DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-202/S-008

Bristol-Myers Squibb
Attention: Eileen Connolly
Associate Director, GRS-CMC
P.O. Box 4000
Princeton, NJ 08543-4000

Dear Ms. Connolly:

Please refer to your supplemental new drug application dated December 12, 2002, received December 13, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Glucophage® XR (metformin HCl extended release tablets).

We acknowledge receipt of your submissions dated March 20, and April 2, 2003.

This supplemental new drug application provided for a new 750 mg tablet strength.

We 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 submitted labeling text. Sufficient stability data has been submitted to support a 12-month expiration date.

The final printed labeling (FPL) must be identical to the labeling (text for the package insert, patient package insert, and immediate carton and container labels), submitted December 12, 2002.

Please submit the FPL electronically 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, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 21-202/S-008." Approval of this submission by FDA is not required before the labeling is used.

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division, the Division of Metabolic and Endocrine Drug Products, HFD-510, and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

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, HF-2
FDA
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, please call Ms. Jena Weber, Regulatory Project Manager, at 301-827-6422.

Sincerely,

{See appended electronic signature page}

David G. Orloff, M.D.
Director
Division of Metabolic and Endocrine Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosure: package insert (final draft submitted on April 11, 2003).

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

/s/

David Orloff

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