DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-178

Bristol-Myers Squibb
Attention: Warren C. Randolph
Director, Metabolic/Endocrine Products
P.O. Box 4000
Princeton, NJ 08543-4000

Dear Mr. Randolph:

Please refer to your correspondence dated May 22, 2002, requesting changes to FDA's January 31, 2001, Written Request, and to the amendment dated October 8, 2001, for pediatric studies for Glucovance® (Glyburide and Metformin HCl tablets).

We 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 January 31, 2001, remain the same.

Timeframe for submitting reports of the studies:

Original Written Request: "Reports of the studies must be submitted to the Agency on or before July 15, 2003."

Proposed Amended Request: "Reports of the studies must be submitted to the Agency on or before July 31, 2003."

Reports of the studies that meet the terms of the Written Request dated January 31, 2001, as amended on October 8, 2001, and by this letter must be submitted to the Agency on or before July 31, 2003, in order to 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 supplement to your 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 Ms. Jena Weber, Regulatory Project Manager, at 301-827-6422.

Sincerely,

{See appended electronic signature page}

David G. Orloff, M.D.
Director
Division of Metabolic and Endocrine Drug Products
Office of Drug Evaluation II
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/

Mary Parks
6/14/02 10:27:47 AM
for Dr. Orloff