DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-829/S-052
20-830/S-053
21-409/S-029

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 June 17, 2009, and received June 17, 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 October 16, and December 07 and 11, 2009, and January 05, 06 and 28, and February 01, 2010.

These Prior Approval Labeling supplemental new drug applications provide for the labeling conversion of the package insert and patient package insert to the Physician Labeling Rule (PLR) format.

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 enclosed agreed upon labeling text.

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/ForIndustry/DataStandards/StructuredProductLabeling/default.htm, that is identical in content to the enclosed labeling (text for the package insert submitted on December 07, 2009, and text for the patient package insert submitted on January 28, 2010). 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-052; NDA 20-830/S-053; NDA 21-409/S-S-029**."

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:

NDA 20-829/S-052
20-830/S-053
21-409/S-029

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).

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

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-21409	SUPPL-29	MERCK RESEARCH LABORATORIES DIV MERCK CO INC	SINGULAIR(MONTELUKAST SODIUM)4MG GRANULE
NDA-20830	SUPPL-53	MERCK AND CO INC	SINGULAIR(MONTELUKAST SODIUM)CHEWABLE TA
NDA-20829	SUPPL-52	MERCK RESEARCH LABORATORIES DIV MERCK CO INC	SINGULAIR (MONTELUKAST SODIUM) TABS

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
04/26/2010