CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

NDA 20-699/S-025

Name:	Effexor XR Extended-Release Capsules
Generic Name:	venlafaxine hydrochloride
Sponsor:	Wyeth Pharmaceuticals Inc.
Approval Date:	08/07/02

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 20-699/S-025

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Approvable Letter	
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Medical Review(s)	
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Microbiology Review(s)	
Clinical Pharmacology/ Biopharmaceutics Review(s)	
Administrative and Correspondence Document(s)	X

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 20-699/S-025

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-699/S-025

Wyeth-Ayerst Labortories
Attention: Patricia Foti Mann
Asociate Director Worldwide Regulatory Affairs
P.O. Box 8299
Philadelphia, PA 19101-8299

Dear Ms. Mann:

Please refer to your supplemental new drug application dated February 11, 2002, received February 12, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Effexor® XR (venlafaxine hydrochloride) Extended Release Capsules (37.5 mg, 75 mg, 100 mg and 150 mg).

This "Changes Being Effected in 30 days" supplemental new drug application provides for [redacted] as an alternate manufacturing site for processing step / steps / of the venlafaxine hydrochloride drug substance synthesis.

We have completed the review of this supplemental application, and it is approved.

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 Paul David, R.Ph., Regulatory Project Manager, at (301) 594-5530.

Sincerely,

{See appended electronic signature page}

Thomas Oliver, Ph.D.
Chemistry Team Leader, Psychiatric Drugs for the
Division of Neuropharmacological Drug Products,
(HFD-120)
DNDC I, Office of New Drug Chemistry
Center for Drug Evaluation and Research

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/s/

Thomas Oliver
8/7/02 03:56:46 PM

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 20-699/S-025

CHEMISTRY REVIEW(S)

CHEMIST REVIEW
OF **SUPPLEMENT**

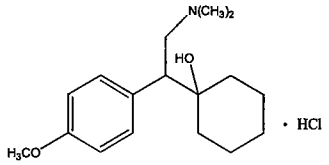
1. **ORGANIZATION:**	HFD-120
2. **NDA**	20-699
3. **SUPPLEMENT NUMBER AND DATES:**	SCM-025
LETTER DATE:	02-11-02
STAMP DATE:	02-12-02
4. **AMENDMENT/REPORTS/DATES**	
5. **RECEIVED BY CHEMIST:**	02-15-02

6. **APPLICANT NAME & ADDRESS:** Wyeth-Ayerst Laboratories
P.O. Box 8299
Philadelphia, PA 19101-8299

7. **NAME OF DRUG:** Effexor ® XR

8. **NONPROPRIETARY NAME:** Venlanfaxine hydrochloride

9. **CHEMICAL NAME and STRUCTURE:**
(*R,S*)-1-[2-(dimethylamino)-1-(4-methoxyphenyl)ethyl] cyclohexanol hydrochloride



10. **DOSAGE FORMS:**	Extended Release Capsules
11. **POTENCY:**	37.5 mg; 75 mg, 100 mg, 150 mg
12. **PHARMACOLOGICAL CATEGORY:**	anti-depressant/ general anti-anxiety disorder
13. **HOW DISPENSED:**	___X___ R(x) _____(OTC)
14. **RECORD and REPORTS CURRENT:**	___X___ Yes _____No
15. **RELATED IND/NDA/DMF:**	Amendment SCM-011(BC)

16. **SUPPLEMENT PROVIDES FOR:** This supplement provides for an alternate manufacturing site for processing steps / and / of the venlafaxine hydrochloride dug substance synthesis. The name and address of the new facility are listed below.

[ ]

17. **ADDITIONAL COMMENTS**: The applicant has proposed to use an alternate site for processing steps / and / of the drug substance synthesis. As a result of this site change, the applicant reports minor changes in the process and equipment. The applicant indicates that there are no changes to the [ ] or to the currently approved methods and specifications for the drug substance. The applicant includes comparative impurity profiles and physical characterization for three lots of the drug substance manufactured at the currently approved site and three lots of the drug substance manufactured from the alternate site. The applicant also includes certificates of analyses for the three batches that were manufactured with the material from the new site. The applicant references DMF [ ] for the new manufacturing site, however, the DMF was not reviewed because the applicant includes adequate information within the application to support these changes.

18. **CONCLUSIONS & RECOMMENDATIONS:** The sponsor has submitted adequate information to support the changes proposed in this supplement. It is the recommendation of the CMC reviewer that this supplement be **APPROVED.**

Sherita D. McLamore, Ph.D. (Review Chemist) Date

Thomas Oliver, Ph.D. (Team Leader) Date

Redacted 3 page(s)

of trade secret and/or

confidential commercial

information from

Chemistry Review

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/s/

Sherita McLamore
8/7/02 02:59:56 PM
CHEMIST

Thomas Oliver
8/7/02 03:51:38 PM
CHEMIST

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 20-699/S-025

ADMINISTRATIVE and CORRESPONDENCE DOCUMENTS

MEMORANDUM TO THE FILE

NDA#	20-699/ SCM-025
DATE:	13-AUG-02
PRODUCT NAME:	Effexor XR
FIRM NAME:	Wyeth Ayerst
SUBJECT:	Corrected letter for S-025
CONVERSATION WITH:	Ms. Patricia Foti Mann
TELEPHONE No.:	(484) 865-3787
Fax No.:	(484) 865-0028

BACKGROUND: The sponsor, in an email to Paul David, R.Ph., has requested a corrected approval letter for S-025. The supplement was filed as a CBE-0 and the sponsor received a CBE-0 acknowledgement letter. However, a CBE-30 approval letter was sent to the sponsor.

****

13-AUG-02: I talked with Ms. Mann. I told her we would fax a copy of the approval letter [CBE-0]. I said the supplement was properly filed as a CBE-0 (Guidance for Industry: Changes to an Approved NDA or ANDA) and apologized for any confusion.

_____
Thomas F. Oliver, Ph.D.

cc: NDA 20-699
HFD-120/DivFile
HFD-120/TOliver
HFD-120/SMcLamore
HFD-120/PM/PDavid

File: memo20-699.s025.CBE0.letter.change

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-699/S- 025

CBE-0 SUPPLEMENT

Wyeth-Ayerst Laboratories
Attention: Patricia F. Mann
Wyeth-Ayerst Laboratories
P.O. Box 8299, Philadelphia, PA 19101-8299

Dear Ms. Mann:

We have received your supplemental drug application submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following:

Name of Drug Product: Effexor® XR (venlafaxine hydrochloride) Extended Release Capsules

NDA Number: 20-699

Supplement number: SCM-025

Date of supplement: February 11, 2002

Date of receipt: February 12, 2002

This supplemental application was submitted as a "Supplement - Changes Being Effected." The appropriateness of reporting the proposed change(s) as changes being effected is under review.

Unless we notify you within 60 days of the receipt date that the application is not sufficiently complete to permit a substantive review, this application will be filed under section 505(b) of the Act on April 13, 2002, in accordance with 21 CFR 314.101(a).

All communications concerning this supplement should be addressed as follows:

U.S. Postal Service:
Center for Drug Evaluation and Research
Division of Neuropharmacological Drug Products, HFD-120
Attention: Division Document Room, 4008
5600 Fishers Lane
Rockville, Maryland 20857

Courier/Overnight Mail:
Food and Drug Administration
Center for Drug Evaluation and Research
Division of Neuropharmacological Drug Products, HFD-120
Attention: Document Room 4008
1451 Rockville Pike
Rockville, Maryland 20852

If you have any question, call Paul David, R.Ph., Senior Regulatory Project Manager, at (301) 594-5530.

Sincerely yours,

Hasmukh B. Patel, Ph.D.
Acting Chemistry Team Leader, Psychiatric Drugs for the
Division of Neuropharmacological Drug Products, (HFD-120)
DNDCI, Office of New Drug Chemistry
Center for Drug Evaluation and Research

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/s/

Hasmukh Patel
5/7/02 10:45:19 AM