



NDA 20-829/S-026, 20-830/S-029 and 21-409/S-007

Merck Research Laboratories
P.O. Box 2000, RY 33-720
Rahway NJ 07065-0900

Attention: William A Hanlon, Ph.D.
Associate Director, Regulatory Affairs

Dear Dr. Hanlon:

Please refer to your supplemental new drug applications dated June 18, 2003, received June 19, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Singulair (montelukast sodium) Tablets, Singulair (montelukast sodium) Chewable Tablets and Singulair (montelukast sodium) Oral Granules.

These "Changes Being Effected" supplemental new drug applications provide for the following revisions to the package insert and patient product information:

1. The addition of "very rarely cholestatic hepatitis" to the Post-Marketing Experience subsection of the ADVERSE REACTIONS section of the package insert and to the "What are the possible side effects of SINGULAIR?" section of the patient product information.
2. Minor editorial changes throughout the package insert and patient product information.
3. Revision of the phrase "a silica gel desiccant canister" to "two silica gel desiccant canisters" for NDC 0006-0711-31 and NDC 0006-0275-31 in the HOW SUPPLIED section of the package insert.

We completed our review of these supplemental new drug applications, they are approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on June 18, 2003.

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 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) 827-5580.

Sincerely,

{See appended electronic signature page}

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

Enclosure

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/s/

Badrul Chowdhury
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