DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-829/S-039
NDA 20-830/S-041
NDA 21-409/S-019

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

Attention: Anne H. Cheung
Director, Regulatory Affairs

Dear Ms. Cheung:

Please refer to your supplemental new drug applications dated June 9, 2006, received June 12, 2006, 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 19, 2006.

These "Changes Being Effected" supplemental new drug applications provide for changes to the PRECAUTIONS, *Pregnancy, Teratogenic Effects* section of the product label.

We completed our review of these supplemental new drug applications, as amended. They are approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on June 19, 2006. A copy of the approved text is attached.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Lori Garcia, Regulatory Project Manager, at (301) 796-1212.

Sincerely,

{See appended electronic signature page}

Badrul A. Chowdhury, M.D., Ph.D.
Director
Division of Pulmonary and Allergy Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

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

12/8/2006 03:20:27 PM