DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 77-532

Cobalt Laboratories
Attention: Richard Sanzen, R.Ph.
Director, Regulatory Affairs
24840 S. Tamiami Trail, Suite 1
Bonita Springs, FL 34134

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated January 10, 2005, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Acarbose Tablets, 25 mg, 50 mg, and 100 mg.

Reference is also made to your amendments dated September 27, 2005; February 9, June 8, August 31, September 13, and September 20, 2006; and January 17, April 9, August 9, September 3, September 14, September 20, September 21, and September 24, 2007.

We have completed the review of this ANDA and have concluded that adequate information has been presented to demonstrate that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly the ANDA is approved, effective on the date of this letter. The Division of Bioequivalence has determined your Acarbose Tablets, 25 mg, 50 mg, and 100 mg, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Precose Tablets, 25 mg, 50 mg, and 100 mg, respectively, of Bayer Pharmaceuticals Corporation (Bayer). Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your ANDA.

The RLD upon which you have based your ANDA, Bayer's Precose Tablets, is subject to a period of patent protection. As noted in the agency's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book"), U.S. Patent No. 4,904,769 (the '769 patent) is scheduled to expire on September 6, 2009.

Your ANDA contains a paragraph IV certification to the '769 patent under section 505(j)(2)(A)(vii)(IV) of the Act stating that the '769 patent is invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Acarbose Tablets, 25 mg, 50 mg, and 100 mg under this ANDA. Section 505(j)(5)(B)(iii) of the Act provides that approval of an ANDA shall be made effective immediately, unless an action was brought against Cobalt Pharmaceuticals Inc. (Cobalt) for infringement of the '769 patent that was the subject of the paragraph IV certification. You have notified the agency that Cobalt complied with the requirements of section 505(j)(2)(B) of the Act, and that no action for infringement of the '769 patent was brought against Cobalt within the statutory 45-day period, which action would have resulted in a 30-month stay of approval under section 505(j)(5)(B)(iii).

With respect to 180-day generic drug exclusivity, we note that Cobalt was the first ANDA applicant to submit a substantially complete ANDA with a paragraph IV certification to the '769 patent. However, as explained in a letter to your counsel, the agency has concluded that the 180-day exclusivity period described in section 505(j)(5)(B)(iv) of the Act shall be forfeited.

Under section 506A of the Act, certain changes in the conditions described in this ANDA require an approved supplemental application before the change may be made.

Postmarketing reporting requirements for this ANDA are set forth in 21 CFR 314.80-81 and 314.98. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

Promotional materials may be submitted to FDA for comment prior to publication or dissemination. Please note that these submissions are voluntary. If you desire comments on proposed launch promotional materials with respect to compliance with applicable regulatory requirements, we recommend you submit, in draft or mock-up form, two copies of both the promotional materials and package insert directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705

We call your attention to 21 CFR 314.81(b)(3) which requires that all promotional materials be submitted to the Division of Drug Marketing, Advertising, and Communications with a completed Form FDA 2253 at the time of their initial use.

Sincerely yours,

{See appended electronic signature page}

Gary Buehler
Director
Office of Generic Drugs
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/

Robert L. West
5/7/2008 05:53:34 PM
Deputy Director, for Gary Buehler