DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-386/S-039
NDA 20-387/S-035

Merck & Co., Inc.
Attention: Jeffrey R. Tucker, M.D.
Director, Regulatory Affairs
P. O. Box 4, BLA-20
West Point, PA 19486

Dear Dr. Tucker:

Please refer to your supplemental new drug applications dated 11 October 2004, received 12 October 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for:

1. NDA 20-386/S-039 Cozaar (losartan potassium) 25, 50 and 100 mg Tablets
2. NDA 20-387/S-035 Hyzaar (losartan potassium-hydrochlorothiazide) 50-12.5 and 100-25 mg Tablets.

These supplemental new drug applications provide for the following revisions:

1. NDA 20-386/S-039

   Under **ADVERSE REACTIONS**, *Post-Marketing Experience*, subheadings were alphabetized and the following information was added:

   a. *Hemic:* Thrombocytopenia (reported rarely)
   b. *Metabolic and Nutrition* subheading

2. NDA 20-387/S-035

   Under **ADVERSE REACTIONS**, *Post-Marketing Experience*, subheadings were alphabetized and the following information was added:

   a. *Hemic:* Thrombocytopenia has been reported rarely with losartan
   b. *Metabolic and Nutrition* subheading

We completed our review of these applications, as amended. These applications are approved, effective on the date of this letter, for use as recommended in the electronic agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the enclosed labeling text for the package insert that was electronically submitted on 11 October 2004.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate these submissions "**FPL for approved supplement NDA ##-###/S-YYY, S-ZZZ**." Approval of these submissions by FDA is not required before the labeling is used.

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, HFD-410
FDA
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:

Cheryl Ann Borden, MSN, RN, CCRN, CCNS
Regulatory Health Project Manager
(301) 594 5312.

Sincerely,

{See appended electronic signature page}
Norman Stockbridge
Acting Director
Division of Cardio-Renal Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

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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