DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-929/S-002

AstraZeneca
Attention: Barbara Blandin
Regulatory Affairs Director
1800 Concord Pike
P.O. Box 8355
Wilmington, DE 19803-8355

Dear Ms. Blandin:

Please refer to your supplemental new drug application dated October 12, 2000, received October 12, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Pulmicort Respules (budesonide) Suspension, 0.25 mg/2 mL, 0.5 mg/2mL, and 1.0 mg/2mL.

We acknowledge receipt of your submission dated May 2, 2006, which constituted a complete response to our August 2, 2005, action letter.

This "Prior Approval" supplemental new drug application provides for changes to the specifications for extractables and leachables.

We completed our review of this supplemental new drug application, as amended, and it is approved.

We remind you that you must comply with the reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Rebecca McKnight, Regulatory Health Project Manager, at (301) 796-1765.

Sincerely,

{See appended electronic signature page}

James D. Vidra, Ph.D.
Branch Chief
Branch VII, Division of Post-Marketing Evaluation
Office of New Drug Quality Assessment
Center for Drug Evaluation and Research

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/s/

Jim Vidra

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