DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 090955

Teva Pharmaceuticals USA
Attention: Jean W. Zwicker
Senior Director, Regulatory Affairs
425 Privet Road
Horsham, PA 19044

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated October 17, 2008, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Montelukast Sodium Oral Granules, 4 mg (base), packaged in Single-dose packets.

Reference is also made to your amendments dated November 9, and December 23, 2009; April 15, and April 16, 2010; September 27, 2011; and May 1, May 18, June 4, July 9, July 17, July 26, and August 8, 2012.

We have completed the review of this ANDA and have concluded that adequate information has been presented to demonstrate that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly the ANDA is approved, effective on the date of this letter. The Division of Bioequivalence has determined your Montelukast Sodium Oral Granules, 4 mg (base), to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Singulair Oral Granules, 4 mg (base)/packet of Merck & Co., Inc (Merck). Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your ANDA.

The RLD upon which you have based your ANDA, Merck's Singulair Oral Granules, is subject to periods of patent protection. As noted in the agency's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book"), U.S. Patent No. 8,007,830 (the '830 patent) is scheduled to expire on October 24, 2022.

Your ANDA contains a paragraph IV certification under section 505(j)(2)(A)(vii)(IV) of the Act stating that the '830 patent is

invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Montelukast Sodium Oral Granules, Eq. to 4 mg (base), under this ANDA. You have notified the agency that Teva Pharmaceuticals USA (Teva) complied with the requirements of section 505(j)(2)(B) of the Act, and that litigation was initiated against Teva for infringement of the '830 patent in the United States District Court for the District of New Jersey [Merck Frosst Canada & Co., Merck Canada, Inc., and Merck Sharp & Dohme Pharmaceuticals v. Teva Pharmaceuticals USA, Inc., Civil Action No. 3:12-cv-00210-FLW-LHG]. You have also notified the agency that this litigation has been dismissed.[1]

Under section 506A of the Act, certain changes in the conditions described in this ANDA require an approved supplemental application before the change may be made.

Please note that if FDA requires a Risk Evaluation & Mitigation Strategy (REMS) for a listed drug, an ANDA citing that listed drug also will be required to have a REMS. See section 505-1(i) of the Act.

Postmarketing reporting requirements for this ANDA are set forth in 21 CFR 314.80-81 and 314.98. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

Promotional materials may be submitted to FDA for comment prior to publication or dissemination. Please note that these submissions are voluntary. If you desire comments on proposed launch promotional materials with respect to compliance with applicable regulatory requirements, we recommend you submit, in draft or mock-up form, two copies of both the promotional materials and package insert(s) directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Office of Prescription Drug Promotion
5901-B Ammendale Road
Beltsville, MD 20705

[1] It is noted that Teva was a first applicant, as defined by the statute, by virtue of its paragraph IV certification to U.S. Patent No. 5,565,473 (the '473 patent) which was listed in the Orange Book when ANDA 090955 was first submitted. Therefore, Teva's paragraph IV certification to the later-listed '830 patent can not confer first applicant status. Teva's eligibility for 180-day exclusivity under section 505(j)(5)(B)(iv) was forfeited in 2010 when Teva amended its certification to the now expired '473 patent. See section 505(j)(5)(D)(i)(III).

We call your attention to 21 CFR 314.81(b)(3) which requires that all promotional materials be submitted to the Office of Prescription Drug Promotion with a completed Form FDA 2253 at the time of their initial use.

As soon as possible, but no later than 14 days from the date of this letter, submit, using the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm, that is identical in content to the approved labeling (including the package insert, and any patient package insert and/or Medication Guide that may be required). 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 via publicly available labeling repositories.

Sincerely yours,

{See appended electronic signature page}

Gregory P. Geba, M.D., M.P.H.
Director
Office of Generic Drugs
Center for Drug Evaluation and Research

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

/s/

ROBERT L WEST

08/03/2012

Deputy Director, Office of Generic Drugs
for Gregory P. Geba, M.D., M.P.H.