



NDA 20-829/S-023, 20-830/S-026 and 21-409/S-005

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 April 2, 2003, received April 3, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Singular (montelukast sodium) Tablets, Singulaire (montelukast sodium) Chewable Tablets, and Singulair (montelukast sodium) Oral Granules.

These "Changes Being Effected" supplemental new drug applications provide for the addition of paresthesia/hypoesthesia to the Post-Marketing subsection of the ADVERSE REACTIONS section of the package insert and pin and needles/numbness to the "What are the possible side effects of SINGULAIR?" Section of the patient product information.

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 April 2, 2003.

We remind you that you must submit patent information on form FDA 3542, *Patent Information Submitted Upon and After Approval of an NDA or Supplement*, within 30 days of the date of this letter as required by 21 CFR 314.53(c)(2)(ii) and 314.53(d)(2) at the address provided by 21 CFR 314.53(d)(4). The form may be obtained at <http://www.fda.gov/opacom/morechoices/fdaforms/cder.html>. To expedite review of this patent declaration form, we request you submit an additional copy of the form to this/these application(s) and to the Center for Drug Evaluation and Research "Orange Book" staff at

Food and Drug Administration
Office of Generic Drugs, HFD-610
Orange Book Staff
7500 Standish Place
Metro Park North II
Rockville, MD 20855-2773

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 Akilah Green, 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

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

Badrul Chowdhury
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