DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-386/S-019 & 029

Merck and Co., Inc.
Attention: Jeffrey R. Tucker, M.D.
Sumneytown Pike
P.O. Box 4, BLA-20
West Point, PA 19486

Dear Dr. Tucker:

Please refer to your supplemental new drug applications dated August 25, 1999 (NDA 20-386/S-019) and December 21, 2001 (NDA 20-386/S-029), submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Cozaar (losartan potassium) 25, 50, and 100 mg Tablets.

We acknowledge receipt of your submissions dated February 27, 2004, (to NDA 20-386/S-019) and October 29, 2002, July 3 and October 28, 2003, and February 27, 2004 (to NDA 20-386/S-029). Your submissions of February 27, 2004 constituted a complete response to our April 11, 2000 and May 20, 2003 approvable letters for NDA 20-386/S-019 and our October 21, 2002 approvable letter for NDA 20-386/S-029.

Electronic Final Printed Labeling (FPL) was submitted on February 27, 2004, received March 1, 2004, revised as follows:

NDA 20-386/S-029

This supplemental new drug application provides for pediatric-related changes to the **CLINICAL PHARMACOLOGY, PRECAUTIONS, ADVERSE REACTIONS**, and **DOSAGE AND ADMINISTRATION** sections of the labeling. In addition, there are other, minor revisions to the **DESCRIPTION** and **CLINICAL PHARMACOLOGY** sections of the labeling.

NDA 20-386/S-019

1. Information regarding interactions of losartan with rifampin, fluconazole, and erythromycin has been added under **CLINICAL PHARMACOLOGY**, *Drug Interactions* and **PRECAUTIONS**, *Drug Interactions*.
2. Under **PRECAUTIONS**, the sub-heading "*Use in the elderly*" has been changed to "*Geriatric Use.*"

We have completed our review of these supplemental new drug applications, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the submitted electronic final printed labeling (package

inserts included in your submissions of February 27, 2004). Accordingly, these supplemental applications are approved effective on the date of this letter.

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 contact:

Mr. Edward Fromm
Regulatory Health Project Manager
(301) 594-5332

Sincerely,

{See appended electronic signature page}

Douglas C. Throckmorton, M.D.
Director
Division of Cardio-Renal Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

Enclosed 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/

Doug Throckmorton
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