CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number NDA 21-178/S-004

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-178/S-004

Bristol-Myers Squibb Pharmaceutical Research Institute
Attention: Warren C. Randolph
Director, Metabolic/Endocrine Products, Regulatory Science
P.O. Box 4000
Princeton, NJ 08543-4000

Dear Mr. Randolph:

Please refer to your supplemental new drug application dated November 30, 2001, received November 30, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Glucovance® (Glyburide and Metformin HCL) Tablets, 1.25 mg/250 mg; 2.5 mg/500 mg; 5 mg/500 mg.

We acknowledge receipt of your submissions dated March 1, May 9 and 15, September 11, 12, 26, and 30, 2002.

This supplemental new drug application provides for the use of Glucovance® (Glyburide and Metformin HCl) tablets with a thiazolidinedione when glycemic control is not obtained with Glucovance® alone.

We 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 attached draft package insert and patient package insert labeling submitted on September 30, 2002.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens must contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred (21 CFR 314.55).

We note that in your November 30, 2001, submission, you requested a waiver.

Based on the information submitted, we are waiving the pediatric study requirement for this supplemental new drug application.

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 inserts 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 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, 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 Drugs 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/

David Orloff
9/30/02 05:02:35 PM

APPEARS THIS WAY
ON ORIGINAL