DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-929/S-022

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

Attention: Peggy Berry
Director, Regulatory Affairs

Dear Ms. Berry:

Please refer to your supplemental new drug application dated September 1, 2004, received September 2, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Pulmicort Respules® (budesonide inhalation suspension)

We also acknowledge receipt of your submissions dated June 1, 24, 28, and 30, 2005.

This supplemental new drug application provides for revisions to the WARNINGS and PRECAUTIONS (Drug Interactions and Information to Patients) sections of the package insert for Pulmicort Respules® (budesonide inhalation suspension) to incorporate the results of your study titled "Rates of Seroconversion Following Varicella Vaccination of Asthmatic Children Between the Ages of 1 and 8 Years Treated with PULMICORT RESPULES® Versus Non-steroidal Conventional Asthma Therapy".

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.

The final printed labeling (FPL) must be identical to the submitted labeling (package insert submitted, June 30, 2005).

Please submit the FPL electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDA. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 20-929/S-022." Approval of this submission by FDA is not required before the labeling is used.

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, HF-2
FDA

5600 Fishers Lane
Rockville, MD 20857

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) 827-9388.

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

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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