DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 22-021

Cobalt Pharmaceuticals Inc.
Attention: Ms. Tirth Uppal
6500 Kitimat Road
Mississauga, Ontario L5N 2B8
Canada

Dear Ms. Uppal:

Please refer to your new drug application **(**NDA) dated January 10, 2006, received January 30, 2006 (date removed from Arrears List) submitted pursuant to section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act for Altace (ramipril) 1.25, 2.5, 5 and 10 mg Tablets.

We acknowledge receipt of your submissions dated January 27 and 30, February 13 and 16, March 7 (two), 13, 14 and 24, June 29, August 17, October 19, November 17, December 26, 2006 and January 10, 23 and 29, and February 13, 2007.

This NDA provides for the use of Altace (ramipril) 1.25, 2.5, 5 and 10 mg Tablets for the treatment of hypertension, reduction in risk of myocardial infarction, stroke and death from cardiovascular causes, and in stable patients who have demonstrated signs of congestive heart failure within the first few days after sustaining acute myocardial infarction.

We have completed our review of this application and it is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text. Within 21 days of this letter, please submit 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 in content to the enclosed labeling text. Upon receipt and verification, we will transmit that version to the National Library of Medicine for posting on the DailyMed website.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert) and immediate container and carton labels submitted October 19, 2006. Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Please submit an electronic version of the FPL 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 but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For

administrative purposes, designate this submission "**FPL for approved NDA 22-021**." Approval of this submission by FDA is not required before the labeling is used.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We are waiving the pediatric study requirement for all indications for this application.

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division and two copies of both the promotional materials and the 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 20705-1266

If you have any questions, please call:

Alisea Crowley, Pharm.D.
Regulatory Project Manager
(301) 796-1144

Sincerely,

{See appended electronic signature page}

Norman Stockbridge, M.D., Ph.D.
Director
Division of Cardiovascular and Renal Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

Enclosure: Agreed-upon labeling text

CC: James Parker, J.D., Ph.D.
U.S. Agent
Strategic Bioscience Corporation
93 Birch Hill Road
Stow, MA 01775
USA

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

/s/

Norman Stockbridge

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