CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:
NDA 20-441/S014

Trade Name: Pulmicort Turbuhaler

Generic Name: budesonide inhalation powder, 200 mcg

Sponsor: Astra Pharmaceuticals

Approval Date: May 18, 2001

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:
NDA 20-441/S014

CONTENTS

Reviews / Information Included in this NDA Review.

Approval Letter	X
Approvable Letter	
Labeling	
Medical Review(s)	
Chemistry Review(s)	X
Pharmacology Review(s)	
Statistical Review(s)	
Microbiology Review(s)	
Clinical Pharmacology/ Biopharmaceutics Review(s)	
Administrative/Correspondence Document(s)	

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 20-441/S014

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-441/S-014

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).

This "Changes Being Effected in 30 days" supplemental new drug application provides for tightening the specifications for [redacted] budesonide for budesonide [redacted] and budesonide [redacted] from LT [redacted] to LT [redacted]

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

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

/s/

Craig Bertha
5/18/01 11:57:11 AM
for G. Poochikian

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 20-441/S014

CHEMISTRY REVIEW(S)

CHEMIST'S REVIEW *Review #1*	1. ORGANIZATION HFD-570 DPADP	2. NDA NUMBER 20-441
3. NAME AND ADDRESS OF APPLICANT *(City and State)* AstraZeneca LP P.O.Box 8355 Wilmington, DE 19803-8355		4. AF NUMBER 5. SUPPLEMENT(S) NUMBER(S) & DATES(S) SCS-014(3/22/01)
6. NAME OF DRUG Pulmicort Turbuhaler®	7. NONPROPRIETARY NAME Budesonide Inhalation Powder	
8. SUPPLEMENT PROVIDES FOR: Per agreement at the March 15,2001 meeting and in the fax dated March 16,2001, AstraZeneca is tightening the specifications for budesonide from LT to LT		
9. PHARMACOLOGICAL CATEGORY Bronchial Asthma	10. HOW DISPENSED RX X OTC ___	11. RELATED IND/NDA/DMF
12. DOSAGE FORM(S) Dry Powder-filled MDI	13. POTENCY 200 µg/dose,	
14. CHEMICAL NAME AND STRUCTURE See USAN Dictionary.		15. RECORDS AND REPORTS CURRENT YES___NO__ REVIEWED YES___NO__
16. COMMENTS: see review notes on page 2 cc: Orig. NDA #20-441 HFD-570/Div. File HFD-570/CHKim/ HFD-570/GPoochikian HFD-570/GTrout HFD-570/MPrucker R/D Init. By:_____ F/T by: CHKim/ *doc* #N20-441SCS.S14.doc		
17. CONCLUSIONS AND RECOMMENDATIONS Chemist recommends approval of the supplement.		
18. REVIEWER NAME Chong-Ho Kim, Ph.D.	SIGNATURE	DATE COMPLETED May 15, 2001

Review

Per agreement at the March 15, 2001 meeting and in the fax dated March 16, 2001,

9 Page(s) Withheld

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

_____ § 552(b)(4) Draft Labeling

_____ § 552(b)(5) Deliberative Process

Withheld Track Number: Chemistry- 20-441
5014

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

/s/

Chong-Ho Kim
5/16/01 07:38:26 AM
CHEMIST

Guiragos Poochikian
5/21/01 11:53:58 AM
CHEMIST