



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-746/S-015

AstraZeneca LP
PO Box 8355
Wilmington DE 19803

Attention: Christopher Blango
Director, Regulatory Affairs

Dear Mr. Blango:

Please refer to your supplemental new drug application dated July 31, 2003, received August 1, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Rhinocort Aqua (budesonide) Nasal Spray.

We acknowledge receipt of your submission dated April 19, 2004.

This supplemental new drug application provides for revisions to the Pregnancy subsection of the PRECAUTIONS section of the package insert.

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 enclosed, submitted labeling (package insert submitted April 9, 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 15 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-015." 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, HFD-410
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, Regulatory Project Manager, at (301) 827-9388.

Sincerely,

{See appended electronic signature page}

Badrul A. Chowdhury, M.D., Ph.D.
Division Director
Division of Pulmonary and Allergy Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosure

**This is a representation of an electronic record that was signed electronically and
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/s/

Badrul Chowdhury
8/25/04 04:08:06 PM