CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

Application Number: 020482/S010

Trade Name: PRECOSE TABLETS

Generic Name: ACARBOSE

Sponsor: BAYER CORPORATION

Approval Date: 08/16/99

INDICATION(s): AS AN ADJUNCT TO DIET TO LOWER BLOOD GLUCOSE LEVELS

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APPLICATION: 020482/S010

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	Included	Pending Completion	Not Prepared	Not Required
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Printed Labeling				X
Medical Review(s)				X
Chemistry Review(s)				X
EA/FONSI				X
Pharmacology Review(s)				X
Statistical Review(s)				X
Microbiology Review(s)				X
Clinical Pharmacology Biopharmaceutics Review(s)				X
Bioequivalence Review(s)				X
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APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

NDA 20-482/S-010

Food and Drug Administration
Rockville MD 20857

Bayer Corporation
Attention: Gautam Shah, Ph.D.
Regulatory Affairs
400 Morgan Lane
West Haven, CT 06516-4175

AUG 16 1999

Dear Dr. Shah:

Please refer to your supplemental new drug application dated August 14, 1998, received August 17, 1998, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Precose® (acarbose) Tablets.

This supplemental new drug application provides for the addition of a Geriatric Use subsection to the **PRECAUTIONS** section of the package insert as per 21 CFR 201.57(f)(10)(ii)(B).

The following paragraph will be added to the end of the **PRECAUTIONS** section, immediately after the "Pediatric Use" paragraph:

> **Geriatric Use:** Of the total number of subjects in clinical studies of Precose® in the United States, 27 percent were 65 and over, while 4 percent were 75 and over. No overall differences in safety and effectiveness were observed between these subjects and younger subjects. The mean steady-state under the curve (AUC) and maximum concentrations of acarbose were approximately 1.5 times higher in elderly compared to young volunteers; however, these differences were not statistically significant.

We have completed the review of this supplemental application 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 draft labeling dated August 13, 1999. Accordingly, the supplemental application is approved effective on the date of this letter.

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 20482/S-010." Approval of this submission by FDA is not required before the labeling is used.

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, Regulatory Project Manager, at (301) 827-6422.

Sincerely,

/S/

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

APPEARS THIS WAY ON ORIGINAL