CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:
NDA 20-441/S007

Trade Name: Pulmicort Turbuhaler

Generic Name: budesonide inhalation powder, 200 mcg

Sponsor: Astra Pharmaceuticals

Approval Date: February 2, 2000

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:
NDA 20-441/S007

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)	X

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 20-441/S007

APPROVAL LETTER

NDA 20-441/S-007

AstraZeneca
725 Chesterbrook Blvd
Wayne, PA 19087-5677

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

Dear Dr. Couture:

Please refer to your supplemental new drug application dated July 30, 1999, received August 2, 1999, 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 August 13, 1999.

This "Changes Being Effected in 30 days" supplemental new drug application provides for an additional [redacted].

We have completed the review of this supplemental application, as amended, 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 Mrs. Gretchen Trout, Project Manager, at (301) 827-1058.

Sincerely yours,

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

cc:
Archival NDA 20-441
HFD-570/Div. Files
HFD-570/G.Trout
HFD-570/Koble
HFD-570/Poochikian
HFD-095/DDMS-IMT
HFD-820/DNDC Division Director
DISTRICT OFFICE

Drafted and final by: GST/February 2, 2000

filename: n:\staff\troutg\20441ap

APPROVAL (AP)

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 20-441/S007

CHEMISTRY REVIEW(S)

FEB 2 2000

CHEMIST'S REVIEW

1. ORGANIZATION	2. NDA NUMBER
HFD-570 DPDP	20-441

3. NAME AND ADDRESS OF APPLICANT (City and State)	4. AF NUMBER	5. SUPPLEMENT(S) NUMBER	DATE
AstraZeneca LP 725 Chesterbrook Blvd Wayne PA 19087-5677		007	30-JUL-99

6. NAME OF DRUG	7. NONPROPRIETARY NAME
Pulmicort	budesonide

8. SUPPLEMENT PROVIDES FOR:	9. AMENDMENT(S), REPORT(S), ETC.
an additional / [redacted] /	13-AUG-99

10. PHARMACOLOGICAL CATEGORY	11. HOW DISPENSED	12. RELATED IND/NDA/DMF
steroid anti-inflammatory	RX X OTC _	

13. DOSAGE FORM(S)	14. POTENCY
inhalation powder	200 ug

15. CHEMICAL NAME AND STRUCTURE	16. RECORDS AND REPORTS
see USAN	CURRENT YES_ NO_ REVIEWED YES_ NO_

17. COMMENTS: See attached

This supplement is submitted as Changes Being Effected in 30 Days.

cc:
Orig. NDA # 20-441
HFD-570/div. File
HFD-570/Dkoble
HFD-570/Gpoochikian
HFD-570/Gtrout
R/D Init. By: 2/2/00
F/T by: Dkoble
doc # 7N20441.cr1

18. CONCLUSIONS AND RECOMMENDATIONS:

From a chemistry, manufacturing, and controls perspective, it is recommended that the supplement be approved. The project manager should draft an approval letter.

19. REVIEWER NAME	20. SIGNATURE	21. DATE COMPLETED
Dale L. Koble	Dale Koble	2/2/00

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 20-441/S007

ADMINISTRATIVE and CORRESPONDENCE DOCUMENTS

AstraZeneca

BC
SCM-007
NDA SUPP AMEND
ORIGINAL

Michael C. Elia, Ph.D., D.A.B.T.
Director, Regulatory Liaison

August 13, 1999

Robert Meyer, M.D., Acting Director
Division of Pulmonary Drug Products
HFD-570 Room 10-B03
Center for Drug Evaluation and Research
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Dear Dr. Meyer:

NDA 20-441
Pulmicort ®Turbuhaler® (budesonide inhalation powder)
Response to FDA Request for Information

Please refer to approved NDA 20-441 and the approved Supplements for Pulmicort Turbuhaler. Reference is also made to our July 30, 1999 submission, Supplement – Changes Being Effected in 30 days (S007), and the Agency's request for additional information via telephone on August 6, 1999.

As requested, we are providing in this submission individual test results (raw data), as well as summary data, for the batches of drug product manufactured using the ——— The data is being provided in both hard copy and electronic formats for your convenience. Also included in this submission is a stability commitment concerning drug product manufactured using the new ———

An exact copy of this submission is concurrently being sent to the New England District Office.

Please direct any questions or requests for additional information to me at 610-695-1365, or, in my absence, to Chris Blango, Regulatory Project Manager at 610-695-1809, or Diane Alleva, Ph.D., Director, Product Operations at 610-578-8845.

Sincerely yours,

M. C. Elia

Michael C. Elia, Ph.D.
Director, Regulatory Liaison

Attachments including (1) 3.5" diskette
cc: Richard Penta, New England District Office
Federal Express: 814425574215

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-441/S-007

AUG 6 1999

AstraZeneca LP
725 Chesterbrook Blvd.
Wayne, PA 19087-5677

Attention: Michael C. Elia, Ph.D.
Director, Regulatory Liaison

Dear Dr. Elia:

We acknowledge receipt of your supplemental application for the following:

Name of Drug: PULMICORT® TURBUHALER® (budesonide) Inhaler, 200 mcg

NDA Number: 20-441

Supplement Number: S-007

Date of Supplement: July 30, 1999

Date of Receipt: August 2, 1999

Unless we find the application not acceptable for filing, this application will be filed under Section 505(b)(1) of the Act on October 1, 1999, in accordance with 21 CFR 314.101(a).

All communications concerning this NDA should be addressed as follows:

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

Sincerely,

Cathie Schumaker
Chief, Project Management Staff
Division of Pulmonary Drug Products, HFD-570
Office of Drug Evaluation II
Center for Drug Evaluation and Research

cc:
Original NDA 20-441/S-007
HFD-570/Div. Files
HFD-570/CSO/Trout, G.

SUPPLEMENT ACKNOWLEDGEMENT

AstraZeneca

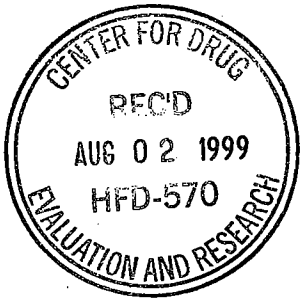
NDA NO 20441 REF NO. 8-007
NDA SUPPL FOR Scm

Michael C. Elia, Ph.D., D.A.B.T.
Director, Regulatory Liaison

ORIGINAL

July 30, 1999

Robert Meyer, M. D., Acting Director
Division of Pulmonary Drug Products
HFD-570 Room 10-B03
Center for Drug Evaluation and Research
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857



Dear Dr. Meyer:

NDA 20-441
Pulmicort® Turbuhaler® (budesonide inhalation powder)
Supplement – Changes Being Effected in 30 Days

Please refer to approved NDA 20-441 and the approved Supplements for Pulmicort Turbuhaler.

Currently, Pulmicort Turbuhaler is manufactured utilizing a _____ in Södertälje, Sweden. Due to the need to increase capacity, a new, additional _____ has been installed and qualified to produce Pulmicort Turbuhaler on the same contiguous campus in Södertälje. AstraZeneca believes that this change has been appropriately qualified, and, following the new Draft Guidance for Industry, *Changes to an Approved NDA or ANDA, June 1999*, this change can be reported as a Supplement – Changes Being Effected in 30 Days. AstraZeneca plans to implement this change at the Södertälje facility 30 days after this submission.

Included with this submission are the following documents:

- Introduction
- _____validation report
- Copy of the Master Production Record
- Summary of results for drug product batches

AstraZeneca LP
725 Chesterbrook Blvd Wayne PA 19087-5677
Tel 610 695 1000
www.astrazeneca-us.com

An exact copy of this submission is concurrently being sent to the New England District Office.

Please direct any questions or requests for additional information to me at 610-695-1365, or, in my absence, to Chris Blango, Regulatory Project Manager at 610-695-1809, or Diane Alleva, Ph.D., Director, Product Operations at 610-578-8845.

Sincerely yours,

M. C. Elia

Michael C. Elia, Ph.D.
Director
Regulatory Liaison

attachments

cc: Richard Penta - New England District Office

Federal Express No. 812858261949