



NDA 20-929/S-032

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

Attention: Barbara Blandin
Director, Regulatory Affairs

Dear Ms. Blandin:

Please refer to your supplemental new drug application dated December 18, 2006, received December 18, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Pulmicort Respules® (budesonide inhalation suspension).

We acknowledge receipt of your submissions dated June 8, and 13, 2007.

This supplemental new drug application provides for a new subsection for Nursing Mothers under CLINICAL PHARMACOLOGY, Pharmacokinetics, Nursing Mothers and a revision to the PRECAUTIONS, Pregnancy, Nursing Mothers subsection.

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 labeling (package insert submitted June 13, 2007). We note that a supplement (S-031) that provided for the addition of a 1 mg/2mL presentation was approved on June 15, 2007. The labeling revisions approved for S-031 may be included when you submit the FPL.

Please submit an electronic version of the FPL 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 but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA20-929/S-032.**" Approval of this submission by FDA is not required before the labeling is used.

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this Division and two copies of both the promotional materials and the package insert directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

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
WO 22, Room 4447
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

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) 796-1230.

Sincerely,

{See appended electronic signature page}

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

Enclosure : Approved Package Insert

**This is a representation of an electronic record that was signed electronically and
this page is the manifestation of the electronic signature.**

/s/

Lydia McClain

6/18/2007 01:22:51 PM

Signing for Dr. Badrul Chowdhury, Division Director in his
absence