

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**21-949**

**APPROVAL LETTER**



NDA 21-949

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

Attention: Barbara Blandin  
Director, Regulatory Affairs

Dear Ms. Blandin:

Please refer to your new drug application (NDA) dated September 12, 2005, received September 12, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for budesonide inhalation powder.

We acknowledge receipt of your submissions dated September 16, October 6, 17, and 18, November 3, and December 19, 2005, and January 9, and 26, February 20, and 28, March 9, and 29, April 7, and 27, May 4 (2), 8, 9, 11, 17, 23, and 31, June 1, 26, 27, and 29 (2), July 7, 10, and 11, 2006 .

This new drug application provides for the use of budesonide inhalation powder for asthma.

We completed our review of this application, as amended. It 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 [copy enclosed], patient instructions for use [copy enclosed], and carton label submitted July 11, 2006, and immediate container label submitted July 10, 2006). Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

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 NDA 21-949.**" Approval of this submission by FDA is not required before the labeling is used.

If you choose to use a proprietary name for this product, the name and its use in the labels must conform to the specifications under 21 CFR 201.10 and 201.15. We recommend that you submit any proprietary name to the Agency for our review prior to its implementation.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We note that you have fulfilled the pediatric study requirement for this application for pediatric studies in patients greater than 6 years of age. We are waiving the pediatric study requirement for pediatric patients ages zero to less than 6 years of age.

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

We have not completed validation of the regulatory methods. However, we expect your continued cooperation to resolve any problems that may be identified.

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, MD, Ph.D.  
Director  
Division of Pulmonary and Allergy Products  
Office of Drug Evaluation II  
Center For Drug Evaluation and Research

Enclosure : Package Insert and Patient Instructions for Use.

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/s/

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Badrul Chowdhury  
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