DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-746/S-024

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 November 21, 2008, received November 21, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Rhinocort Aqua (budesonide) Nasal Spray.

This supplemental new drug application submission provides for revisions to the Package Insert and the Patient's Instructions for Use in order to comply with the Agency's request to harmonize all of AstraZeneca's budesonide labeling for consistency with NDA 21-949 PULMICORT FLEXHALER labeling.

We have completed our review of this application. This application 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 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 submitted November 21, 2008). 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 20-746/S-024."

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
HFD-001, Suite 5100
5515 Security Lane
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, Project Manager, at (301) 796-1230.

Sincerely,

{See appended electronic signature page}

Badrul A. Chowdhury, MD, Ph.D.
Director
Division of Pulmonary and Allergy Drug Products, HFD-570
Office of Drug Evaluation II
Center For Drug Evaluation and Research

Enclosure: Approved Package Insert and Patient's Instructions for Use

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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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