



NDA 20-829/S-046
20-830/S-048
21-409/S-023

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

Attention: Margaret E. McCann
Associate Director, Worldwide Regulatory Affairs

Dear Dr. McCann:

Please refer to your supplemental new drug applications dated October 02, 2007, received October 02, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Singularir (montelukast sodium) tablets, chewable tables and oral granules.

These "Changes Being Effected" supplemental new drug applications provides for the additions of erythema nodusum and suicidal thinking and behavior to the Post-Marketing Experience subsection of the ADVERSE REACTIONS section of the package insert.

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 final printed labeling (FPL) submitted on October 12, 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 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. In the future, do not make submissions to this NDA except for the final printed labeling requested above.

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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

Enclosure: Approved Labeling

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/s/

Badrul Chowdhury
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