DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 090372

Dr. Reddy's Laboratories, Inc.
U.S. Agent for: Dr. Reddy's Laboratories Limited
Attention: Kumara Sekar, Ph.D.
Senior Director, Global Regulatory Affairs
200 Somerset Corporate Blvd., 7th Floor
Bridgewater, NJ 08807

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated February 11, 2008, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Zafirlukast Tablets, 10 mg and 20 mg.

Reference is also made to the tentative approval letter issued by this office on June 1, 2010, and to your amendments dated August 20, October 7, and October 21, 2010. We also acknowledge receipt of your communications dated November 12, and November 17, 2010, addressing patent issues associated with this ANDA.

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 Zafirlukast Tablets, 10 mg and 20 mg, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Accolate Tablets, 10 mg and 20 mg, respectively, of AstraZeneca UK Limited (AZ). 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, AZ's Accolate Tablets, is subject to periods of patent protection. The following patents and their expiration dates are currently listed in the agency's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book") for this drug product:

U.S. Patent Number	Expiration Date
5,294,636 (the '636 patent)	December 11, 2011
5,319,097 (the '097 patent)	December 11, 2011
5,482,963 (the '963 patent)	January 9, 2013
5,612,367 (the '367 patent)	March 18, 2014
6,143,775 (the '775 patent)	December 11, 2011

Your ANDA contains paragraph IV certifications under section 505(j)(2)(A)(vii)(IV) of the Act stating that each of these patents is invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Zafirlukast Tablets, 10 mg and 20 mg, under this ANDA. Section 505(j)(5)(B)(iii) of the Act provides that approval of an ANDA shall be made effective immediately, unless an action was brought against Dr. Reddy's Laboratories Limited (DRL) for infringement of one or more of these patents that were the subjects of the paragraph IV certifications. You have notified the agency that DRL complied with the requirements of section 505(j)(2)(B) of the Act, and litigation against DRL was initiated within the 45-day statutory period for infringement of the '097, '963, and '775 patents in the United States District Court for the District of New Jersey [AstraZeneca UK Limited and AstraZeneca Pharmaceuticals LP v. Dr. Reddy's Laboratories LTD. and Dr. Reddy's Laboratories, Inc., Civil Action No. 3:08-cv-03237-MLC-TJB]. You notified the agency that the case with respect to the '097 and '775 patents was dismissed without prejudice, and that the court decided that DRL did not infringe the '963 patent.

With respect to 180-day generic drug exclusivity, we note that DRL was the first ANDA applicant to submit a substantially complete ANDA with paragraph IV certifications to the patents listed above. Therefore, with this approval, DRL is eligible for 180 days of generic drug exclusivity for Zafirlukast Tablets, 10 mg and 20 mg. This exclusivity, which is provided for under section 505(j)(5)(B)(iv) of the Act, will begin to run from the date of the commercial marketing identified in section 505(j)(5)(B)(iv). Please submit correspondence to this ANDA informing the agency of the date the exclusivity begins to run.

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.

We 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 directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705

We call your attention to 21 CFR 314.81(b)(3) which requires that all promotional materials be submitted to the Division of Drug Marketing, Advertising, and Communications 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/U_CM072392.pdf

The SPL will be accessible via publicly available labeling repositories.

Sincerely yours,

{See appended electronic signature page}

Keith Webber, Ph.D.
Deputy Director
Office of Pharmaceutical Science
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

11/18/2010

Deputy Director, Office of Generic Drugs
for Keith Webber, Ph.D.