

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

21-929

APPROVAL LETTER



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-929

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

Attention: Mark DeSiato
Director, Regulatory Affairs

Dear Mr. DeSiato:

Please refer to your new drug application (NDA) dated September 23, 2005, received September 23, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for SYMBICORT® (budesonide/formoterol fumarate dihydrate) Inhalation Aerosol.

We acknowledge receipt of your submissions dated October 21, November 2, 8, and 29, and December 8, 15 (2), 19, and 27, 2005, and January 19, and 30, March 16 (2) and 17 (2), April 11, 13, 19, 26, and 27, May 9, 10, 15 (2), and 31, June 1, 14, 16, and 27, and July 11, 12, 17, 19, and 20, 2006.

This new drug application provides for the use of SYMBICORT® for the long term maintenance treatment of asthma in patients 12 years of age and older.

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] and Medication Guide [copy enclosed] submitted July 20, 2006, the immediate container label submitted July 11, 2006, and the foil, shield, and carton label submitted July 20, 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 21-929.**" Approval of this submission by FDA is not required before the labeling is used.

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 are deferring submission of your pediatric studies in patients 6 to less than 12 years of age until December

NDA 21-929

Page 2

31, 2007. We are waiving the pediatric study requirement for pediatric patients ages zero to less than 6 years of age.

We remind you of your post-approval Chemistry, Manufacturing, and Controls agreements as listed in your amendment dated July 12, 2006.

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 Medication Guide.