DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-829/S-031
NDA 20-830/S-033
NDA 21-409/S-010

Merck & Co., Inc.
P.O. Box 2000, RY 33-720
Rahway, New Jersey 07065-0900

Attention: Frank Seebach, M.D., RAC
Director, Regulatory Affairs

Dear Dr. Seebach:

Please refer to your supplemental new drug applications dated June 23, 2004, received June 24, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Singulair (montelukast sodium) Tablets, Chewable Tablets, and Oral Granules.

These "Changes Being Effected in 30 days" supplemental new drug applications provide for the insertion of the post-marketing adverse reaction "drowsiness" into the "What are the possible side effects of SINGULAIR?" section of the patient product information.

We completed our review of these applications. These applications are approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on June 23, 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 reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Lori Garcia, Regulatory Project Manager, at (301) 827-5580.

Sincerely,

{See appended electronic signature page}

Badrul A. Chowdhury, M.D., Ph.D.
Director
Division of Pulmonary and Allergy Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosure

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Badrul Chowdhury

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