DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-829/S-033
NDA 20-830/S-035
NDA 21-409/S-012

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 September 30, 2004, received September 30, 2004, 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 October 11, November 30, and December 3, 2004, and January 18, and 24, June 30, and July 1, 18, 19, and 22, 2005.

These supplemental new drug applications provide for the use of Singulair (montelukast sodium) Tablets, Chewable Tablets, and Oral Granules for the relief of symptoms of perennial allergic rhinitis (PAR) in adults and pediatric patients 6 months of age and older.

We 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.

The final printed labeling (FPL) must be identical to the submitted labeling [package insert submitted July 19, 2005, (copy enclosed), patient package insert, immediate container and carton labels submitted July 22, 2005].

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but 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 submission(s) "**FPL for approved supplements NDA 20-829/S-033, NDA 20-830/S-035 and NDA 21-409/S-012."** 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. A partial waiver for pediatric studies for these applications and this indication was granted for children

less than 6 months of age in the letter dated March 3, 2005. We note that you have fulfilled the pediatric study requirement for this application.

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 this division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

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, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

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) 827-5580.

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

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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