CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

21-526/S004

Trade Name: Ranexa 500 and 1000 mg Extended-Release (ER)

Generic Name: ranolazine

Sponsor: CV Therapeutics

Approval Date: November 5, 2008

Indications: For the treatment of chronic angina

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APPLICATION NUMBER:

21-526/S004

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APPLICATION NUMBER:

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APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-526/S-004

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

Dear Ms. Karp:

Please refer to your supplemental new drug application (NDA) dated September 27, 2007, received September 27, 2007, 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 also refer to your submissions dated September 27, October 18 and 23, November 26, December 11, 19, 20, and 21, 2007, and January 9, March 6 and 11, April 4, May 22 and 29, June 3, 5, 9, 11, 12, 16, 24 (twice), and 26, July 13, August 26, September 11, 12 and 30, October 2 and 7 and November 3, 2008.

This supplemental new drug application provides for the use of Ranexa (ranolazine) 500 and 1000 mg Extended-Release (ER) Tablets for the treatment of chronic angina. The second-line restriction on the use of ranolazine to treat patients with chronic stable angina is removed.

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 patient package insert) submitted November 3, 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-004."

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 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 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

11/5/2008 03:58:15 PM