IND 49,465
NDA 20-972

SEP 17 1999

DuPont Pharmaceuticals Company
Attention: Patricia Dewalt, Ph.D.
Chestnut Run Plaza, MR 2202
974 Centre Road
Wilmington, DE 19805

Dear Dr. Dewalt:

Reference is made to your correspondence dated June 16, 1999, requesting a change to FDA's September 17, 1998, Written Request for pediatric studies of Sustiva (efavirenz) liquid formulation. We acknowledge the delay (secondary to our administrative error) in responding to your June 16, 1999 request that we amend the timeframe for submitting reports of the studies' section in the Written Request.

We have reviewed your proposed changes and are amending the below listed section of the Written Request. All other terms stated in our Written Request issued on September 17, 1998, remain the same.

Timeframe for submitting reports of the studies:
On or before September 30, 2001

Reports of the studies should be submitted as a supplement to your approved NDA 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 you 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 further amendments to your Written Request as amended, please submit changes and the reasons for the proposed changes to your application. Submissions of proposed changes to your Written 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 your 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, please contact Ms. Christine Kelly, RN, MS, MBA, Regulatory Health Product Manager, at 301 827 2335.

Sincerely yours,

Sandra L. Kweder, MD
Acting Director
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

Concurrence:
HFD-530/Dir/Jolson 9/14/99
HFD-530/DepDir/Birnkrant DB 9/13/99
HFD-530/SCSO/DeCicco ID 9.10.99
HFD-530/AMOTL/Kukich SK 9/9/99
HFD-530/MO/Haverkos 9/9/99
HFD-104/T. Hassall TH 9/10/99

cc:
Original NDA 20-972
HFD-530/Div. Files
HFD-530/CSO/Kelly
HFD-530/Haverkos
HFD-530/Kukich
HFD-530/Jolson
HFD-104/DMurphy
HFD-600/Office of Generic Drugs
HFD-2/MLumpkin
HFD-6/Kroberts

AMMENDED PEDIATRIC WRITTEN REQUEST LETTER (PWR)