



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 20-929/S-043

SUPPLEMENT APPROVAL

AstraZeneca
1800 Concord Pike
PO Box 8355
Wilmington, DE 19850-8355

Attention: Barbara Blandin
Director, Regulatory Affairs

Dear Ms. Blandin:

Please refer to your supplemental new drug application dated March 26, 2009, received March 26, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for PULMICORT RESPULES® (budesonide inhalation suspension).

We acknowledge receipt of your submissions dated September 18, and 23, 2009.

This "Prior Approval" supplemental new drug application provides for the addition of anaphylactic reaction to the ADVERSE REACTIONS section of the Package Insert, the addition of a statement regarding hypersensitivity reaction to the WARNINGS section of the Package Insert, and a revision to the *What are the Possible Side Effects of PULMICORT RESPULES?* section of the Patient Information and Instructions for Use leaflet.

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)(1)(i)] in structured product labeling (SPL) format as described at <http://www.fda.gov/oc/datacouncil/spl.html> that is identical to the enclosed labeling (text for the package insert submitted September 23, 2009, and text for the patient information and instructions use leaflet submitted September 18, 2009). Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission, "SPL for approved NDA 20-929/S-043.

Within 14 days from the date of this letter, please amend all pending supplemental applications for this NDA, including pending "Changes Being Effected" (CBE) supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in structured product labeling (SPL) format that includes the changes approved in this supplemental application.

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit, in triplicate, a cover letter requesting advisory comments, the proposed materials in draft or mock-up form with annotated references, and the package insert(s) 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

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the package insert(s), at the time of initial dissemination or publication, accompanied by a Form FDA 2253. For instruction on completing the Form FDA 2253, see page 2 of the Form. For more information about submission of promotional materials to the Division of Drug Marketing, Advertising, and Communications (DDMAC), see <http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm>.

LETTERS TO HEALTH CARE PROFESSIONALS

If you issue a letter communicating important safety related information about this drug product (i.e., a “Dear Health Care Professional” letter), we request that you submit an electronic copy of the letter to both this NDA and to the following address:

MedWatch
Food and Drug Administration
5600 Fishers Lane, Room 12B05
Rockville, MD 20857

REPORTING REQUIREMENTS

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, Senior Regulatory Health 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
Center for Drug Evaluation and Research

Enclosures: Approved Package Insert and Patient Information and Instructions for Use.

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
----- NDA-20929	----- SUPPL-43	----- ASTRAZENECA LP	----- PULMICORT RESPULES

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

/s/

BADRUL A CHOWDHURY
10/05/2009