DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-829/S-041
NDA 20-829/S-042
NDA 20-829/S-043
NDA 20-830/S-043

Merck and Co., Inc
P.O. Box 2000, RY32-605
Rahway, NJ 07065-0900

Attention: Anne H. Cheung
Director, Regulatory Affairs

Dear Ms. Cheung:

Please refer to your supplemental new drug applications dated October 13 (NDA 20-829/S-041 and NDA 20-830/S-043, November 10 (NDA 20-829/S-042) and December 20, 2006 (NDA 20829/S-043, received October 16, November 13, and December 26, 2006, respectively, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Singulair (montelukast sodium) Tablets and Chewable Tablets.

We acknowledge receipt of your submissions dated November 10, 2006, to NDA 20-829/S-041 and NDA 20-830/S-043, April 10, 2007, to NDA 20-829/S-041 and NDA 20-830/S-043, and April 11, 2007, to NDA 20-829/S-042 and NDA 20-829/S-043

These "Changes Being Effected" supplemental new drug applications provide for changes to the carton and immediate container labeling.

We completed our review of these supplemental new drug applications, as amended. They are approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on November 10, 2006 (NDA 20-829/S-041, NDA 20-829/S-042 and NDA 20-830/S-043), and December 20, 2006 (NDA 20-829/S-043).

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
Food and Drug Administration
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

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 LCDR Lori Garcia, Regulatory Project Manager, at (301) 796-1212.

Sincerely,

{See appended electronic signature page}

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

Badrul Chowdhury

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