



NDA 20-357/S-030

NDA 21-202/S-015

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

Dear Mr. Silberstein:

Please refer to your supplemental new drug applications dated October 16, 2006, received October 17, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for:

NDA 20-357/S-030 for Glucophage (metformin HCl) tablets 500 mg, 850 mg, and 1000 mg, and NDA 21-202/S-015 for Glucophage XR (metformin HCl extended-release) tablets 500 and 750 mg.

We acknowledge receipt of your submission dated October 17, 2006, to NDA 20-357/S-030.

These "Changes Being Effected in 30 days" supplemental new drug applications provide for the deletion of CHF from the **CONTRAINDICATIONS** section of the package insert, and editorial changes.

We have 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.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate these submissions "**FPL for approved supplements NDA 20-357/S-030 and NDA 21-202/S-015.**" Approval of these submissions by FDA is not required before the labeling is used.

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

MEDWATCH
Food and Drug Administration
WO 22, Room 4447
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

NDA 20-357/S-030

NDA 21-202/S-015

Page 2

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, please call Ms. Jena Weber, 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

Enclosure (PI)

**This is a representation of an electronic record that was signed electronically and
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/s/

Mary Parks
11/1/2006 11:07:34 AM