DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-829/S-051
20-830/S-052
21-409/S-028

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 May 01, 2009, and received May 01, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Singulair (montelukast sodium) tablets, chewable tablets and oral granules.

We also acknowledge receipt of your submissions dated May 22, June 01, and July 07, 2009.

These Prior Approval Labeling supplemental new drug applications provide for the following additions and revisions to the package insert and to the patient package insert:

1. The terms “hostility” and “somnambulism” were added to the Post-Marketing Experience subsection of the ADVERSE REACTIONS section of the package insert and to the list of the behavior and mood related changes reported in the patient package insert.

2. A Neuropsychiatric Events subsection was added to the PRECAUTIONS section of the package insert.

3. A statement advising patients to notify their physician if neuropsychiatric events occur while using Singulair was added to the Information for Patient subsection of the package insert.

4. The term “very rarely” prior to the term “seizure” was deleted from the Post-Marketing Experience subsection of the ADVERSE REACTIONS section.

5. A list of behavior and mood related changes under the less common side effects in the patient information and a new paragraph was added following the side effects with new language describing the neuropsychiatric events. Also, the addition of a statement instructing patients to inform their physicians of neuropsychiatric events was included at the end of the paragraph.

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We have completed our review of these applications. 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 July 07, 2009.

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/oc/datacouncil/spl.html, that is identical in content to the enclosed labeling (text for the package insert and text for the patient package insert submitted on July 07, 2009). Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission, "**SPL for approved NDA 20-829/S-051; NDA 20-830/S-052; NDA 21-409/S-S-028**."

In addition, the Division of Drug Marketing, Advertising, and Communications (DDMAC) has reviewed the revised product labeling and has determined that it contains significant updated risk information relating to your drug product. We are hereby informing you that all promotional materials for your drug product that include representations about your drug product should be revised to include the new risk information immediately. *See* 21 CFR 314.70(a)(4), 601.12(a)(4). These revisions should include prominent disclosure of the important new information described in the PRECAUTIONS section that appears in the revised package labeling. Please submit a written response to this request within one week of receipt of this letter, stating whether you intend to comply with this request, to the Food and Drug Administration, Center for Drug Evaluation and Research, Division of Drug Marketing, Advertising, and Communications by facsimile at (301) 847-8444 or at 5901-B Ammendale Road, Beltsville, MD 20705.

For more information about submission of promotional materials to DDMAC, see http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm.

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 reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

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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

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

/s/

BADRUL A CHOWDHURY
08/19/2009