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Menostar (Berlex) 06/08/2004 Approval [Postmenopausal Osteoporosis]: Approval Letter; Final Labeling

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Approval Package for:

APPLICATION NUMBER:

21-674

Trade Name: Menostar

Generic Name:

Sponsor: Berlex Laboratories

Approval Date: June 8, 2004

Indications: Provides for the use of Menostar for the prevention of postmenopausal osteoporosis

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APPLICATION NUMBER:

21-674

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EA/FONSI	
Pharmacology Review(s)	X
Statistical Review(s)	X
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APPLICATION NUMBER:

21-674

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-674

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 new drug application (NDA) dated August 7, 2003, received August 8, 2003, submitted under section 505b of the Federal Food, Drug, and Cosmetic Act for Menostar (estradiol transdermal system).

We acknowledge receipt of your submissions dated October 7, November 14, December 17, 2003 and March 15, May 4, 12, 14, and June 2, and 8 (2 submissions), 2004.

This new drug application provides for the use of Menostar (estradiol transdermal system) for prevention of postmenopausal osteoporosis.

We have completed our review of this application and it is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text and with the minor editorial changes to the foil pouches, containers and cartons listed below. The changes to the foil pouches must be implemented before manufacture of batch no. 2.

General Revisions to foil pouches, containers and cartons:

1. Relocate the graphic that covers the beginning letter 'M' of the proprietary name so that it does not interfere with the readability of the proprietary name.

2. Increase the prominence of the established name and strength, so that they are at least one-half the size of the proprietary name.

3. Eliminate the terminal zeros listed throughout the container labels and carton labeling since they could be misinterpreted (e.g., 1.0 as 10).

Specific Revision to the foil pouches (sample and trade):

1. Include the route of administration on the principal display panel (e.g., For Transdermal Use).

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