application.

The RLD upon which you have based your ANDA, Warner Chilcott's Loestrin 24 Fe, 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. 5,552,394 (the '394) patent is scheduled to expire on July 22, 2014.

You have notified the agency that Watson Laboratories, Inc. (Watson) complied with the requirements of section 505(j)(2)(B) of the Act, and that litigation was initiated against Watson for infringement of the '394 patent in the United States District Court for the District of New Jersey [Warner Chilcott Company, Inc. v. Watson Laboratories, Inc., Civil Action No. CA-06-3491]. You have also notified the agency that the court decided that '394 is/are invalid, unenforceable, or not infringed; therefore, under section 505(j)(5)(B)(iii) your ANDA is eligible for approval.

FDA has determined that Watson was the first applicant to submit a substantially complete application that contained a paragraph IV certification to the '394 patent for Norethindrone Acetate and Ethinyl Estradiol Tablets USP, 1 mg/0.02 mg and Ferrous Fumarate Tablets 75 mg (24-day regimen), and therefore, was eligible for 180-day generic-drug exclusivity under section 505(j)(5)(B)(iv) of the Act. However, your eligibility for 180-day exclusivity was forfeited under section 505(j)(5)(D)(i)(IV). Your ANDA was received by the agency on April 17, 2006, and was never granted tentative approval. The ANDA filing date plus 30 months was October 17, 2008; therefore, this ANDA was not granted tentative approval within the 30-month period described in section 505(j)(5)(D)(i)(IV). We also have determined that the requirements for approval of this ANDA were not changed or reviewed after your ANDA was filed, nor was a related citizen petition submitted[1] that would extend the 30-month period as described in section 505(q)(1)(G) of the Act. We therefore conclude that the 180-day exclusivity period described in section 505(j)(5)(B)(iv) of the Act for Norethindrone Acetate and Ethinyl Estradiol Tablets USP, 1 mg/0.02 mg and Ferrous Fumarate Tablets 75 mg (24-day regimen) was forfeited by Watson.

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.

[1] A 505(q) citizen petition regarding bioequivalence criteria for this product was submitted approximately 3 weeks after the expiration of Watson's 30-month period. See Docket No. FDA-2008-P-0587. Therefore, at the time of submission of the citizen petition, the forfeiture event had already occurred. Furthermore, approval of this ANDA was not delayed because of the petition.

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.

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 78-267"***.

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
09/01/2009
Deputy Director, for Gary Buehler