



DEPARTMENT OF HEALTH & HUMAN SERVICES

Weber
Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-482/S-010

AUG 24 1998

Bayer Corporation Pharmaceutical Division
400 Morgan Lane
West Haven, CT 06516

Attention: Richard J. Fanelli, Ph.D.

Dear Dr. Fanelli:

We acknowledge receipt of your supplemental application for the following:

Name of Drug:	Precose® (acarbose) Tablets
NDA Number:	20-482
Supplement Number:	S-010
Date of Supplement:	August 14, 1998
Date of Receipt:	August 17, 1998

Unless we find the application not acceptable for filing, this application will be filed under Section 505(b)(1) of the Act on October 16, 1998 in accordance with 21 CFR 314.101(a).

All communications concerning this NDA should be addressed as follows:

Center for Drug Evaluation and Research
Division of Metabolic and Endocrine Drug Products, HFD-510
Office of Drug Evaluation II
Attention: Document Control Room 14B-19
5600 Fishers Lane
Rockville, MD 20857

Sincerely,

/s/ [Redacted Signature]

Enid Galliers
Chief, Project Management Staff
Division of Metabolic and Endocrine
Drug Products, HFD-510
Office of Drug Evaluation II
Center for Drug Evaluation and Research



Pharmaceutical
Division

Bayer Corporation
400 Morgan Lane
West Haven, CT 06516-4175

August 13, 1999

Dr. Solomon Sobel
Division of Metabolic
and Endocrine Drug Products
Food and Drug Administration
Office of Drug Evaluation II (HFD-510)
Center for Drug Evaluation and Research
Document Control Room 14B-04
5600 Fishers Lane
Rockville, MD 20857.

RE: Precose® (Acarbose) Tablets
NDA # 20-482
Geriatric Labeling

Dear Dr. Sobel,

As requested by Ms. Jena Weber by a phone call on August 10, 1999, concerning our Geriatric Labeling Supplement that was submitted on August 14, 1998, enclosed are the following items:

1. Mocked-up package insert for geriatric labeling for Precose® tablets.
2. Debarment Certification.

Please do not hesitate to contact me at (203) 812- 3051 if there are any questions.

Sincerely,

A handwritten signature in dark ink, appearing to read "Gautam Shah".

Gautam Shah, Ph.D.
Associate Director
Regulatory Affairs

Fax: Jena Weber, CSO



August 14, 1998

ORIGINAL

Pharmaceutical
Division

Bayer Corporation
400 Morgan Lane
West Haven, CT 06516-4175
Phone: 203 812-2000

Solomon Sobel, M.D., Director
Division of Metabolism and Endocrine Drug Products
Office of Drug Evaluation II (HFD-510)
Center for Drug Evaluation and Research
Food and Drug Administration
ATTN: DOCUMENT CONTROL ROOM 14B-04
5600 Fishers Lane
Rockville, MD 20857

RE: NDA #20-482 Precose® (acarbose) tablets
Geriatric Labeling Supplement

Dear Dr. Sobel:

Pursuant to Title 21 CFR 201.57(f)(10), Bayer Corporation Pharmaceutical Division hereby submits a Geriatric Labeling Supplement for Precose® (acarbose) tablets (NDA #20-482). The labeling is being revised under paragraph (f)(10)(ii)(B), and includes standard language in support of the statement on the use of Precose® in the geriatric population. As justified in Appendix 1, we feel that our clinical studies include a sufficient number of geriatric subjects to determine that the elderly do not respond differently, in terms of both the safety and efficacy of Precose®.

Since the information provided has been summarized from clinical studies which have already been submitted to the Division, it is our understanding that a user fee is not required.

In order to place all geriatric information together, a statement already in the approved labeling in the Special Populations paragraph of the Pharmacokinetics section has been moved to this new section. The following paragraph is to be added to the approved labeling at 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 area 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.

Please do not hesitate to contact me at (203) 812-2010 if there are any questions.

Sincerely,


Richard J. Fanelli, Ph.D.
Associate Director, Regulatory Affairs

/RJF

REVIEWS COMPLETED	
Desk Copies:	Robert J. Misbin, M.D. Jena M. Weber, CSO
CSO ACTION:	
☐ LETTER ☐ N.A.I. ☐ MEMO	
CSO ACTION:	DATE

