DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-460/S-007

Bristol-Myers Squibb Company
Attention: David L. Silberstein
Associate Director, Global Regulatory Sciences
P.O. Box 4000
Princeton, NJ 08543-4000

Dear Mr. Silberstein:

Please refer to your supplemental new drug application dated February 7, 2008, received February 7, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Metaglip (glipizide and metformin HCl) Tablets.

We acknowledge receipt of your submissions dated April 2, and August 13, 2008.

This supplemental new drug application provides for the following changes to the Package Insert, which were requested in a supplement request letter dated November 21, 2007.

1. The INDICATIONS AND USAGE section was changed to "METAGLIP is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus."

2. The following statement was added to the PRECAUTIONS section: "Macrovascular Outcomes: There have been no clinical studies establishing conclusive evidence of macrovascular risk reduction with METAGLIP or any other anti-diabetic drug."

3. Several sub-section headings and table titles were changed in the CLINICAL STUDIES and DOSAGE AND ADMINISTRATION sections.

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

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to the enclosed labeling (text for the package insert, submitted August 13, 2008**)**. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission, "SPL for approved NDA 21-460/S-007."

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH
Food and Drug Administration
Suite 12B05
5600 Fishers Lane
Rockville, MD 20857

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, call Julie Marchick, Regulatory Project Manager, at (301) 796-1280.

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

Enclosure: 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 Parks

8/18/2008 04:38:27 PM