



NDA 20-929/S-013

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

Attention: Christopher Blango  
Director, Regulatory Affairs

Dear Mr. Blango:

Please refer to your supplemental new drug application dated August 30, 2002, received September 3, 2002, 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 November 26, 2002 and January 22, February 12, and 20, 2003.

This supplemental new drug application proposes changes to the CLINICAL PHARMACOLOGY, Pharmacodynamics, and PRECAUTIONS, Pediatric Use sections of the label to include information on children 6 to 12 months of age.

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 February 20, 2003).

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-013." 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) 827-5584.

Sincerely,

{See appended electronic signature page}

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

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/s/

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Badrul Chowdhury  
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