DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-949/S-003

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

Attention: Patti Neal
Director, Regulatory Affairs

Dear Ms. Neal:

Please refer to your supplemental new drug application dated October 11, 2007, received October 11, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for PULMICORT FLEXHALER® (budesonide inhalation powder).

We acknowledge receipt of your submissions dated April 1, 9, and 11, 2008.

This supplemental new drug application provides for updates to the Patient's Instructions for Use and to the Prescribing Information to clarify the priming instructions, to clarify how to read the dose indicator window, and to include information related to postmarketing safety events in patients with milk allergy.

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling text.

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 the submitted labeling, copy enclosed (text for the package insert and the patient information and instructions for use submitted April 11, 2008). 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 21-949/S-003."

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 Prescribing Information and Patient Information and Instructions for Use.

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Lydia McClain
4/11/2008 06:48:39 PM
For Dr. Badrul Chowdhury