CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

NDA 20-829/S-025
NDA 20-830/S-028

Trade Name: Singulair Tablets
Singulair Chewable Tablets

Generic Name: montelukast sodium

Sponsor: Merck Research Laboratories

Approval Date: November 5, 2003

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 20-829/S-025
NDA 20-830/S-028

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Approvable Letter	
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Microbiology Review(s)	
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CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 20-829/S-025
NDA 20-830/S-028

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-829/S-025 and 20-830/S-028

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 May 6, 2003, received May 7, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Singulair (montelukast sodium) Tablets and Singulair (montelukast sodium) Chewable Tablets.

These "Changes Being Effected" supplemental new drug applications provide for revisions to the Physician's Sample carton and container to indicate a change in the quantity, replace "Complimentary" with "Sample- Not For Sale", increase the prominence of the term "For Asthma", and add the asthma indication and a warning from the package insert to the carton.

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 May 6, 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 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 this page is the manifestation of the electronic signature.

/s/

Badrul Chowdhury
11/5/03 04:09:24 PM

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 20-829/S-025
NDA 20-830/S-028

APPROVED LABELING

SINGULAIR® 10 mg Tablets
(MONTELUKAST SODIUM)
ONE TABLET DAILY

SINGULAIR® 10 mg Tablets
(MONTELUKAST SODIUM)
ONE TABLET DAILY

10 Patient Packs, 4 Tablets Each

Sample
Not For Sale
No. 3761

MRK 117

For Asthma

SINGULAIR® 10 mg Tablets
(MONTELUKAST SODIUM)
ONE TABLET DAILY

15+ YEARS For Adults 15 Years of Age and Older

Each tablet contains 10.4 mg Montelukast Sodium equivalent to 10 mg Montelukast.
USUAL DOSAGE: One 10-mg tablet daily.
For asthma: to be taken in the evening.
See accompanying circular.

Rx only

Package not child resistant. Keep this and all drugs out of the reach of children.

MERCK & CO., INC.

SINGULAIR® 4 mg Chewable Tablets
(MONTELUKAST SODIUM)
ONE TABLET DAILY

SINGULAIR® 4 mg Chewable Tablets
(MONTELUKAST SODIUM)
ONE TABLET DAILY

10 Patient Packs, 4 Tablets Each

Sample
Not For Sale
No. 3796

MRK 711

For Asthma

SINGULAIR® 4 mg Chewable Tablets

(MONTELUKAST SODIUM)

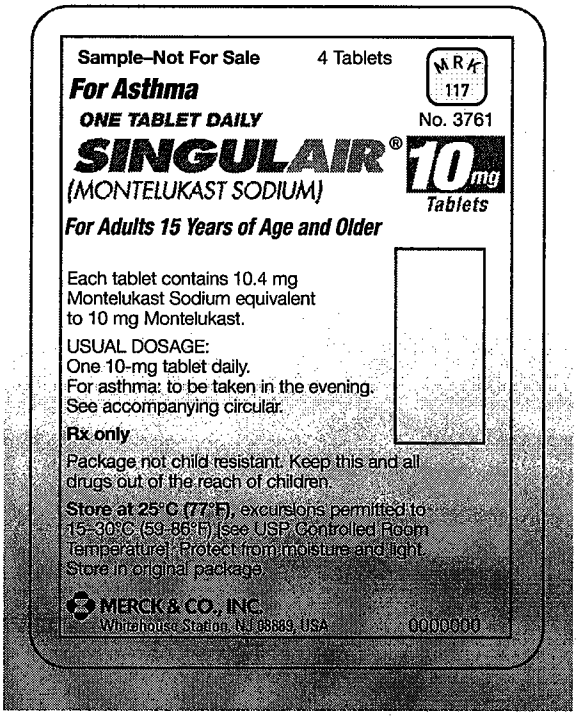
ONE TABLET DAILY

2-5 YEARS

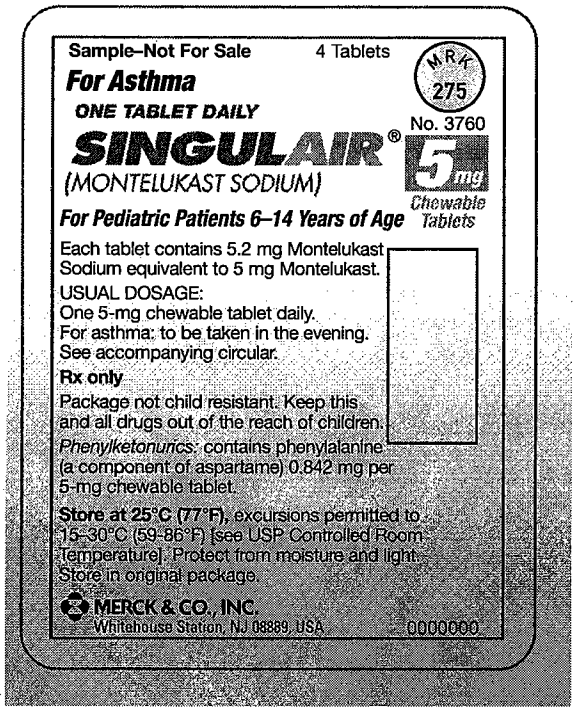
For Pediatric Patients 2-5 Years of Age

Each tablet contains 4.2 mg Montelukast Sodium equivalent to 4 mg Montelukast.
USUAL DOSAGE: One 4-mg chewable tablet daily.
For asthma: to be taken in the evening.
See accompanying circular.
Rx only
Package not child resistant. Keep this and all drugs out of the reach of children.

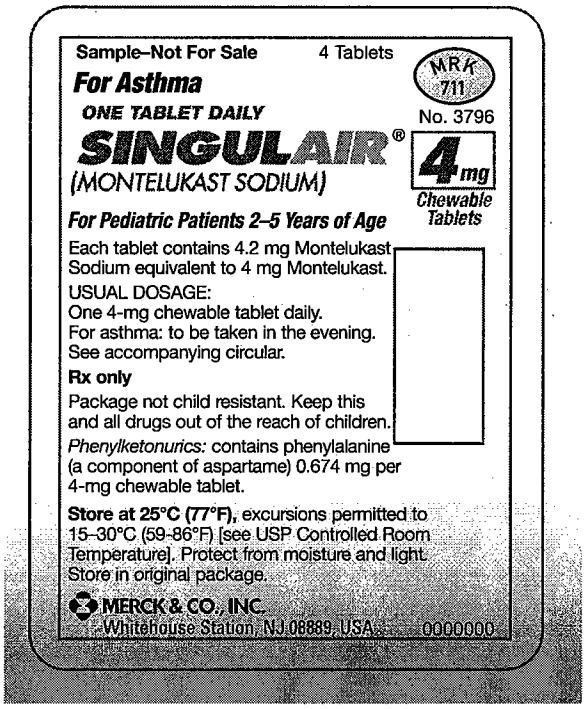
MERCK & CO., INC.


Sample–Not For Sale
4 Tablets
MRK 117
For Asthma
ONE TABLET DAILY
No. 3761
SINGULAIR®
10 mg
(MONTELUKAST SODIUM)
Tablets
For Adults 15 Years of Age and Older
Each tablet contains 10.4 mg Montelukast Sodium equivalent to 10 mg Montelukast.
USUAL DOSAGE:
One 10-mg tablet daily.
For asthma: to be taken in the evening.
See accompanying circular.
Rx only
Package not child resistant. Keep this and all drugs out of the reach of children.
Store at 25°C (77°F), excursions permitted to 15–30°C (59–86°F) [see USP Controlled Room Temperature]. Protect from moisture and light. Store in original package.
MERCK & CO., INC.
Whitehouse Station, NJ 08889, USA
0000000


SINGULAIR 10
(MONTELUKAST SODIUM)


Sample–Not For Sale
4 Tablets
MRK
275
For Asthma
ONE TABLET DAILY
No. 3760
SINGULAIR®
(MONTELUKAST SODIUM)
5 mg
Chewable Tablets
For Pediatric Patients 6–14 Years of Age
Each tablet contains 5.2 mg Montelukast Sodium equivalent to 5 mg Montelukast.
USUAL DOSAGE:
One 5-mg chewable tablet daily.
For asthma: to be taken in the evening.
See accompanying circular.
Rx only
Package not child resistant. Keep this and all drugs out of the reach of children.
Phenylketonurics: contains phenylalanine (a component of aspartame) 0.842 mg per 5-mg chewable tablet.
Store at 25°C (77°F), excursions permitted to 15–30°C (59–86°F) [see USP Controlled Room Temperature]. Protect from moisture and light. Store in original package.
MERCK & CO., INC.
Whitehouse Station, NJ 08889, USA
0000000


SINGULAIR®
5 mg
Chewable Tablets
ONE TABLET DAILY
(MONTELUKAST SODIUM)
0000000


Sample–Not For Sale
4 Tablets
MRK 711
For Asthma
ONE TABLET DAILY
No. 3796
SINGULAIR®
(MONTELUKAST SODIUM)
4 mg
Chewable Tablets
For Pediatric Patients 2–5 Years of Age
Each tablet contains 4.2 mg Montelukast Sodium equivalent to 4 mg Montelukast.
USUAL DOSAGE:
One 4-mg chewable tablet daily.
For asthma: to be taken in the evening.
See accompanying circular.
Rx only
Package not child resistant. Keep this and all drugs out of the reach of children.
Phenylketonurics: contains phenylalanine (a component of aspartame) 0.674 mg per 4-mg chewable tablet.
Store at 25°C (77°F), excursions permitted to 15–30°C (59-86°F) [see USP Controlled Room Temperature]. Protect from moisture and light. Store in original package.
MERCK & CO., INC.
Whitehouse Station, NJ 08889, USA
0000000


ONE TABLET DAILY
SINGULAIR®
(MONTELUKAST SODIUM)
0000000
4 mg
Chewable Tablets

SINGULAIR® 5 mg Chewable Tablets
(MONTELUKAST SODIUM)
ONE TABLET DAILY

SINGULAIR® 5 mg Chewable Tablets
(MONTELUKAST SODIUM)
ONE TABLET DAILY

10 Patient Packs, 4 Tablets Each

Sample
Not For Sale
No. 3760

MRT 275

For Asthma

SINGULAIR® 5 mg Chewable Tablets
(MONTELUKAST SODIUM)
ONE TABLET DAILY

6-14 YEARS For Pediatric Patients 6-14 Years of Age

Each tablet contains 5.2 mg Montelukast Sodium equivalent to 5 mg Montelukast.

USUAL DOSAGE: One 5 mg chewable tablet daily. For asthma: to be taken in the evening. See accompanying circular.

Rx only

Package not child resistant. Keep this and all drugs out of the reach of children.

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 20-829/S-025
NDA 20-830/S-028

ADMINISTRATIVE DOCUMENTS AND CORRESPONDENCE

Project Manager Labeling Review

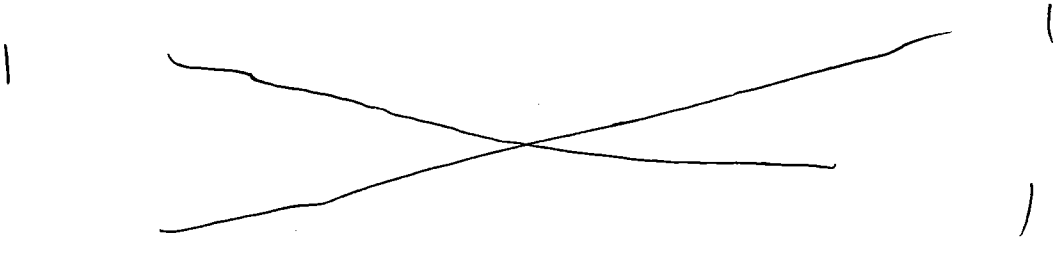
NDA 20-829/S-025/ Singulair (montelukast sodium) Tablets
20-830/S-029/ Singulair (montelukast sodium) Chewable Tablets

SPONSOR: Merck

SUBMISSIONS DATED: May 6, 2003
RECEIVED: May 7, 2003

These changes being effected supplements provide for the following revisions to the Physician's Sample carton and container of the "asthma specific labeling".

1. Statement that package now contains "10 Patient Packs, 4 Tablets Each."
2. Complimentary has been replaced by "Sample-Not For Sale."
3. The Statement "For Asthma" has been made more prominent on the carton and blisters.
4. the following text has been added to the carton from the package insert:



I compared the labeling dated May 6, 2003, to the last approved labeling for each of these applications and there are no changes other than those requested by these supplements, and the revisions are acceptable to the Clinical Team Leader and the Chemistry Team Leader, therefore these supplements should be approved.

Sandy Barnes
Chief, Project Management Staff
Division of Pulmonary and Allergy Drug Products

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Sandra Barnes
11/5/03 03:45:05 PM
CSO

Eugene Sullivan
11/5/03 04:11:12 PM
MEDICAL OFFICER