DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 13-402/S-085

Merck & Company, Inc.
Attention: Mr. Kenneth A. Kramer
Sumneytown Pike, P.O. Box 4, BLA-20
West Point, PA 19486

Dear Mr. Kramer:

Please refer to your electronic supplemental new drug application dated August 26, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Aldoril (methyldopa/hydrochlorothiazide) 250/15, 250/25, 500/30 & 500/50 mg Tablets.

We acknowledge receipt of your submissions dated March 10, and September 1, 2004. Your submission of September 1, 2004 constituted a complete response to our February 27, 2004 action letter.

This electronic supplemental new drug application provides for final printed labeling (FPL) revised by adding a Geriatric Use subsection under PRECAUTIONS as follows:

> Geriatric Use
> Clinical studies of ALDORIL did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.
>
> This drug is known to be substantially excreted by the kidney, and the risk of toxic reactions to this drug may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function.

We have completed our review of this supplemental new drug application, as amended, and it is approved, effective on the date of this letter, for use as recommended in the FPL submitted on September 1, 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

Mr. Daryl Allis
Regulatory Project Manager
(301) 594-5332

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

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

12/14/04 02:46:04 PM