



DEPARTMENT OF HEALTH & HUMAN SERVICES

ANDA 76-549

Food and Drug Administration  
Rockville MD 20857

OCT 24 2005

Strategic Bioscience Corporation  
U.S. Agent for: Cobalt Pharmaceuticals, Inc.  
Attention: James Parker, Ph.D.  
93 Birch Hill Road  
Stow, MA 01775

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated November 26, 2002, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for Ramipril Capsules, 1.25 mg, 2.5 mg, 5 mg, and 10 mg.

Reference is also made to your amendments dated May 29, 2003; October 22, and December 3, 2004; and February 9, March 31, May 2, and June 1, 2005. We also acknowledge receipt of your correspondence dated April 8, and August 18, 2003, pertaining to the patent issues associated with this ANDA.

We have completed the review of this ANDA and have concluded that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly, the ANDA is approved. The Division of Bioequivalence has determined your Ramipril Capsules, 1.25 mg, 2.5 mg, 5 mg, and 10 mg, to be bioequivalent and, therefore, therapeutically equivalent to the listed drug Altace Capsules, 1.25 mg, 2.5 mg, 5 mg, and 10 mg, respectively, of King Pharmaceuticals, Inc. Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your ANDA.

The referenced listed drug product (RLD) in your ANDA, Altace Capsules of King Pharmaceuticals Inc. (King), is subject to periods of patent protection. As noted in the agency's publication entitled Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book"), U.S. Patent 5,061,722 (the '722 patent) is scheduled to expire on October 29, 2008, and U.S. Patent 5,403,856 (the '856 patent) is scheduled to expire on April 4, 2012.

With respect to the '856 patent, your ANDA contains a statement under section 505(j)(2)(A)(viii) of the Act that the '856 patent is a method of use patent that does not claim a use for which you are seeking approval in this ANDA.

With respect to the '722 patent, your ANDA contains a paragraph IV patent certification under section 505(j)(2)(A)(vii)(IV) of the Act stating that the patent is invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Ramipril Capsules, 1.25 mg, 2.5 mg, 5 mg, and 10 mg under this ANDA. Section 505(j)(5)(B) 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 '722 patent. This action must have been brought against Cobalt prior to the expiration of 45 days from the date the notice you provided under paragraph (2)(B)(i) was received by the NDA/patent holder(s). You have notified the agency that Cobalt complied with the requirements of section 505(j)(2)(B) of the Act, and that a patent infringement suit was initiated against Cobalt involving Ramipril Capsules, 1.25 mg, 2.5 mg, 5 mg, and 10 mg, with respect to the '722 patent (and the '856 patent) in the United States District Court for the District of Massachusetts (Aventis Pharma Deutschland GMBH and King Pharmaceuticals, Inc. v. Cobalt Pharmaceuticals, Inc., Civil Action No. 03-10492JLT). We acknowledge that the 30-month stay provided under section 505(j)(5)(B)(iii) of the Act expired on August 10, 2005.

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. Therefore, with this approval, Cobalt is eligible for 180-days of market exclusivity. This exclusivity, which is provided for under section 505(j)(5)(8)(iv) of the Act,<sup>1</sup> will begin to run from the earlier of the commercial marketing or court decision dates identified in section 505(j)(5)(B)(iv). Please submit correspondence to the ANDA informing the agency of the date the exclusivity begins to run.

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.

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<sup>1</sup> Because your ANDA was filed before the date of enactment of the Medicare Prescription Drug, Improvement and Modernization Act (MMA) (Public Law 108-173) on December 8, 2003, this reference to the 180-day exclusivity provision is to the section of the Act as in effect prior to December 8, 2003. See MMA § 1102(b)(1).

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(s) directly to:

Food and Drug Administration  
Division of Drug Marketing, Advertising, and Communications  
5901-B Ammendale Road  
Beltsville, MD 20705-1266

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 (HFD-42) with a completed Form FDA 2253 at the time of their initial use.

Sincerely yours,



Gary Buehler  
Director  
Office of Generic Drugs  
Center for Drug Evaluation and Research