DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 20-547/S-031

SUPPLEMENT APPROVAL

AstraZeneca Pharmaceuticals LP
1800 Concord Pike
PO Box 8355
Wilmington DE 19803-8355

Attention: Patricia Neall
Director, Regulatory Affairs

Dear Ms. Neall:

Please refer to your Supplemental New Drug Application (sNDA) dated February 09, 2011, received February 09, 2011, under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Accolate (zafirlukast) tablets.

This Prior Approval Supplemental new drug application provides for revisions to the CONTRAINDICATIONS and DOSAGE AND ADMINISTRATION sections of the package insert and to the ”Who should not take” section of the patient package insert.

We have completed our review of this supplemental application. It is approved, effective on the date of this letter, for use as recommended in the content labeling [21 CFR 314.50(1)] in structured product labeling (SPL) format submitted on February 09, 2011.

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 package insert and text for the 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 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 MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes and annotate each change. To facilitate review of your submission, 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).

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}

Badrul A. Chowdhury, M.D., Ph.D.
Director
Division of Pulmonary, Allergy, and Rheumatology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosure: Approved Labeling

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

/s/

LYDIA I GILBERT MCCLAIN
08/08/2011
Deputy Division Director