DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-829/S-017
NDA 20-830/S-020

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 applications dated February 28, 2002, received March 1, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Singulair (montelukast sodium) Tablets, 10 mg, and Singulair (montelukast) Chewable Tablets, 4 mg and 5 mg.

We acknowledge receipt of your submissions dated May 30, June 20 and 28, September 13, December 17, 20, 27 and 30, 2002.

These supplemental new drug applications provide for the use of Singulair Tablets and Chewable Tablets for the relief of symptoms of seasonal allergic rhinitis in adults and pediatric patients 2 years of age and older.

We have 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 package insert and patient package insert submitted December 27, 2002, physician's sample (complimentary) carton labels for the 4, 5 and 10 mg cartons (Seasonal Allergic Rhinitis-specific and non Seasonal Allergic Rhinitis-specific) submitted December 30, 2002, and the immediate container labeling for the trade cartons, containers and the physician's sample immediate container labels (4, 5 and 10 mg 7 tablet bottles), blister foils, and trays submitted December 20, 2002, with the agreed upon revisions listed below. These revisions are terms of the approval of these applications.

Modify the Usual Dosage statement on each of the labels for all of the non Seasonal Allergic Rhinitis-specific cartons and containers to abide by the format of the following example:

Singulair Chewable Tablets, 4 mg:

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

We remind you of your agreement to include the statement "For Seasonal Allergic Rhinitis" on the 4, 5 and 10 mg blister pack sample foils in a similar manner and proportion as found on the 4, 5 and 10 mg blister pack sample cartons within 3 months of the date of this letter or at their next printing, whichever is sooner.

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, these submissions should be designated "FPL for approved supplement NDA 20-829/S-017 AND NDA 20-830/S-020." Approval of these submissions 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 of your agreement to phase into distribution the newly approved packaging and phase out the current packaging within 3 months of the date of this letter or at the next printing, whichever is sooner.

We also 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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