NDA 20-496/S-002

Hoechst Marion Roussel, Inc.
Attention: J. Michael Nicholas, Ph.D.
Director, U.S. Regulatory Affairs
10236 Marion Park Drive
Kansas City, MO 64134-0627

Dear Dr. Nicholas:

Please refer to your supplemental new drug application dated November 3, 1997, received February 10, 1998, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Amaryl (glimepiride tablets) 1, 2 and 4 mg.

We acknowledge receipt of your submission dated August 25, 1998, received August 27, 1998, submitted in response to our August 10, 1998, approvable letter. We also acknowledge receipt of your November 12, 1998, submission.

This supplemental new drug application provides for the use of Amaryl tablets concomitantly with metformin when diet, exercise, and Amaryl or metformin alone do not result in adequate glycemic control.

We have completed the review of this supplemental application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon labeling text. Accordingly, the supplemental application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the submitted draft labeling (package insert dated August 1997, submitted on November 3, 1997. Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Please submit 20 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 20-496/S-002." Approval of this submission by FDA is not required before the labeling is used.

In addition, please submit three copies of the introductory promotional materials that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to this Division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-40
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Practitioner" letter) is issued to physicians and others responsible for patient care, 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 contact Ms. Jena Weber, Project Manager, at (301) 827-6422.

Sincerely,

Solomon Sobel, M.D.
Director
Division of Metabolic and Endocrine Drug Products
Office of Drug Evaluation II