DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 21-642/S-002

Canreg, Inc.
Attention: John Killackey, Ph.D.
U.S. Agent for QOL Medical, LLC
450 North Lakeshore Drive
Mundelein, IL 60060-2850

Dear Dr. Killackey:

Please refer to your supplemental new drug application dated May 12, 2006, received May 15, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Nascobal (cyanocobalamin, USP) Nasal Spray.

This "Changes Being Effected" supplemental new drug application provides for revised text concerning removal of the safety clip in the **INFORMATION FOR PATIENTS** subsection of the **PRECAUTIONS** section, the **Priming (Activation) of Pump** subsection of the **DOSAGE AND ADMINISTRATION** section, and the **INFORMATION FOR PATIENTS** section of the package insert, and the carton label.

We have completed our review of this supplemental application. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on May 12, 2006 (package insert and carton label).

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Randy Hedin, R.Ph., Senior Regulatory Management Officer, at (301) 796-1224.

Sincerely,

{See appended electronic signature page}

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

Enclosure

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

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