DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-830/S-011

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

Attention: David Altarac, M.D., M.P.A.
Director, Regulatory Affairs

23 NOV 2001

Dear Dr. Altarac:

Please refer to your supplemental new drug application dated May 25, 2000, received May 26, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Singulair (montelukast sodium) Chewable Tablets.

We acknowledge receipt of your submissions dated March 12, August 7 and September 20, 2001. Your submission of September 20, 2001, constituted a complete response to our September 13, 2001, action letter.

This supplemental new drug application provides additional information for the use of Singular 4 mg Chewable Tablets for long-term chronic treatment of asthma in children 2-5 years of age.

We have completed the review of this supplemental application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon labeling text. Accordingly, the supplemental application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the enclosed draft labeling (draft package insert text submitted August 7, 2001), which includes the revision as discussed between Dr. Craig Ostroff and Ms. Michelle Kloss, of your firm, on November 21, 2001. These revisions are terms of approval for this application.

Please submit the copies of final printed labeling (FPL) electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Please individually mount ten of the copies on heavyweight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 20-830/S-011." Approval of this submission by FDA is not required before the labeling is used.

In addition, please submit three copies of the introductory promotional materials that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to this Division 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, Maryland 20857

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" 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 Dr. Craig Ostroff, Regulatory Management Officer, at (301) 827-5585.

Sincerely,

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