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APPROVAL PACKAGE FOR:

APPLICATION NUMBER

19-221/S-026
18-998/S-058

Approval Letter

Department of Health & Human Services

Food and Drug Administration
Rockville MD 20857

NDA 19-309/S-023
NDA 18-998/S-058
NDA 19-221/S-026

Merck and Company, Inc.
Attention: Ms. Virginia G. Snyder
Sumneytown Pike
P.O. Box 4, BLA-20
West Point, PA 19486

Dear Ms. Snyder:

Please refer to your supplemental new drug applications dated July 20, 1999, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Vasotec I.V. (enalaprilat), Vasotec (enalapril maleate) Tablets, and Vaseretic (enalapril maleate/hydrochlorothiazide) Tablets.

We acknowledge receipt of your submissions dated July 31, 2001 (NDA 18-998) and August 2, 2001 (NDAs 19-221 and 19-309). Your submissions of July 31, 2001 and August 2, 2001 constituted a complete response to our August 25, 2000 and January 2, 2001 action letters.

These supplemental new drug applications provide for final printed labeling revised by adding information regarding a study in which the use of indomethacin and sulindac did not show evidence of a blunting of the antihypertensive action of enalapril maleate. In addition, class labeling text stating that non-steroidal anti-inflammatory drugs may diminish the antihypertensive effect of ACE inhibitors has been added.

We have completed the review of these supplemental applications, as amended, and have concluded that adequate information has been presented to demonstrate that the drug products are safe and effective for use as recommended in the submitted final printed labeling (package insert included in your July 31 and August 2, 2001 submissions). 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:

Ms. Sandra Birdsong
Regulatory Project Manager
(301) 594-5334

Sincerely,

/S/

{See appended electronic signature page}

Raymond J. Lipicky, 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/

Raymond Lipicky
11/27/01 02:33:29 PM