DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

IND 56, 897

Bristol Myers Squibb
Attention: Cynthia Piccirillo
Director, Global Regulatory Science
Pharmaceutical Research Institute
5 Research Parkway/Mail Stop 2CW-1038
P.O.Box 5100
Wallingford, CT 06492-7660

Dear Ms. Piccirillo:

Please refer to your correspondence dated June 30, 2003, requesting an extension in the timeframe to FDA's August 2001, Written Request for pediatric studies for atazanavir.

After reviewing your request for an extension of the Written Request, we agree it is reasonable to extend the timeframe to October 31, 2006. We also understand that BMS will submit an amendment to protocol (SN 301) submitted on July 9, 2002 when available. At this time all other terms stated in our Written Request issued on August 2, 2001 and reissued on August 9, 2002 remain the same.

Reports of the studies that meet the terms of the Written Request dated August 2, 2001 and reissued August 9, 2002, must be submitted to the Agency on or before October 31, 2006, in order to possibly qualify for pediatric exclusivity extension under Section 505A of the Act.

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. 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.

Submit reports of the studies as a **new drug application (NDA) / supplement to an approved NDA** with the proposed labeling changes you believe are warranted based on the data derived from these studies. When submitting the reports, 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. In addition, 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, submit proposed changes and the reasons for the proposed changes to your application. Clearly mark submissions of proposed changes to this request **"PROPOSED CHANGES IN WRITTEN REQUEST FOR PEDIATRIC STUDIES"** in large font, bolded type at the beginning of the cover letter of the submission. We will notify you in writing if we agree to any changes to this Written Request.

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 Vasavi Reddy, R.Ph., Regulatory Project Manager, at 301-827-2335.

Sincerely,

{See appended electronic signature page}

Mark Goldberger, M.D., MPH
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/

Edward Cox
8/25/03 03:15:16 PM
for Mark Goldberger, MD, MPH