DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-830/S-047

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

Attention: Anne H. Cheung
Director, Worldwide Regulatory Affairs

Dear Ms. Cheung:

Please refer to your supplemental new drug application dated June 06, 2007, received June 07, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Singulair, (montelukast sodium) chewable tablets (4mg and 5mg).

This "Changes Being Effected" supplemental new drug application provides for changes to the Usual Dosage section of the 30 count and 90 count bottle labeling, and 100 count hospital unit dose cartons, to align with the approved Singulair tablets labeling.

We have completed our review of this supplemental new drug application. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on June 06, 2007.

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 Sadaf Nabavian, Regulatory Project Manager, at (301) 796-2777.

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 of 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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