



NDA 20-547/S-022

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

Attention: Nicholas J. Troise
Director, Regulatory Affairs

Dear Mr. Troise:

Please refer to your supplemental new drug application dated December 16, 2004, received December 17, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Accolate (zafirlukast) Tablets.

This "Changes Being Effected" supplemental new drug application provides for changes to the ADVERSE REACTIONS section of the package insert for Accolate (zafirlukast) Tablets.

We completed our review of this supplemental new drug application. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on December 16, 2004 (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, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

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 Lori Garcia, Regulatory Project Manager, at (301) 827-5580.

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

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/s/

Badrul Chowdhury
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