DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-526/S-002

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 December 15, 2006, received December 16, 2006, submitted under section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act for Ranexa (ranolazine) 500 and 1000 mg Extended-Release (ER) Tablets.

We acknowledge receipt of your submissions dated June 21 and November 19, 2007.

Your submission of August 3, 2007 constituted a complete response to our June 15, 2007 action letter.

This supplemental new drug application provides for the revision of the current labeling to include information on the pharmacology and mechanism of action for this drug.

We have completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text. The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert).

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(1)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to the enclosed agreed-upon labeling text. 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-[redacted]."** Please amend any pending applications for this NDA with content of labeling in structured product labeling (SPL) format to include the changes approved in this application.

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: agreed-upon labeling text

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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