



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-746/S-016

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 September 30, 2003, received October 1, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Rhinocort Aqua (budesonide) Nasal Spray.

We also acknowledge receipt of your submissions dated November 17, and December 11, 2003, and January 22, July 22, 28, and 30, 2004.

This supplemental new drug application proposes changes to the PRECAUTIONS, Pediatric Use sections of the label to describe the growth study and its results.

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, July 30, 2004).

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 20-746/S-016." 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

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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
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/s/

Badrul Chowdhury
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