DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-655/S-011

Watson Laboratories, Inc.
Attention: Paul G. Long
Manager, Regulatory Liaison
US Proprietary Products
417 Wakara Way
Salt Lake City, Utah 84108

Dear Mr. Long:

Please refer to your supplemental new drug application dated November 18, 2004, received November 19, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Alora® Estradiol Transdermal System, 0.025 mg/day, 0.05 mg/day, 0.075 mg/day, and 0.1 mg/day.

This supplemental new drug application provides for changes to update the labeling with information regarding the Women's Health Initiative Memory Study (WHIMS).

We completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the attached agreed-upon labeling text.

Please submit an electronic version of the FPL according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format - NDA. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 20-655/S-011**." Approval of this submission by FDA is not required before the labeling is used.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call George Lyght, R.Ph., Regulatory Health Project Manager, at (301) 827-4260.

Sincerely,

{See appended electronic signature page}

Daniel Shames, M.D.
Division Director
Division of Reproductive and Urologic Drug Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

Enclosure:

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

/s/

Margaret Kober
5/19/05 05:21:49 PM
signed for Dr. Shames