DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-547/S-027

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 dated May 22, 2008, received May 22, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Accolate (zafirlukast) tablets.

We also acknowledge receipt of your submission dated July 14, 2009.

This Prior Approval Labeling Supplemental new drug application provides for the following revisions and additions to the PRECAUTIONS and ADVERSE REACTIONS sections of the package insert.

1. Neuropsychiatric Events was added as a separate subsection to the PRECAUTIONS section of the package insert.

2. Neuropsychiatric adverse events with the terms “depression” and “insomnia” were added to the adverse events listed in the ADVERSE REACTIONS section of the package insert.

We have completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the content of labeling [21 CFR 314.50(1)] in structured product labeling (SPL) format submitted on July 14, 2009, with the revision listed below and agreed upon via email on August 20, 2009.

- Add the statement "Patients should be instructed to notify their physician if neuropsychiatric events occur while using ACCOLATE (see PRECAUTIONS, Neuropsychiatric Events)" to the Precautions section, Information for Patients subsection of the package insert.

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/oc/datacouncil/spl.html, that is identical to, except for including the revision indicated, the enclosed labeling (text for the package insert). Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission, “**SPL for approved NDA 20-547/S-027.**”

In addition, the Division of Drug Marketing, Advertising, and Communications (DDMAC) has reviewed the revised product labeling and has determined that it contains significant updated risk information relating to your drug product. We are hereby informing you that all promotional materials for your drug product that include representations about your drug product should be revised to include the new risk information immediately. *See* 21 CFR 314.70(a)(4), 601.12(a)(4). These revisions should include prominent disclosure of the important new information described in the PRECAUTIONS section that appears in the revised package labeling. Please submit a written response to this request within one week of receipt of this letter, stating whether you intend to comply with this request, to the Food and Drug Administration, Center for Drug Evaluation and Research, Division of Drug Marketing, Advertising, and Communications by facsimile at (301) 847-8444 or at 5901-B Ammendale Road, Beltsville, MD 20705.

For more information about submission of promotional materials to DDMAC, see http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm.

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
Food and Drug Administration
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

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 and Allergy Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research
Enclosure: Approved Labeling

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/

BADRUL A CHOWDHURY
08/21/2009