DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 200407

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 September 26, 2009, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Levonorgestrel and Ethinyl Estradiol Tablets 0.1 mg/0.02 mg and Ethinyl Estradiol Tablets 0.01 mg.

Reference is also made to your amendments dated May 20, and November 9, 2010; and February 11, March 14, April 3, April 29, May 20, June 1, and June 15, 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 0.1mg/0.02mg and Ethinyl Estradiol Tablets 0.01 mg, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), LoSeasonique Tablets 0.1 mg/0.02 mg and 0.01 mg of Teva Women's Health, Inc. (Teva). 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, Teva's LoSeasonique 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"):

U.S. Patent Number	Expiration Date
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 0.1mg/0.02mg and Ethinyl Estradiol Tablets 0.01 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. The agency also notes that none of these patents were listed when your ANDA was submitted, that your paragraph IV certifications were submitted in amendments to your ANDA, and therefore approval of your ANDA is not stayed regardless of whether litigation has been brought against Watson.

With respect to 180-day generic drug exclusivity, we note that Watson was a first applicant to submit a substantially complete ANDA for Levonorgestrel and Ethinyl Estradiol Tablets USP, 0.1 mg and 0.02 mg, and Ethinyl Estradiol Tablets USP, 0.01 mg, with a paragraph IV certification to the ‘545 patent. Therefore, with this approval, Watson is eligible for 180 days of generic drug exclusivity for Levonorgestrel and Ethinyl Estradiol Tablets USP, 0.1 mg and 0.02 mg, and Ethinyl Estradiol Tablets USP, 0.01 mg. This exclusivity, which is provided for under section 505(j)(5)(B)(iv) of the Act, will begin to run from the date of the commercial marketing identified in section 505(j)(5)(B)(iv). 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.

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.

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 O. Webber, Ph.D.
Deputy Director
Office of Pharmaceutical Science
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

10/25/2011

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