DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-949/S-002

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

Attention: Ian Wogan
Director, Regulatory Affairs

Dear Mr. Wogan:

Please refer to your supplemental new drug application dated December 21, 2006, received December 21, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for PULMICORT FLEXHALER® (budesonide inhalation powder).

We acknowledge receipt of your submission dated June 8, 2007.

This supplemental new drug application provides for a new subsection for Nursing Mothers under CLINICAL PHARMACOLOGY, Pharmacokinetics, Nursing Mothers and a revision to the PRECAUTIONS, Pregnancy, Nursing Mothers subsection.

We 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 submitted text, copy enclosed (submitted June 8, 2007).

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this Division and two copies of both the promotional materials and the package insert directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

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
WO 22, Room 4447

10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

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

Enclosure : Approved Package Insert

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

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