CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

Application Number: NDA 4-782/S-093

Trade Name: PREMARIN TABLETS

Generic Name:(conjugated estrogens, USP)

Sponsor:Wyeth-Ayerst Research

Approval Date: September 8, 1998

INDICATION: Provides for draft labeling text, to incorporate changes to the DESCRIPTION section regarding the description of estrogen components found in Premarin, as well as other things, to be consistent with the 1992 Estrogen Drug Products Labeling Guidance

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION:NDA 4-782/S-093

CONTENTS

	Included	Pending Completion	Not Prepared	Not Required
Approval Letter	X			
Tenative Approval Letter				X
Approvable Letter	X			
Final Printed Labeling		X		
Medical Review(s)	X			
Chemistry Review(s)			X	
EA/FONSI			X	
Pharmacology Review(s)			X	
Statistical Review(s)			X	
Microbiology Review(s)			X	
Clinical Pharmacology Biopharmaceutics Review(s)	X			
Bioequivalence Review(s)	X			
Administrative Document(s)	X			
Correspondence	X			

CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number: NDA 4-782/S-093

APPROVAL LETTER

VF

SEP 8 1998

NDA 4-782/S-093

Wyeth-Ayerst Research
Attention: Joseph S. Sonk, Ph.D., Senior Director
Women's Health Care
U.S. Regulatory Affairs
P. O. Box 8299
Philadelphia, PA 19101-8299

Dear Dr. Sonk:

Please refer to your supplemental new drug application dated February 15, 1994, received February 22, 1994, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Premarin®, conjugated estrogens, USP, Tablets.

We acknowledge receipt of your submissions dated June 19, 1995; April 30, and October 10, 1996; March 2, and July 24, 1998. Your submission of July 24, 1998 constituted a full response to our February 22, 1995, approvable letter.

This supplemental new drug application provides for draft labeling text, to incorporate changes to the DESCRIPTION section regarding the description of estrogen components found in Premarin®, as well as other things, to be consistent with the 1992 Estrogen Drug Products Labeling Guidance.

We have completed the review of this supplemental 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 submitted labeling dated March 2, 1998, with the revisions listed below. Accordingly, the supplemental application is approved effective on the date of this letter.

Physician Package Insert

Patient Package Insert:

These revisions are terms of the approval. Marketing the product before making the revisions, exactly as requested, in the product's final printed labeling (FPL) may render the product misbranded and an unapproved new drug.

Please submit 20 copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavyweight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement 4-782/S-093." Approval of this submission by FDA is not required before the labeling is used.

If additional information relating to the safety or effectiveness of this drug becomes available before we receive the final printed labeling, revision of that labeling may be required.

In addition, please submit three copies of the introductory promotional materials that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to this Division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-40
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

If a letter communicating important information about this drug product (i.e., a "Dear Healthcare Practitioner" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

Please submit one market package of the drug product when it is available.

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, contact Diane Moore, Project Manager, at (301) 827-4260.

Sincerely,

/S/ 9/4/98

Lisa D. Rarick, M.D.
Director
Division of Reproductive and Urologic Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

cc:
Archival NDA 4-782/S-093
HFD-580/Div. Files
HFD-580/D.Moore
HFD-580/LRarick/MMann/Tvan der Vlugt/MRhee/DLin
HFD-580/KRaheja/AJordan/ADorantes/AParekh
HFD-580/KMeaker/JMele
HF-2/MedWatch (with labeling)
HFD-002/ORM (with labeling)
HFD-102/ADRA (with labeling)
HFD-40/DDMAC (with labeling)
HFD-613/OGD (with labeling)
HFD-95/DDMS (with labeling)
HFD-820/DNDC Division Director
DISTRICT OFFICE

Drafted by: dm/June 12, 1998 9/3/98

filename: N4782S093AP02.DOC

Concurrence:
JMarkow, Tvan der Vlugt, DLin, MRhee 08.18.98/KRaheja 08.19.98/AJordan 08.31.98
KMeaker, JMele, AParekh, MMann 09.01.98/LRarick 09.02.98

DESI Approval Date: May 8, 1942

APPROVAL (AP)

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:NDA 4-782/S-093

APPROVABLE LETTER

NDA 4-782/S-093

FEB 2 2 1995

Wyeth-Ayerst Laboratories
Attention: Ms. Joan E. Barton
Manager, Marketed Products
Drug Regulatory Affairs
P.O. Box 8299
PHILADELPHIA PA 19101-1245

Dear Ms. Barton:

Please refer to your February 15, 1994, supplemental new drug application submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Premarin (conjugated estrogens) Tablets.

We have completed the review of this supplemental application as submitted with draft labeling. Before this supplement may be approved, however, it will be necessary for you to submit draft labeling revised as follows:

BOXED WARNING:

Redacted 8

pages of trade

secret and/or

confidential

commercial

information

If additional information relating to the safety or effectiveness of this drug becomes available, revision of the FPL may be required.

Please submit four copies of the revised draft labeling.

Within ten days after the date of this letter, you are required to amend this supplemental application, notify us of your intent to file an amendment, or follow one of your other options under 21 CFR 314.110. In the absence of such action, FDA may take action to withdraw this supplemental application.

These changes may not be implemented until you have been notified in writing that this supplemental application is approved.

Should you have any questions, please contact:

Ms. Christina Kish
Consumer Safety Officer
Telephone: (301) 443-3510

Sincerely yours,

/S/ 2/22/95

Solomon Sobel, M.D.
Director
Division of Metabolism and
Endocrine Drug Products (HFD-510)
Office of Drug Evaluation II
Center for Drug Evaluation and Research

cc:
Original NDA
HF-2/MEDWATCH (with labeling)
DISTRICT OFFICE
HFD-80
HFD-510
HFD-510/LGolden
HFD-730
HFD-510/CKish/2.22.95/n4782.93

SUPPLEMENT APPROVABLE (S/AE)
CK 2/22/95