DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-829/S-055
20-830/S-056
21-409/S-031

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

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

Dear Dr. McCann:

Please refer to your supplemental new drug applications dated April 14, 2010, and received April 14, 2010, 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 05, and July 01 and 12, 2010.

These Changes Being Effected supplemental new drug applications provide for the addition of the term disorientation to the WARNINGS and PRECAUTIONS and ADVERSE REACTIONS sections of the package insert and to the possible side effects section of the patient package insert.

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, submit, using the FDA automated drug registration and listing system (eLIST), 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 to the enclosed labeling (text for the package insert) and include the labeling changes proposed in any pending "Changes Being Effected" (CBE) supplements. Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications for this NDA, including pending "Changes Being Effected" (CBE) supplements, for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format that includes the changes approved in this supplemental application.

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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).

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, Allergy, and
Rheumatology 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-31	MERCK RESEARCH LABORATORIES DIV MERCK CO INC	SINGULAIR(MONTELUKAST SODIUM)4MG GRANULE
NDA-20830	SUPPL-56	MERCK AND CO INC	SINGULAIR(MONTELUKAST SODIUM)CHEWABLE TA
NDA-20829	SUPPL-55	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
08/10/2010