DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-375/S-023

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

Dear Mr. Millington:

Please refer to your supplemental new drug application dated, October 31, 2005, received November 1, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Menostar® (estradiol transdermal system).

We acknowledge receipt of your submission dated December 19, 2005, and our telephone conversation of December 27, 2005.

This "Changes Being Effected" supplemental new drug application provides for the removal of two paragraphs from the Indications and Usage section of the Physician Insert section of the label and additional revisions to reflect discontinuation of the estrogen alone arm of the Women's Health Initiative Memory Study.

We completed our review of this application. This application is approved, effective on the date of this letter, for use as recommended in the 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 20-375/S-023.**" Approval of this submission by FDA is not required before the labeling is used.

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) 796-2130.

Sincerely,

{See appended electronic signature page}

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

Enclosure: