DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-387/S-045

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 February 5, 2009, received February 5, 2009, submitted under section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act for Hyzaar (losartan potassium-hydrochlorothiazide) 50-12.5 mg, 100-12.5 mg, and 100-25 mg Tablets.

We acknowledge receipt of your submissions dated February 13 and April 6, 2009.

This supplemental new drug application provides for changes to the **ADVERSE REACTIONS** section of the label. The following changes were proposed:

1. In **ADVERSE REACTIONS/Losartan Potassium**, General disorders and administration site conditions: Malaise; has been added to the second paragraph, fifth sentence.

2. In **ADVERSE REACTIONS/Hydrochlorothiazide/Post-Marketing Experience,** the third sentence has been changed from:

   Hemic: Thrombocytopenia has been reported rarely with losartan.

   To:

   Hemic: Thrombocytopenia.

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 February 13, 2009.

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, 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

6/12/2009 06:09:06 PM