



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville, MD 20857

NDA 20-829/S-034  
NDA 20-830/S-036  
NDA 21-409/S-014

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 January 28, 2005, received January 31, 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 March 29, May 4, 11, and 13, September 12, and 14, and November 22, 2005.

These supplemental new drug applications provide clinical data to support changes to the Singulair Tablets, Chewable Tablets, and Oral Granules label to include information regarding the effect of montelukast sodium on growth rates in prepubertal children.

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 September 14, 2005 (copy enclosed), and the patient package insert submitted November 22, 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-034; NDA 20-830/S-036; NDA 21-409/S-014.**" 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

NDA 20-829/S-034  
NDA 20-830/S-036  
NDA 21-409/S-014  
Page 2

Food and Drug Administration  
WO 22, Room 4447  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002

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,

*{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

Enclosure

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**This is a representation of an electronic record that was signed electronically and  
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/s/

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Badrul Chowdhury  
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