DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-387/S-037

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

Dear Dr. Tucker:

Please refer to your supplemental new drug application dated 17 December, 2004, received 20 December 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for HYZAAR (losartan/potassium hydrochlorothiazide) 50-12.5, 100-12.5, and 100-25 mg Tablets.

We acknowledge receipt of your submissions dated 19 and 25 July 2005, 15 and 30 August 2005.

This supplemental new drug application provides for registration of a losartan 100 mg and hydrochlorothiazide 12.5 mg fixed-dose combination tablet.

We completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the electronic final printed labeling (FPL) submitted on 30 August 2005.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We are waiving the requirement for pediatric studies for all age groups for this application.

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to the Division of Cardiovascular and Renal Products and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
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
LCDR, United States Public Health Service
Regulatory Health Project Manager
(301) 796 1046.

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: Electronic Labeling

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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