DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 75-406/S-016

Watson Laboratories Inc.
Attention: Robert Dieso
311 Bonnie Circle
Corona, CA 92880

Dear Sir:

This is in reference to your supplemental new drug application dated April 17, 2008, submitted pursuant to 21 CFR 314.70(c)(6)(Supplement - Changes Being Effected) regarding your abbreviated new drug application for Norgestrel and Ethinyl Estradiol Tablets USP, 0.5 mg/0.05 mg.

The supplemental application provides for revisions to the package insert labeling to be in accordance with an Agency letter of October 4, 2006.

We have completed the review of this supplemental application and it is approved. However at the time of next printing, please make the following revisions. The revised labeling may be submitted to an annual report provided the changes are described in full.

> In accordance with the requirements for a toll-free number for the reporting of adverse events, include the following text at the end of the patient information:
>
> > Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800- FDA 1088.

We remind you that you must comply with the requirements for an approved abbreviated new drug application described in 21 CFR 314.80-81.

The material submitted is being retained in our files.

Sincerely yours,

{See appended electronic signature page}

Wm Peter Rickman
Director
Division of Labeling and Program Support
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/

John Grace
12/4/2008 10:34:30 AM
for Wm Peter Rickman