



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-829/S-035
NDA 20-830/S-037
NDA 21-409/S-015

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

Attention: Frank A. Seebach, M.D.

Dear Dr. Seebach:

Please refer to your supplemental new drug applications dated February 7, 2005, received February 8, 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 April 29, 2005.

These "Changes Being Effected" supplemental new drug applications provide for changes to the package insert to include information regarding the *in vitro* inhibition of cytochrome P450 2C8 by montelukast.

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 (text for the package insert submitted April 29, 2005, copy enclosed).

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 submissions "**FPL for approved supplement NDA 20-829/S-035, NDA 20-830/S-037, NDA 21-409/S-015.**" 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

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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
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/s/

Badrul Chowdhury
5/26/05 10:17:15 AM