DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-386/S-049

Merck & Co., Inc.
Attention: Bea Loran, M.D.
Director, Worldwide Regulatory Affairs
P.O. Box 2000, RY33-208
Rahway, NJ 07065-0900

Dear Dr. Loran:

Please refer to your supplemental new drug application dated December 12, 2008, received December 12, 2008, submitted under section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act for COZAAR (losartan potassium) 25 mg, 50 mg, and 100 mg Tablets.

We acknowledge receipt of your submissions dated January 29, 2009.

This "Changes Being Effected" supplemental new drug application provides for a revision to the **ADVERSE REACTIONS**/*Post Marketing Experience* section of the label. The following revision was proposed:

1. In **ADVERSE REACTIONS**/*Post Marketing Experience*, the following sentence was added:

   General Disorders and Administration Site Conditions: Malaise

We have completed our review of this application, as amended,
and it is approved, effective on the date of this letter, for use as recommended in the electronic labeling (SPL) submitted on December 12, 2008.

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

Quynh Nguyen, Pharm.D., RAC
Regulatory Project Manager
(301) 796-0510

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: Approved 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

6/4/2009 10:15:40 AM