DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-357/S-031
NDA 21-202/S-016

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

Dear Mr. Silberstein:

Please refer to your supplemental new drug applications dated January 18, 2008, received January 18, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Glucophage (metformin HCl) and Glucophage XR (metformin HCl extended-release) Tablets.

We acknowledge receipt of your submissions dated March 18, and August 6, 2008.

These supplemental applications are in response to our supplement request letters dated November 20, and 21, 2007, and propose labeling revisions to the **INDICATIONS AND USAGE** and **PRECAUTIONS** sections of the shared package insert.

We completed our review of these applications, as amended. These applications are **approved**, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the attached labeling (text for the shared package insert) submitted dated August 6, 2008.

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 shared package insert) submitted August 6, 2008). Upon receipt, we will transmit this version to the National Library of Medicine for public dissemination. For administrative purposes, please designate these submissions, "SPL for approved NDA 20-357/S-031 and NDA 21-202/S-016."

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 & Endocrinology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosure (shared 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

8/27/2008 05:22:08 PM