DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-409/S-003

Merck Research Laboratories
P.O. Box 2000, RY33-720
Rahway, NJ 07065

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

Dear Dr. Hanlon:

Please refer to your supplemental new drug application dated December 13, 2002, received December 16, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Singulair (montelukast sodium) Oral Granules, 4 mg.

We acknowledge receipt of your submissions dated December 20, 27 and 30, 2002.

This supplemental new drug application provides for the use of Singulair Oral Granules for the relief of symptoms of seasonal allergic rhinitis in pediatric patients 2 to 5 years of age.

We have completed our review of this application, as amended. This application is 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 package insert and patient package insert submitted December 27, 2002, physician's sample (complimentary) carton label submitted December 30, 2002, and the labeling for the trade carton and the foil sachet submitted December 20, 2002, with the agreed upon revision listed below. This revision is a term of approval for this application.

Modify the Usual Dosage statement on the trade foil sachet and carton as follows:

> "USUAL DOSAGE: One 4-mg packet daily. For asthma: to be taken in the evening. See accompanying circular."

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 ten of the copies on heavyweight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 21-409/S-003." Approval of this submission by FDA is not required before the labeling is used.

We have not completed validation of the regulatory methods. However, we expect your continued cooperation to resolve any problems that may be identified.

In addition, submit three copies of the introductory promotional materials that you propose to use for these products. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

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, HF-2
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 Dr. Craig Ostroff, Regulatory Management Officer, at 301-827-5585.

Sincerely,

{See appended electronic signature page}

Badrul A. Chowdhury, M.D., Ph.D.
Acting 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/

Badrul Chowdhury

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