



NDA 20829/S-070, S-071
NDA 20830/S-072, S-073
NDA 21409/S-048, S-049

SUPPLEMENT APPROVAL

Merck & Co., Inc.
1 Merck Drive
P.O. Box 100
Whitehouse Station, NJ, 08889-0100

Attention: Dana Wiegand
Manager, Worldwide Regulatory Affairs

Dear Ms. Wiegand:

Please refer to your Supplemental New Drug Applications (sNDAs) dated June 22, September 14 and 17, 2018, received June 22, September 14 and 17, 2018, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Singulair (montelukast sodium) Tablets, Chewable Tablets, and Oral Granules.

These Prior Approval supplemental new drug applications submitted on June 22, 2018, propose to update the labeling to comply with the requirements of the Pregnancy and Lactation Labeling Rule (PLLR) of the Prescribing Information.

These "Changes Being Effected" new drug applications submitted on September 14 and 17, 2018, propose to include the term "obsessive-compulsive symptoms" to sections 6.2, Post-Marketing Experience, and 5.4, Neuropsychiatric Events, of the Prescribing Information and Patient Information Leaflet.

APPROVAL & LABELING

We have completed our review of these supplemental applications, as amended. They are approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

WAIVER OF ½ PAGE LENGTH REQUIREMENT FOR HIGHLIGHTS

Please note that we have previously granted a waiver of the requirements of 21 CFR 201.57(d)(8) regarding the length of Highlights of Prescribing Information.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>. Content of labeling must be identical to the enclosed labeling (text for the Prescribing Information, Patient Package Insert), with the addition of any labeling changes in pending “Changes Being Effected” (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eList may be found in the guidance for industry titled “SPL Standard for Content of Labeling Technical Qs and As” at <http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf>.

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that include labeling changes for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in Microsoft Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes. To facilitate review of your submission(s), provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

REPORTING REQUIREMENTS

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 Sadaf Nabavian, Regulatory Project Manager, at (301) 796-2777.

Sincerely,
{See appended electronic signature page}
Sally Seymour, M.D.
Acting Director
Division of Pulmonary, Allergy, and
Rheumatology Products
Office of Drug Evaluation II
Center of Drug Evaluation and Research

ENCLOSURE(S):

Content of Labeling
Prescribing Information and Patient Package Insert

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

BANU A KARIMI SHAH

12/21/2018

signing with the delegated authority of Dr. Sally Seymour, Acting Division Director, DPARP