NDA 20-482/S-007 and S-008

Bayer Pharmaceutical Division
Attention: Richard J. Fanelli, Ph.D.
Associate Director, Regulatory Affairs
400 Morgan Lane
West Haven, CT 06516-4175

Dear Dr. Fanelli:

Please refer to your supplemental new drug applications dated September 29, 1997 (S-007), received September 30, 1997, and November 24, 1997 (S-008), received November 25, 1997, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Precose® (acarbose) Tablets.

We acknowledge receipt of your submissions dated October 20, 1997, for S-007, and February 13 and July 7, 1998, for both S-007 and S-008. The user fee goal dates are September 30, 1998 (for S-007), and November 25, 1998 (for S-008).

These supplemental new drug applications provide for the new combination use of Precose for patients with type 2 diabetes treated with diet plus insulin (S-007) and for the new combination use of Precose for patients with type 2 diabetes treated with diet plus metformin (S-008).

We have completed the review of these supplemental applications, 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 submitted labeling text. Accordingly, the supplemental applications are approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the submitted labeling (text for the package insert dated July 7, 1998). 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 supplements NDA 20-482/S-007 and S-008." 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
Center for Drug Evaluation and Research