



NDA 20-386/S-040
NDA 20-387/S-034

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-040 Cozaar (losartan potassium) 25, 50 and 100 mg Tablets
2. NDA 20-387/S-034 Hyzaar (losartan potassium-hydrochlorothiazide) 50-12.5 and 100-25 mg Tablets.

These "Changes Being Effected in 30 days" supplemental new drug applications for 20-386/S-040 and 287/S-034 provides for:

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

Musculoskeletal: Rare cases of rhabdomyolysis have been reported in patients receiving angiotensin II receptor blockers

2. Under **HOW SUPPLIED** (20-386/S-040):

NDC 0006-0951-58 unit of use bottles of 100 was deleted
NDC 0006-0952-58 unit of use bottles of 100 was deleted
NDC 0006-0960-58 unit of use bottles of 100 was deleted

3. Under **HOW SUPPLIED** (20-387/S-034):

NDC 0006-0717-58 unit of use bottles of 100 was deleted
NDC 0006-0747-58 unit of use bottles of 100 was deleted
NDC 0006-0747-82 bottles of 1,000 was added
Label issue date to be updated

NDA 20-386/S-040

NDA 20-387/S-034

Page 2

We completed our review of these supplemental new drug applications. They are approved, effective on the date of this letter, for use as recommended in the electronic final printed labeling (eFPL) submitted on 11 October 2004.

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 the requirements for an approved NDA set forth under 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, M.D., Ph.D.

Acting Director

Division of Cardio-Renal Drug Products

Office of Drug Evaluation I

Center for Drug Evaluation and Research

Enclosure:

**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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