CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: 20-830/S008

APPROVAL LETTER

Hilfiker

NDA 20-830/S-008

Merck and Co., Inc.
P.O. Box 2000
Rahway, NJ 07065-0900

MAR 3 2000

Attention: Steven E. Caffé, M.D.
Senior Director
Regulatory Affairs

Dear Dr. Caffé:

Please refer to your supplemental new drug application dated May 6, 1999, received May 7, 1999, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Singulair (montelukast sodium) Chewable Tablets, 4 mg.

We acknowledge receipt of your submissions dated June 24, September 1 and 29, November 24, and December 2, 9, 21, and 23, 1999, January 28, and March 3, 2000.

This supplemental new drug application provides for the use of Singulair (montelukast sodium) Chewable Tablets, 4 mg for prophylaxis of asthma in pediatric patients 2 to 5 years of age.

We have completed the review of this supplemental application, as amended, and it is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the submitted draft labeling (package insert and patient package insert submitted March 3, 2000, and immediate container and carton labels submitted December 2 and 21, 1999).

Please submit 20 copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Submit ten individually-mounted copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 20-830/S-008." Approval of this submission by FDA is not required before the labeling is used.

Validation of the regulatory methods has not been completed. At the present time, it is the policy of the Center not to withhold approval because the methods are being validated. Nevertheless, we expect your continued cooperation to resolve any problems that may be identified.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Practitioner" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
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, call Mr. David Hilfiker, Project Manager, at (301) 827-1084.

Sincerely yours,

/S/

Robert J. Meyer, M.D.
Director
Division of Pulmonary and Allergy Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

APPEARS THIS WAY
ON ORIGINAL