DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-929/S-004

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

Attention: Patricia Neall
Director, Regulatory Affairs

Dear Ms. Neall:

Please refer to your supplemental new drug application dated May 10, 2007, received May 10, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for SYMBICORT® (budesonide/formoterol fumarate dihydrate) Inhalation Aerosol.

We acknowledge receipt of your submission dated July 19, 2007.

This supplemental new drug application provides for the addition of information regarding lactation in a subsection entitled Nursing Mothers under CLINICAL PHARMACOLOGY, Pharmacokinetics, 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 agreed-upon labeling text.

As soon as possible, but no later than 14 days of the date of this letter, please submit 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 in content to submitted labeling (package insert and Medication Guide submitted July 19, 2007). This submission should include the revision approved on October 26, 2007, under NDA 21-929/S-006. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission "Product Correspondence – Final SPL for approved NDA 21-929/S-004."

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 reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Colette Jackson, Regulatory Health 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

10/31/2007 11:19:35 AM