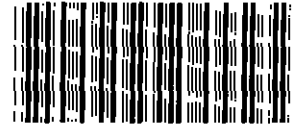


# foi



\* 5228320 \*



\* A \*

**5228320    A**

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

**This document was provided by:    FOI Services, Inc**

704 Quince Orchard Road • Suite 275  
Gaithersburg MD 20878-1751 USA  
Phone:        301-975-9400  
Fax:           301-975-0702  
Email:        infofoi@foiservices.com

**Do you need additional U.S. Government information?**

Since 1975, FOI Services, Inc has specialized in acquiring government files using the Freedom of Information Act. We have millions of pages of unpublished documentation already on file and available for immediate delivery.

**Many of the documents you need are available for immediate downloading at:**

***[www.foiservices.com](http://www.foiservices.com)***

Unless specified otherwise, all of FOI Services' documents have been released by the U.S. Government under the provisions of the Freedom of Information Act and are therefore available to the general public. FOI Services, Inc. does not guarantee the accuracy of any of the information in these documents; the documents will be faithful copies of the information supplied to FOI Services, Inc.

**CENTER FOR DRUG EVALUATION AND RESEARCH**

**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

# CENTER FOR DRUG EVALUATION AND RESEARCH

*APPLICATION NUMBER:*

**21-674**

## CONTENTS

### Reviews / Information Included in this NDA Review.

<b>Approval Letter</b>	<b>X</b>
<b>Approvable Letter 1</b>	
<b>Approvable Letter 2</b>	
<b>Final Printed Labeling</b>	<b>X</b>
<b>Medical Review(s)</b>	<b>X</b>
<b>Chemistry Review(s)</b>	<b>X</b>
<b>EA/FONSI</b>	
<b>Pharmacology Review(s)</b>	<b>X</b>
<b>Statistical Review(s)</b>	<b>X</b>
<b>Microbiology Review(s)</b>	
<b>Clinical Pharmacology/ Biopharmaceutics Review(s)</b>	<b>X</b>
<b>Administrative/Correspondence Document(s)</b>	<b>X</b>

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**21-674**

**APPROVAL LETTER**



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).

# Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

## Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

## Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

## Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

## API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

## LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

## FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

## E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.