DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-949/S-001

AstraZeneca LP
1800 Concord Pike
P.O. Box 8355
Wilmington, DE 19803-8355

Attention: Nicholas J. Troise
Regulatory Affairs Director

Dear Mr. Troise:

Please refer to your supplemental new drug application dated August 31, 2006, received September 1, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for budesonide inhalation powder 90 and 180 mcg.

We acknowledge receipt of your submissions dated September 12, 2006, and February 16, 2007.

This supplemental new drug application provides for revisions to the labeling to include Pulmicort Flexhaler as the proprietary name.

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 and with the revisions to the Patient's Instructions for Use, and carton and container labels agreed to in your submission dated February 16, 2007, and listed below.

1. Ensure that the established name is at least one-half the size of the proprietary name in accordance with 21 CFR 201.10(g)(2) on all carton and container labels.

2. Relocate the strength printed on the lower half of the primary display panel of the cartons towards the top half of the primary display panel, so that it is further away from the net quantity.

3. Increase the size and prominence of the strength that is located to the right of the proprietary name on the cartons.

4. Use a contrasting color or other means (i.e., boxing) to distinguish one of the strengths on the cartons.

5. Use a more distinguishable color scheme (similar to the professional sample carton) to differentiate between the two strengths for the commercial products, rather than using inversion of colors.

6. Include information showing the amount of budesonide actually delivered per inhalation on the cartons.

7. Increase the prominence of the statement "PROFESSIONAL SAMPLE NOT FOR SALE" on the Professional Sample carton.

8. Revise the "PRIMING INSTRUCTIONS" section of the Patient's Instructions for Use to read as follows.

> **Before you use a new PULMICORT FLEXIHALER for the first time, you should prime it.** To do this, hold the unit so that the white cover points upward, grasp the inhaler by the brown base grip in one hand and with the other hand, turn the white cover and lift it off. Hold PULMICORT FLEXHALER by the brown grip, in the upright position (with mouthpiece up) in one hand. Using the thumb and index finger of your other hand, grasp the inhaler in the middle. DO NOT HOLD THE INHALER AT THE TOP OF THE MOUTHPIECE. Twist the brown grip as far as it will go in one direction and then fully back again in the other direction until it stops. You will hear a click. Repeat. **You do not have to prime it any other time after this, even if you put it aside for a prolonged period of time.** Now you are ready to take your first dose (see instructions for "TAKING A DOSE").

9. Move the sentence "*Do not hold the mouthpiece when you load the inhaler*" that is currently the last sentence in the "LOADING A DOSE" section of the Patient's Instructions for Use to make it the first sentence in that section.

The final printed labeling (FPL) must be identical to the enclosed packaged insert, submitted on September 12, 2006, and include the revisions indicated, to the text for the Patient's Instructions for Use, immediate container and carton labels. These revisions are terms of the approval of this application.

Please submit an electronic version or 20 paper copies of the FPL as soon as it is available (no more than 30 days after it is printed). If paper copies are submitted, individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 21-949/SLR-001**." Approval of this submission by FDA is not required before the labeling is used.

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 the Division of Pulmonary and Allergy Products 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
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

We remind you of the agreement listed in your letter dated February 12, 2007, to monitor for reports of issues related to patient reading comprehension of the information included in the Patients Instructions for Use.

We also remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

As discussed in the telephone conversation on February 15, 2007, between Robert J. Orzolek, Astra Zeneca and Sandy Barnes, Division of Pulmonary and Allergy Products, you may use the carton and container labeling submitted on August 31, 2006, and the Patient's Instructions for Use submitted on September 12, 2006, until the revisions listed above can be implemented, within approximately three months of the date of this letter.

If you have any questions, call Carol Hill, Regulatory Project Manager, at (301) 796-1226.

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: 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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