DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-526/S-007

CV Therapeutics
Attention: Carol D. Karp
3172 Porter Drive
Palo Alto, CA 94304

Dear Ms. Karp:

Please refer to your supplemental new drug application dated November 25, 2008, received November 26, 2008, submitted under section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act, for Ranexa (ranolazine) 500 mg Extended-Release (ER) Tablets.

This supplemental new drug application provides CMC information to support the registration of Patheon as a second supplier of the 500 mg tablet. We also note minor revisions to the **HIGHLIGHTS OF PRESCRIBING INFORMATION** and **USE IN SPECIFIC POPULATIONS** sections of the labeling.

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 enclosed labeling text.

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 the enclosed labeling (text for the package insert) submitted November 25, 2008. 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 21-526 S-007."

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

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

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, please call Mr. John David, Regulatory Project Manager at (301) 796-1059.

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: enclosed labeling (text for the 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/

Norman Stockbridge

3/26/2009 07:46:45 AM