

CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:
NDA 20-441/S013

Trade Name: Pulmicort Turbuhaler

Generic Name: budesonide inhalation powder, 200 mcg

Sponsor: Astra Pharmaceuticals

Approval Date: July 1, 2001

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**APPLICATION NUMBER:
NDA 20-441/S013**

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APPLICATION NUMBER:
NDA 20-441/S013

APPROVAL LETTER



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-441/S-013

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

Attention: Eric Couture, Ph.D.
Director, Regulatory Affairs

Dear Dr. Couture:

Please refer to your supplemental new drug application dated March 22, 2001, received March 23, 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 submission dated April 20, 2001.

This "Changes Being Effected in 30 days" supplemental new drug application, as amended, provides for tightening the specifications for _____ for Pulmicort Turbuhaler (M0-ESP) 200 mcg/dose, 200 doses, and for Pulmicort Turbuhaler (M0) 200 mcg/200 doses _____ from NMT ~ to LT ~

We have completed the review of this supplemental application, and it is approved.

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 Gretchen Trout, Project Manager, at (301) 827-1058.

Sincerely yours,

{See appended electronic signature page}

Guirag Poochikian, Ph.D.
Chemistry Team Leader
Division of Pulmonary and Allergy Drug Products, HFD-570
DNDC II, Office of New Drug Chemistry
Center for Drug Evaluation and Research

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/s/

Guiragos Poochikian
7/3/01 02:36:11 PM

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APPLICATION NUMBER:

NDA 20-441/S013

CHEMISTRY REVIEW(S)

10 Page(s) Withheld

✓ § 552(b)(4) Trade Secret /
Confidential

 § 552(b)(4) Draft Labeling

 § 552(b)(5) Deliberative Process

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/s/

Chong-Ho Kim
6/25/01 04:36:07 PM
CHEMIST

Guiragos Poochikian
6/25/01 04:47:57 PM
CHEMIST

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APPLICATION NUMBER:
NDA 20-441/S013

ADMINISTRATIVE and CORRESPONDENCE
DOCUMENTS



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-441

CBE-30/CBE-0 SUPPLEMENT

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

Attention: Eric Couture, Ph.D.
Director, Regulatory Affairs

Dear Dr. Couture:

We have received your supplemental drug application submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following:

Name of Drug Product: Pulmicort Turbuhaler (budesonide inhalation powder)

NDA Number: 20-441

Supplement number: S-013

Date of supplement: March 22, 2001

Date of receipt: March 23, 2001

This supplemental application, submitted as "Supplement - Changes Being Effectuated in 30 days," proposes the following change: tightening the specifications for budesonide for Pulmicort Turbuhaler.

Unless we notify you within 60 days of the receipt date that the application is not sufficiently complete to permit a substantive review, this application will be filed under section 505(b) of the Act on May 22, 2001 in accordance with 21 CFR 314.101(a). If the application is filed, the user fee goal date will be September 23, 2001.

All communications concerning this supplement should be addressed as follows:

U.S. Postal Service:

Center for Drug Evaluation and Research
Division of Pulmonary and Allergy Drug Products, HFD-570
Attention: Division Document Room, 10B-03
5600 Fishers Lane
Rockville, Maryland 20857

Courier/Overnight Mail:

Food and Drug Administration

Center for Drug Evaluation and Research

Division of Pulmonary and Allergy Drug Products, HFD-570

Attention: Document Room 10B-03

5600 Fishers Lane

Rockville, Maryland 20857

If you have any question, call Ms. Gretchen Trout Regulatory Project Manager, at (301) 827-1058.

Sincerely yours,

Sandy Barnes

Chief, Project Management Staff

Division of Pulmonary and Allergy Drug Products

Office of Drug Evaluation II

Center for Drug Evaluation and Research

/s/

Gretchen Trout
4/3/01 08:06:35 AM
for SBarnes