PEDIATRIC PAGE

(Complete for all original application and all efficacy supplements)

NDA/BLA Number:	20482	**Trade Name:**	PRECOSE(ACARBOSE) TABS ORAL 50/100/200MG
Supplement Number:	10	**Generic Name:**	ACARBOSE
Supplement Type:	SE8	**Dosage Form:**	TAB
Regulatory Action:		**Proposed Indication:**	Language to support Geriatric Labeling.

ARE THERE PEDIATRIC STUDIES IN THIS SUBMISSION?

NO, No waiver and no pediatric data

What are the INTENDED Pediatric Age Groups for this submission?

____NeoNates (0-30 Days) ____Children (25 Months-12 years)

____Infants (1-24 Months) ____Adolescents (13-16 Years)

Label Adequacy	Does Not Apply
Formulation Status	-
Studies Needed	-
Study Status	-

Are there any Pediatric Phase 4 Commitments in the Action Letter for the Original Submission? NO

COMMENTS:

This Page [illegible] from a PROJECT MANAGER/CONSUMER SAFETY OFFICER, JENA W

/S/ [redacted]

Signatu /S/ [redacted] 8/10/99

Aug 11 1999

Date

Bayer

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 Supplement

DEBARMENT CERTIFICATION

Bayer hereby certifies under FD&C Act Section 306 (k) (1) that it did not and will not use in any capacity the services of any person debarred under section 306 of the Federal Food, Drug and Cosmetic Act in connection with this application.

Please call Gautam Shah, Ph.D. if you have any further questions regarding this application.

Sincerely,

Carl E. Calcagni, R.Ph.
Vice President
Regulatory Affairs

AUG - 9 1999

NDA 20-482
Precose – Geriatric Labeling
Stamp date: August 17, 1998

The Sponsor proposes to add a statement that 27% of patients in the clinical trials were 65 and over, and 4 % were 75 and over. There were no differences in safety and efficacy between younger and older patients. The mean steady state concentrations and AUC were 1.5times higher in elderly patients but the difference was not statistically significant.

The following data was cited to support the label change:

The mean dose was 71.9 mg tid in younger patients compared to 69.6 mg tid in patients 65 and over. The mean placebo-subtracted reduction of HbA1c was 0.56% for younger patients and 0.47 for patients 65 and older. The placebo-subtracted reduction in one-hour postprandial glucose was 39 mg/dl in younger patients and 38 mg/dl in older patients. Both treatment effects were significantly different from zero ($p<0.0002$) but there was no significant difference between the older and younger groups. Gastrointestinal AE's leading to discontinuation of treatment occurred in both groups but there was no difference between younger and older patients. For instance, 8% of younger patients discontinued because of flatulence compared to 5% of older patients ($p=0.28$). With respect to hypoglycemia the placebo-subtracted Reporting was 0% for younger patients and 3% for older patients. The difference was not statisitically significant ($p=0.5$). Furthermore, hypoglycemia in patients on acarbose is generally due to concomittant antidiabetic therapy with sulfonylureas or insulin. ALT elevation and serious AE's were no different in younger and older patients.

Recommendation:

The labeling change should be approved.

/S/ [redacted]

Robert I Misbin MD
HFD 510
August 6, 1999

/S/ [redacted]

APPEARS THIS WAY ON ORIGINAL