DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-655/S-008

APPROVAL LETTER

Watson Laboratories, Inc.
Attention: Dorothy Frank, M.S., R.A.C.
Director, Regulatory Affairs
Research Park
417 Wakara Way
Salt Lake City, UT 84108

Dear Ms. Frank:

Please refer to your supplemental new drug application dated June 12, 2001, received June 13, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Alora (estradiol transdermal system) 0.025mg/day, 0.05mg/day, 0.075mg/day, and 0.1 mg/day.

We acknowledge receipt of your submissions dated November 19, 2001, and January 14 and 16, 2002. Your submission dated February 5, 2002, constituted a complete response to our January 18, 2002, action letter.

This supplement proposes the following changes: addition of a new indication, prevention of postmenopausal osteoporosis, and a new strength, 0.025 mg/day.

We have completed the review of this application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon enclosed labeling text that reflects the minor editorial revisions provided to you by secured e-mail on April 5, 2002. These revisions are terms of the approval of this application.

Accordingly the application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to, the enclosed labeling (text for the package insert, text for the patient package insert).

Please submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please mount individually ten of the copies on heavy-weight paper or similar material. Alternatively, you may submit the FPL electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format – NDAs* (January 1999). For administrative purposes, this/these submission(s) should be designated "FPL for approved supplement NDA 20-655/S-008" Approval of this submission by FDA is not required before the labeling is used.

If you have any questions, call Dornette Spell-LeSane, NP-C, Regulatory Project Manager, at (301) 827-4260.

Sincerely,

{See appended electronic signature page}

Daniel Shames, M.D.
Acting 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/

Daniel A. Shames

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