DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 079218

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 October 5, 2007, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Levonorgestrel and Ethinyl Estradiol Tablets USP, 0.09 mg/0.02 mg.

Reference is also made to your amendments dated November 19, 2008; July 24, September 3, and December 15, 2009; February 5, 2010; and March 28, and May 25, 2011.

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 Levonorgestrel and Ethinyl Estradiol Tablets USP, 0.09 mg/0.02 mg, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Lybrel Tablets, 0.09 mg/0.02 mg, of Wyeth 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, Wyeth's Lybrel 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. 6,500,814 (the '814 patent), is scheduled to expire on September 3, 2018.

Your ANDA contains a paragraph IV certification under section 505(j)(2)(A)(vii)(IV) of the Act stating that the ‘814 patent is invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Levonorgestrel and Ethinyl Estradiol Tablets USP, 0.09 mg/0.02 mg, under this ANDA. 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 '814 patent within the statutory 45-day period in the United States District Court for the District Court of Delaware [Wyeth v. Watson Laboratories, Inc. and Watson Pharmaceuticals, Inc., Civil Action No. 08-145]. You have also notified the agency that Civil Action 08-145 was dismissed on April 27, 2009.

Watson was the first ANDA applicant to submit a substantially complete ANDA with a paragraph IV certification to the ‘814 patent. As a first applicant, Watson was eligible for 180 days of generic drug exclusivity for Levonorgestrel and Ethinyl Estradiol Tablets USP, 0.09 mg/0.02 mg. The Agency has determined, however, that Watson has forfeited its 180-day exclusivity period because it failed to obtain tentative approval of this ANDA within 30 months after the date on which the ANDA was filed.[1] See section 505(j)(5)(D)(I)(IV) of the Act.

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.

[1] Watson’s ANDA 079218 was received (filed) on October 5, 2007. 30 months from that date was April 5, 2010. ANDA 79218 was never tentatively approved. The agency finds that this failure to obtain tentative approval by April 5, 2010, was not caused by a change in or a review of the requirements for approval, nor was a related citizen petition submitted that was subject to section 505(q) of the Act.

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, submit, using the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 314.50(l)] 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_CM072392.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

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**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**

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/s/

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ROBERT L WEST

06/06/2011

Deputy Director, Office of Generic Drugs
for Keith Webber, Ph.D.