DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration Silver Spring MD 20993

NDA 021178/S-012

SUPPLEMENT APPROVAL

Bristol-Myers Squibb Company
Attention: Madhu Anant, Ph.D.
Director, Mature Brands & Geographic Optimization
Route 206 & Province Line Road
Princeton, NJ 08543

Dear Dr. Anant:

Please refer to your Supplemental New Drug Application (sNDA) dated May 25, 2010, received May 26, 2010, submitted under 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Glucovance (glyburide and metformin HCl) tablets, 1.25 mg/250 mg, 2.5 mg/500 mg, and 5 mg/500 mg.

This "Changes Being Effected" supplemental new drug application provided for revised labeling to the **ADVERSE REACTIONS** section, **Gastrointestinal Reactions** subsection of the package insert to appear as requested in our letter dated April 5, 2010.

> In postmarketing reports cholestatic jaundice and hepatitis may occur rarely which may progress to liver failure; Glucovance should be discontinued if this occurs.

We have completed our review of this supplemental application. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

We note that your May 25, 2010, submission includes final printed labeling (FPL) for your package insert and patient package insert labeling. We have not reviewed this FPL. You are responsible for assuring that the wording in this printed labeling is identical to that of the approved content of labeling in the structured product labeling (SPL) format.

As soon as possible, but no later than 14 days from the date of this letter, submit, using the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm, that is identical to the enclosed labeling (text for package insert and patient package insert) and include the labeling changes proposed in any pending "Changes Being Effected" (CBE) supplements.

Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications for this NDA, including pending "Changes Being Effected" (CBE) supplements, for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format that includes the changes approved in this supplemental application.

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, please call Ms. Jena Weber, Regulatory Project Manager, at 301-796-1306.

Sincerely,

{See appended electronic signature page}

Mary H. Parks, M.D.
Director
Division of Metabolism and Endocrinology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

ENCLOSURES (package insert and patient package insert)

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

MARY H PARKS
11/24/2010