DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 21-460/S-008 **APPROVAL LETTER**

Bristol-Myers Squibb Company
Attention: Daniel J. Papa
Director, Mature Products, Global Regulatory Sciences
P.O. Box 4000
Princeton, NJ 08543-4000

Dear Mr. Papa:

Please refer to your supplemental new drug application dated April 6, 2009, received April 6, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Metaglip (glipizide/metformin HCl fixed-dose combination) Tablets.

We acknowledge receipt of your submission dated July 30, 2009.

This "Changes Being Effected" supplemental new drug application, submitted in response to our supplement request letter dated January 15, 2009, provides for: (1) addition of language regarding hemolytic anemia under the PRECAUTIONS section of the Package Insert, and (2) addition of language regarding hemolytic anemia in the Patient Package Insert.

We have completed our review of this supplemental new drug application, as amended. It is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text (package insert and patient package insert submitted on July 30, 2009).

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 the requirements for an approved NDA set forth under 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

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
08/07/2009