DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 078834

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 6, 2007, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Levonorgestrel and Ethinyl Estradiol Tablets and Ethinyl Estradiol Tablets, 0.15 mg/0.03 mg and 0.01 mg.

Reference is made to the tentative approval issued by this office dated May 20, 2010, and your amendments dated January 23, February 18, May 29, and July 17, 2008; November 10, 2010; and January 4, February 11, and March 29, 2011. We also acknowledge your correspondences dated March 14, April 27, May 11, and May 13, 2011, addressing 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 Levonorgestrel and Ethinyl Estradiol Tablets and Ethinyl Estradiol Tablets, 0.15 mg/0.03 mg and 0.01 mg, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Seasonique Tablets (Levonorgestrel and Ethinyl Estradiol, 0.15 mg/0.03 mg Tablets and Ethinyl Estradiol, 0.01 mg Tablets), of Duramed Research, Inc. (Duramed). 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, Duramed’s Seasonique (Levonorgestrel and Ethinyl Estradiol, 0.15 mg/0.03 mg Tablets and Ethinyl Estradiol, 0.01 mg Tablets), 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
7,320,969 (the '969 patent)	January 30, 2024
7,615,545 (the '545 patent)	June 15, 2023
7,855,190 (the '190 patent)	December 5, 2028
7,858,605 (the '605 patent)	June 23, 2023

Your ANDA contains paragraph IV certifications under section 505(j)(2)(A)(vii)(IV) of the Act stating that each of these patents is invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Levonorgestrel and Ethinyl Estradiol Tablets and Ethinyl Estradiol Tablets, 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. The '969, '545, '190, and '605 patents were not listed in the Orange Book when the Office of Generic Drugs (OGD) received your ANDA on April 6, 2007, and your paragraph IV certifications were submitted in amendments to your ANDA. Therefore, the agency has determined that, under these circumstances, a 30-month stay of approval does not apply to this ANDA.

Watson was the first ANDA applicant to submit a substantially complete ANDA with paragraph IV certifications to one or more of the patents listed above. As a first applicant, Watson was eligible for 180 days of generic drug exclusivity for Levonorgestrel and Ethinyl Estradiol Tablets and Ethinyl Estradiol Tablets, 0.15 mg/0.03 mg and 0.01 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.

[1] Watson's ANDA 078834 was received (filed) on April 9, 2007, and was tentatively approved on May 20, 2010. The ANDA filing date plus 30 months was October 9, 2009; therefore, Watson's ANDA was not tentatively approved within 30 months. The agency does not find that Watson's failure to obtain tentative approval in 30 months was caused by a change in or a review of the requirements for approval, nor was a related citizen petition submitted prior to October 9, 2009, that was subject to section 505(q) of the Act.

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.

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