DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 19-778/S-034

Merck & Co., Inc.
Attention: Michael C. Elia, Ph.D.
P.O. Box 4, BLA-20
Sumneytown Pike
West Point, PA 19486

Dear Dr. Elia:

Please refer to your supplemental new drug application dated December 31, 2001, received January 2, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Prinzide (lisinopril/hydrochlorothiazide) Tablets 10/12.5 mg, 20/12.5 mg and 20/25 mg.

This "Changes Being Effected in 30 days" supplemental new drug application provides for Merck Frosst in Kirkland, Quebec as a alternate manufacturing/testing/packaging site for the 10/12.5 mg, 20/12.5 mg and 20/25 mg strengths of PRINZIDE™ Tablets.

We have completed the review of this supplemental application, and it is approved.

Please submit final printed labeling (FPL) for PRINZIDE™ identical to the submitted draft labeling in your next annual report.

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, call Ms. Sandra L. Birdsong, Regulatory Health Project Manager, at (301) 594-5312.

Sincerely,

{See appended electronic signature page}

Kasturi Srinivasachar, Ph.D.
Chemistry Team Leader, DNDC I for the
Division of Cardio-Renal Drug Products, (HFD-110)
DNDC I, Office of New Drug Chemistry
Center for Drug Evaluation and Research

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/s/

Kasturi Srinivasachar

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