



NDA 20-441/S-012

AstraZeneca LP  
1800 Concord Pike  
P.O. Box 8355  
Wilmington, DE 19803-8355

Dear Mr. Blango:

Please refer to your supplemental new drug application dated February 16, 2001, received February 20, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Pulmicort Turbuhaler® (budesonide inhalation powder).

We acknowledge receipt of your submissions dated October 22, November 1 and 15, and December 28, 2001. Your submission of October 22, 2001 constituted a complete response to our August 21, 2001, action letter.

This supplemental new drug application provides for changes to the Pregnancy subsection of the Precautions section related to a change in the pregnancy category from "C" to "B".

We have completed the review of this supplemental application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon labeling text. Accordingly, the supplemental application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the submitted draft labeling (package insert submitted December 28, 2001).

Please submit the copies of final printed labeling (FPL) electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). 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. 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 20-441/S-012." Approval of this submission by FDA is not required before the labeling is used.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, 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 the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Anthony M. Zeccola, Regulatory Management Officer, at 301-827-1058.

Sincerely,

{See appended electronic signature page}

Robert J. Meyer, M.D.  
Director  
Division of Pulmonary and Allergy Drug Products  
Office of Drug Evaluation II  
Center for Drug Evaluation and Research

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

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Robert Meyer  
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