DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-482/S-023

Bayer HealthCare Pharmaceuticals
Attention: Thomas B. Delvers, R.Ph.
Deputy Director, Global Regulatory Affairs
P.O. Box 1000
Montville, NJ 07045-1000

Dear Mr. Delvers:

Please refer to your supplemental new drug application dated January 17, 2008, received January 18, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Precose (acarbose) Tablets.

We acknowledge receipt of your submission dated August 8, 2008.

This supplemental application is in response to our supplement request letter dated November 19, 2007, and proposes labeling revisions to the **INDICATIONS AND USAGE,** and **PRECAUTIONS** sections of the package insert.

We 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 to the attached labeling (text for the package insert) submitted dated August 8, 2008.

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to the enclosed labeling (text for the package insert) submitted August 8, 2008). Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission, "SPL for approved NDA 20-482/S-023."

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 301-796-1306.

Sincerely,

{See appended electronic signature page}

Mary H. Parks, M.D.
Director
Division of Metabolism & Endocrinology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosure (package insert)

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

/s/

Mary Parks

8/23/2008 09:43:31 AM