CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

NDA 20-699/S-028

Name:	Effexor XR Extended-Release Capsules
Generic Name:	venlafaxine hydrochloride
Sponsor:	Wyeth Pharmaceuticals Inc.
Approval Date:	11/19/02

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 20-699/S-028

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APPLICATION NUMBER:

NDA 20-699/S-028

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-699/S-028

Wyeth-Ayerst Laboratories
Attention: Ms. Jo Anne Calleri, Manager Worldwide Regulatory Affairs
P.O. Box 8299
Philadelphia, PA 19101-8299

Dear Ms. Calleri:

Please refer to your supplemental new drug application dated July 1, 2002, received July 2, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Effexor® XR (venlafaxine hydrochloride) 37.5, 75, 100 and 150 mg Capsules.

This "CBE-0" supplemental new drug application provides for a modification to method [redacted]

We have completed our review of this supplemental new drug application, and it is approved.

We remind you that you must comply with the reporting 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
11/19/02 03:11:41 PM

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APPLICATION NUMBER:

NDA 20-699/S-028

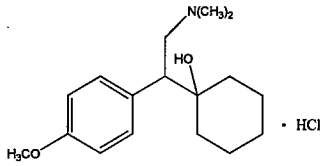
CHEMISTRY REVIEW(S)

CHEMIST REVIEW
OF **SUPPLEMENT**

1. **ORGANIZATION**: HFD-120
2. **NDA** 20-699
3. **SUPPLEMENT NUMBER AND DATES**: SCM-028
   LETTER DATE: 09-01-02
   STAMP DATE: 09-02-02
4. **AMENDMENT/REPORTS/DATES**
5. **RECEIVED BY CHEMIST**:

6. **APPLICANT NAME & ADDRESS**: Wyeth-Ayerst Laboratories
   P.O. Box 8299
   Philadelphia, PA 19101-8299
7. **NAME OF DRUG**: Effexor ® XR
8. **NONPROPRIETARY NAME**: Venlafaxine 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:

16. **SUPPLEMENT PROVIDES FOR:** This supplement provides for a minor modification in the [redacted] method for Residual Solvents (Method [redacted]

[redacted]

17. **ADDITIONAL COMMENTS**: The applicant seeks to make minor changes to the analytical procedure for the Residual Solvents. The change includes the following:

1. [redacted]
2.
3.
4.

The applicant indicates that there are no changes in the specifications, acceptance criteria or in the approved tests for the drug substance. The applicant indicates that these changes were made because in May of 2002, a FDA inspector indicated that the method was not optimized for accurate residual solvent determinations. The applicant includes a validation report and indicates that the proposed changes do not affect the linearity, precision, accuracy, specificity or sensitivity of the method. Furthermore, the applicant provides revised analytical procedures for the aforementioned test. These revised procedures include: a list of equipment and materials, standard and sample preparation, sample analysis, data analysis and sample chromatograms.

18. **CONCLUSIONS & RECOMMENDATIONS:** The changes in the method are all improvements and provide increased assurance in the analytical procedure. Accordingly, 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

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

Redacted 1 page(s)

of trade secret and/or

confidential commercial

information from

Chemistry Review

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/s/

Sherita McLamore
11/19/02 03:00:30 PM
CHEMIST

Thomas Oliver
11/19/02 03:06:30 PM
CHEMIST

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 20-699/S-028

ADMINISTRATIVE and CORRESPONDENCE DOCUMENTS

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-699/S-028

CBE-0 SUPPLEMENT

Wyeth-Ayerst Laboratories
Attention: Jo Anne Calleri, Manager Worldwide Regulatory Affairs
P.O. Box 8299, Philadelphia, PA 19101-8299

Dear Ms Calleri:

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 (venlafaxine hydrochloride) Capsules, 37.5mg, 75mg, 100mg, 150mg

NDA Number: 20-699

Supplement number: S-028

Date of supplement: July 1, 2002

Date of receipt: July 2, 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 August 31, 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 questions, please contact Paul David, R.Ph., Senior Regulatory Project Manager, at (301) 594-5530.

Sincerely yours,

Thomas F. 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
7/10/02 09:12:28 AM