NDA 20-699/S-001

MAR 1 1 1999

Wyeth-Ayerst Research
Attention: Roy Baranello
P.O. Box 8299
Philadelphia, PA 019101

Dear Mr. Baranello:

Please refer to your supplemental new drug application dated January 30, 1998, received January 30, 1998, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Effexor® XR (venlafaxine hydrochloride) Extended Release Capsules.

This supplement provides for the use of Effexor® XR (venlafaxine hydrochloride) Extended Release Capsules for the treatment of generalized anxiety disorder as a new indication.

The User Fee goal date for this application is April 5, 1999.

We acknowledge receipt of your amendment dated February 4, 1999 (revised labeling).

We also refer to the February 23 and March 2, 1999, teleconferences during which agreement was reached on the final wording for the 'Clinical Trials', 'Adverse Reactions', 'Indications and Usage', and 'Dosage and Administration' sections of the labeling regarding this new indication.

We have completed the review of this 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 enclosed labeling text. Accordingly, the application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the enclosed labeling. Marketing the product with FPL that is not identical to the approved labeling text 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 heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved NDA 20-699/S-001." Approval of this submission by FDA is not required before the labeling is used.

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 send one copy to the Division of Neuropharmacological Drug Products 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

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 Anna Marie Homonnay-Weikel, R.Ph., Project Manager, at (301) 594-5535.

Sincerely,

3/11/99

Russell Katz, M.D.
Acting Director
Division of Neuropharmacological Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

Enclosure