DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Rockville MD 20857

HFD-104
JUL 7 2000 Murphy

NDA 20 151
NDA 20-699

Wyeth-Ayerst Laboratories
Attention: Roy J. Baranello, Jr.
Director, Regulatory Affairs
P.O. Box 8299
Philadelphia, PA 19101-1245

Dear Mr. Baranello:

Please refer to your New Drug Applications submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Effexor (venlafaxine hydrochloride) Immediate-Release Tablets (NDA 20-151) and Effexor XR (venlafaxine hydrochloride) Extended-Release Capsules (NDA 20-699).

We additionally refer to an Agency pediatric Written Request letter dated April 28, 1999.

We acknowledge receipt of your submissions dated February 16, 2000, providing for proposed changes in the Written Request for all studies.

We have reviewed your proposed changes and are amending the below listed sections of the Written Request. All other terms stated in our Written Request letter issued on April 28, 1999, remain the same.

- **Pediatric Depression: Age Group in Which Study(ies) will be Preformed – All Studies**

  We are amending this section to change the age ranges for children to be 7 through 12 years old and adolescents to be ages 13 through 17 years old from ages 7 through 11 and ages 12 through 17, respectively.

  We have not amended the upper age limit for adolescents (b) (4) as proposed in your submission, because we believe that it is important to have a consistent regulatory policy for this class of drugs.

Your other proposed changes to the Written Request (b) (4) (b) (4) (b) (4) have not been accepted and are not terms of the Written Request.

Additionally, we are not amending the Written Request, as proposed in your February 16, 2000 submission, to extend the 3 year timeframe for fulfilling the requirements for exclusivity. We believe that 3 years is a sufficient time period to allow for completion and reporting of the required studies. However, we would be willing to revisit this issue as your pediatric program proceeds.

Reports of the studies that meet the terms of the Written Request dated April 28, 1999, as amended by this letter must be submitted to the Agency on or before April 28, 2002 to possibly qualify for a pediatric exclusivity extension under section 505A of the Federal Food, Drug, and Cosmetic Act.

Reports of the studies should be submitted as a supplement to your approved NDAs with the proposed labeling changes you believe would be warranted based on the data derived from these studies. When submitting the reports, please clearly mark your submission **"SUBMISSION OF PEDIATRIC STUDY REPORTS - PEDIATRIC EXCLUSIVITY DETERMINATION REQUESTED"** in large font, bolded type at the beginning of the cover letter of the submission and include a copy of this letter. Please also send a copy of the cover letter of your submission, via fax (301-594-0183) or messenger to the Director, Office of Generic Drugs, HFD-600, Metro Park North II, 7500 Standish Place, Rockville, MD 20855-2773.

If you wish to discuss any amendments to this Written Request, please submit proposed changes and the reasons for the proposed changes to your application. Submissions of proposed changes to this request should be clearly marked **"PROPOSED CHANGES IN WRITTEN REQUEST FOR PEDIATRIC STUDIES"** in large font, bolded type at the beginning of the cover letter of the submission. You will be notified in writing if any changes to this Written Request are agreed upon by the Agency.

We hope you will fulfill this pediatric study request. We look forward to working with you on this matter in order to develop additional pediatric information that may produce health benefits to the pediatric population.

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

Sincerely,

Robert Temple, M.D.
Director
Office of Drug Evaluation I
Center for Drug Evaluation and Research

cc:
Archival NDA 20-151
Archival NDA 20-699
HFD-120/Div. Files
HFD-120/P.David
HFD-120/R.Katz/T.Laughren
HFD-120/G.Dubitsky/A.Mosholder/R.Glass
HFD-100/R.Temple/R.Behrman
HFD-600/Office of Generic Drugs
HFD-101/ADRA (with labeling)
HFD-2/M.Lumpkin
HFD-104/Peds/T.Crescenzi (with labeling)
HFD-40/DDMAC (with labeling)
HFD-104/D.Murphy

7/3/00
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PEDIATRIC WRITTEN REQUEST LETTER
INFORMATION REQUEST (IR)