DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-829/S-032
NDA 20-830/S-034
NDA 21-409/S-011

Merck & Co., Inc.
P.O. Box 2000, RY 33-200
Rahway, New Jersey 07065-0900

Attention: Frank A. Seebach, M.D.
Director, Regulatory Affairs

Dear Dr. Seebach:

Please refer to your supplemental new drug applications dated June 28, 2004, received June 29, 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 December 17, 2004.

These "Changes Being Effected" supplemental new drug applications provide for revisions to the Singulair Package Circular.

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 December 17, 2004, and container label submitted December 17, 2004.).

Please submit the FPL electronically 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, in no case more than 30 days after it is printed. Please individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, these submissions should be designated "FPL for approved supplement NDA 20-829/S-032, NDA 20-830/S-034, and NDA 21-409/S-011." Approval of these submissions by FDA is not required before the labeling is used.

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

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/

Eugene Sullivan
12/29/04 12:50:28 PM
For Badrul A. Chowdhury