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
## Reviews / Information Included in this NDA Review.

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CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:
NDA 20-699/S-025

APPROVAL LETTER
NDA 20-699/S-025

Wyeth-Ayerst Laboratories
Attention: Patricia Foti Mann
Associate 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 ☐ ☐ ☐ ☐ 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
This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Thomas Oliver
8/7/02 03:56:46 PM
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:
   LETTER DATE: SCM-025 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:

8. NONPROPRIETARY NAME:
   Effexor® XR
   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:
    Amendment SCM-011(BC)

16. SUPPLEMENT PROVIDES FOR: This supplement provides for an alternate manufacturing site for processing steps /
    and / of the venlafaxine hydrochloride drug 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
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
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
This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

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