DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-375/S-021

Berlex, Inc.
Attention: Geoffrey Millington
Manager, Drug Regulatory Affairs
P.O. Box 1000
Montville, NJ 07045-1000

Dear Mr. Millington:

Please refer to your supplemental new drug application dated September 27, 2004, received September 28, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Climara (estradiol transdermal system); Menostar (NDA 21-674) Type 6 NDA to Climara.

This "Changes Being Effected" supplemental new drug application provides for final printed labeling.

We completed our review of this supplemental new drug application. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on September 27, 2004.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

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

Sincerely,

{See appended electronic signature page}

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

Margaret Kober
3/18/05 01:52:26 PM
signed for Dr. Shames