DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-829/S-036
NDA 20-830/S-038
NDA 21-409/S-016

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

Attention: Frank Seebach, MD, RAC
Director, Regulatory Affairs

Dear Dr. Seebach:

Please refer to your supplemental new drug applications dated February 17, 2005, received February 18, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Singulair (montelukast sodium) Tablets, Chewable Tablets, and Oral Granules.

We acknowledge receipt of your submissions dated June 09, 2005, October 12, 2006, and April 3 and 9, 2007.

Your submission of October 12, 2006, constituted a complete response to our December 16, 2005, action letter.

These supplemental new drug applications provide for the use of Singulair (montelukast sodium) Tablets, Chewable Tablets, and Oral Granules for the prevention of exercise-induced bronchoconstriction in patients 15 years of age and older.

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 agreed-upon labeling text and with the minor editorial revisions indicated in the enclosed labeling.

The final printed labeling (FPL) must be identical, and include the minor editorial revisions indicated, to the enclosed labeling (text for the package insert and text for the patient package insert submitted on April 9, 2007). These revisions are terms of the approval of these applications.

Please submit an electronic version or 20 paper copies of the FPL as soon as it is available (no more than 30 days after it is printed). Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate these submissions "**FPL for approved supplement NDA 20-829/S-036; NDA 20-830/S-038; NDA 21-409/S-016."** Approval of these submissions by FDA is not required before the labeling is used.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and

effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We are waiving the pediatric study requirement for ages 0 to 3 years and deferring pediatric studies for ages 4 to 14 years for this application.

Your deferred pediatric studies required under section 2 of the Pediatric Research Equity Act (PREA) are considered required postmarketing study commitments. The status of this postmarketing study shall be reported annually according to 21 CFR 314.81. This commitment is listed below.

1. Deferred pediatric study under PREA for the prevention of exercise-induced bronchoconstriction in pediatric patients ages 4 to 14 years of age.

   Final Report Submission: December 31, 2009

Submit final study reports to this NDA. For administrative purposes, all submissions related to this pediatric postmarketing study commitment must be clearly designated "**Required Pediatric Study Commitment**".

In addition, submit three copies of the introductory promotional materials that you propose to use for these products. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to the Division of Pulmonary and Allergy products and two copies of both the promotional materials and the package insert directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

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

Please submit one market package of the drug product when it is available.

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 Lori Garcia, Regulatory Project Manager, at (301) 796-1212.

Sincerely,

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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