DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-829/S-048
20-830/S-050
21-409/S-026

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

Attention: Margaret E. McCann, D.V.M, Ph.D.
Associate Director, Worldwide Regulatory Affairs

Dear Dr. McCann:

Please refer to your supplemental new drug applications dated February, 25, 2008, received February, 25, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Singulair (montelukast sodium) tablets, chewable tables and oral granules.

We acknowledge receipt of your submission dated March 26, 2008.

These "Changes Being Effected" supplemental new drug applications provide for the following revisions to the Post-Marketing Experience subsection of the package insert and to the less common side effect section of the patient package insert:

1. The term suicidality was replaced with the term including suicide
2. The term psychomotor hyperactivity was replaced with the term anxiousness

In addition, the list of adverse reactions in the Post-Marketing Experience subsection of the ADVERSE REACTIONS section was reorganized by a System Organ Classification.

We have completed our review of these applications, as amended. These applications are approved, effective on the date of this letter, for use as recommended in the content of labeling [21 CFR 314.50(1)] in structured product labeling (SPL) format submitted on March, 26, 2008.

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

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We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

All 15-day alert reports, periodic (including quarterly) adverse drug experience reports, field alerts, annual reports, supplements, and other submissions should be addressed to the original NDAs (20-829, NDA 20-830, NDA 21-409) for this drug product, not to this NDAs.

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 Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research
Enclosure: Approved Labeling

Enclosure: Approved Labeling

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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