DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring, MD 20993

NDA 22-041/S-005

Merck Santé s.a.s
P.O. Box 5283
Chapel Hill, NC 27514-5003

Attention: Cindy Marshall
US Agent

Dear Ms. Marshall:

Please refer to your supplemental new drug application dated September 30, 2008, received October 1, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Cyanokit (hydroxocobalamin).

We acknowledge receipt of your submissions dated April 8 and 21, 2009, received, April 10 and 22, respectively.

This supplemental new drug application provides for the inclusion of additional information regarding the physical and chemical incompatibility between Cyanokit and various commonly co-administered medications. This study was completed to address Post Marketing Commitment 2, listed below, from the December 15, 2006 approval letter.

2. Chemistry, Manufacturing, and Controls (CMC): To study in vitro the biochemical compatibility of hydroxocobalamin with the most frequently administered resuscitation drugs and blood products.

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text and with the minor editorial revisions listed below.

Modify the "Recent Major Changes" and Highlights "Revised" dates to 6/2009 versus 4/2009.

CONTENT OF LABELING

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, except for including the revisions listed, the enclosed labeling (text for the package submitted April 21, 2009).. These revisions are terms of the supplemental NDA approval. 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 22-041/S-005."

LETTERS TO HEALTH CARE PROFESSIONALS

If you issue a letter communicating important safety related information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit an electronic copy of the letter to both this NDA and to the following address:

MedWatch
Food and Drug Administration
Suite 12B05
5600 Fishers Lane
Rockville, MD 20857

REPORTING REQUIREMENTS

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, call Matt Sullivan, Regulatory Project Manager, at 301-796-1245.

Sincerely,

{See appended electronic signature page}

Bob A. Rappaport, M.D.
Director
Division of Anesthesia, Analgesia
and Rheumatology 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/

Rigoberto Roca
6/4/2009 06:16:06 PM
for Bob Rappaport, M.D.