DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-441/S-020

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

Attention: Judy Firor
Director, Regulatory Affairs

Dear Ms. Firor:

Please refer to your supplemental new drug application dated February 20, 2007, received February 20, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for PULMICORT TURBUHALER® (budesonide inhalation powder).

This "Changes Being Effected" supplemental new drug application provides for harmonization with the PULMICORT FLEXHALER® approved labeling.

We completed our review of this application. 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 February 20, 2007.

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 Colette Jackson, Regulatory Project Manager, at (301) 796-1230.

Sincerely,

{See appended electronic signature page}

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

Enclosure: Approved package insert and patient package insert

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/s/

Badrul Chowdhury
8/20/2007 11:06:38 AM