DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-972
IND 49,465

Bristol-Myers Squibb
Attention: Ms. Marie-Laure Papi
Manager
Global Regulatory Science
5 Research Parkway
P.O. Box 5100
Wallingford, CT 064922-7660

Dear Ms. Papi:

Reference is made to your correspondence dated April 22, 2003, requesting additional changes to FDA's September 17, 1998, Written Request for pediatric studies for Sustiva™ (efavirenz) liquid formulation. Reference is made to the FDA letter dated August 8, 2001, which agreed to amend the timeframe for submitting reports of studies to June 30, 2003.

We have reviewed your proposed change 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 October 31, 2005.

Reports of the studies that meet the terms of the Written Request dated September 17, 1998, as amended by this letter must be submitted to the Agency on or before October 31, 2005, in order to possibly qualify for pediatric exclusivity extension under Section 505A of the Act.

Please submit protocols for the above studies to an investigational new drug application (IND) and clearly mark your submission, "PEDIATRIC PROTOCOL SUBMITTED FOR PEDIATRIC EXCLUSIVITY STUDY" in large font, bolded type at the beginning of the cover letter of the submission. Please notify us as soon as possible if you wish to enter into a written agreement by submitting a proposed written agreement. Please clearly mark your submission, "PROPOSED WRITTEN AGREEMENT FOR PEDIATRIC STUDIES" in large font, bolded type at the beginning of the cover letter of the submission.

Reports of the studies should be submitted as a supplement to your approved NDA, new drug application, or an amendment to a pending application 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, contact Sylvia D. Lynche, Pharm.D., Regulatory Project Manager at (301) 827-2335.

Sincerely,

{See appended electronic signature page}

Mark Goldberger, M.D.
Director
Office of Drug Evaluation 4
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/

Mark Goldberger
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NDA 20972 and NDA 49465 pediatric extension letter