CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

NDA 20-699/S-024

Name:	Effexor XR Extended-Release Capsules
Generic Name:	venlafaxine hydrochloride
Sponsor:	Wyeth Pharmaceuticals Inc.
Approval Date:	10/23/01
Indications:	For the treatment of depression and generalized anxiety disorder.

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APPLICATION NUMBER:

NDA 20-699/S-024

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APPLICATION NUMBER:

NDA 20-699/S-024

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-699/S-024

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

Dear Ms. Mann:

Please refer to your supplemental new drug application dated September 14, 2001, received September 17, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Effexor® XR (venlafaxine hydrochloride) Extended Release Tablets.

This "Changes Being Effected" supplemental new drug application provides for a process change in the production of the [redacted] during the synthesis of venlafaxine hydrochloride.

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}

Robert H. Seevers, 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/

Robert H. Seevers
10/23/01 09:48:33 AM

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 20-699/S-024

CHEMISTRY REVIEW(S)

CHEMIST REVIEW
OF **SUPPLEMENT**

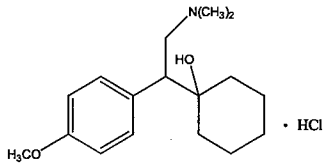
1. **ORGANIZATION**:	HFD-120
2. **NDA**	20-699
3. **SUPPLEMENT NUMBER AND DATES**:	SCM-024
LETTER DATE:	09-14-01
STAMP DATE:	09-17-01
4. **AMENDMENT/REPORTS/DATES**	
5. **RECEIVED BY CHEMIST**:	09-27-01

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 a process change in the production of the [ ] during the synthesis of venlafaxine hydrochloride.

17. **ADDITIONAL COMMENTS**: The applicant has proposed a minor change in the synthesis of the drug substance. The applicant has developed a new [ ] process for the production of the [ ] in this step synthesis in an effort to increase the batch size and reduce the amount of [ ] used. The applicant includes impurity profiles for three batches of the drug substance produce via the old and three batches of the drug substance produced via the new process. The applicant also includes certificates of analyses for these batches as well as time zero stability data for the drug substance produced via this new process. The applicant references DMF [ ] for the manufacture of the drug substance. DMF [ ] was reviewed on 10-18-01 and was found to be adequate to support the changes proposed in this supplement.

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

Robert Seevers, Ph.D. (Team Leader) Date

cc:
Division File NDA 20-699
HFD-120/RSeevers
HFD-120/SMcLamore
HFD-120/PDavid

Redacted 2 page(s)

of trade secret and/or

confidential commercial

information from

Chemistry Review

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/s/

Sherita McLamore
10/23/01 09:38:33 AM
CHEMIST

Robert H. Seevers
10/23/01 09:43:36 AM
CHEMIST

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 20-699/S-024

ADMINISTRATIVE and CORRESPONDENCE DOCUMENTS

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-699

CBE SUPPLEMENT

Wyeth-Ayerst Research
Attention: Patricia Foti Mann, Associate Directore, Worldwide Regulatory Affairs
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: 024

Date of supplement: September 14, 2001

Date of receipt: September 17, 2001

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 November 16, 2001 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: Division Document Room, 4008

1451 Rockville Pike
Rockville, Maryland 20852-1420

If you have any questions, call Paul David, Regulatory Project Manager, at (301) 594-5530.

Sincerely yours,

Robert H. Seevers, Ph.D.
Chemistry Team Leader
Psychiatric Drugs for the
Division of Neuropharmacological Drug Products
HFD-120
DNDC 1, Office of New Drug Chemistry
Center for Drug Evaluation and Research

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/s/

Robert H. Seevers
9/27/01 08:51:20 AM