DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-387/S-024

Merck & 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 application dated February 7, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Hyzaar (losartan potassium/hydrochlorothiazide) Tablets, 50/12.5 and 100/25 mg.

This "Changes Being Effected" supplemental new drug application provides for electronic final printed labeling revised as follows:

1. Under **DOSAGE AND ADMINISTRATION**, the sentence "Dosing must be individualized" has been added to the beginning of this section.

2. Under **DOSAGE AND ADMINISTRATION**, **Dose Titration by Clinical Effect**, the phrase "or hydrochlorothiazide alone" has been added to the first sentence of this subsection.

We note that several minor editorial changes have been made to the labeling.

We have completed the review of this supplemental application 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 insert included in your submission of February 8, 2002). Accordingly, the supplemental application is 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 call:

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

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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