DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-482/S-011

Bayer Corporation
Attention: Margaret Foley
Regulatory Compliance Associate, Regulatory Affairs
400 Morgan Lane
West Haven, CT 06516

Dear Ms. Foley:

Please refer to your supplemental new drug application dated November 3, 1999, received November 4, 1999, submitted under 505(b) pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Precose® (acarbose) Tablets, 25 mg, 50 mg, and 100 mg.

We acknowledge receipt of your submissions dated March 4, August 13, and September 6, 2002.

Your submission of March 4, 2002, constituted a completed response to our June 6, 2000, approvable letter.

This supplemental new drug application provides for changes to the **Drug-Drug Interactions** subsection of the **CLINICAL PHARMACOLOGY** section, and to the **Drug Interactions** subsection of the **PRECAUTIONS** section of the package insert.

We have completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical, and include the revisions indicated to the labeling text for the package insert submitted to FDA on September 6, 2002. These revisions are terms of the approval of this application.

Please submit the FPL electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDA. Alternatively, you may submit 20 paper 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 heavyweight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 20-482/S-011." Approval of this submission by FDA is not required before the labeling is used.

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, please call Ms. Jena Weber, Regulatory Project Manager, at 301-827-6422.

Sincerely,

{See appended electronic signature page}

David G. Orloff, M.D.
Director
Division of Metabolic and Endocrine Drug Products
Office of Drug Evaluation ODE II
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

David Orloff

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