DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-547/S-025

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

Attn: Patricia Neall, Director
Regulatory Affairs

Dear Ms. Neall:

Please refer to your supplemental new drug application dated December 20, 2007, received December 20, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Accolate® (zafirlukast) tablet, 10 mg and 20 mg.

We acknowledge receipt of your submission dated January 14, 2008.

This "Changes Being Effected" supplemental new drug application provides for a revision to the WARNINGS section of the Accolate ® prescribing information.

We have completed our review of this supplemental new drug application, as amended. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on December 20, 2007 (copy enclosed).

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 the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call LCDR Sadaf Nabavian, Sr. Regulatory Management Officer, at (301) 796-2777.

Sincerely,

{See appended electronic signature page}

Badrul A. Chowdhury, M.D., Ph.D.
Director
Division of Pulmonary and Allergy Products
Office of Drug Evaluation II
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/

Badrul Chowdhury

5/29/2008 10:14:53 AM