CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:
NDA 20-441/S003

Trade Name: Pulmicort Turbuhaler

Generic Name: budesonide inhalation powder, 200 mcg

Sponsor: Astra Pharmaceuticals

Approval Date: April 9, 1999

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:
NDA 20-441/S003

CONTENTS

Reviews / Information Included in this NDA Review.	
Approval Letter	X
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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/S003

APPROVAL LETTER

NDA 20-441/S-003

Astra Pharmaceuticals
725 Chesterbrook Blvd.
Wayne, PA 19087-5677

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

Dear Dr. Elia:

Please refer to your supplemental new drug application dated December 17, 1998, received December 18, 1998, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Pulmicort (budesonide) Turbuhaler.

This supplement was submitted under 21 CFR 314.70(c), Special Supplement - Changes Being Effected, and the Post-Approval Changes (PAC) for Analytical Testing Laboratory Sites Guidance.

This supplemental new drug application provides for addition of a new laboratory at the Westborough, Massachusetts site of Astra Pharmacueticals for analytical testing of sub-batches and final batches of Pulmicort Turbuhaler Inhalers.

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

Sincerely yours,

Guirag Poochikian, Ph.D.
Chemistry Team Leader
Division of Pulmonary 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/4-9-99
HFD-570/Koble
HFD-570/Poochikian
HFD-820/Gibbs
DISTRICT OFFICE

Drafted by: GST/April 8, 1999
Initialed by: Schumaker/4-8-99
Koble/4-8-99
Bertha (for Poochikian)/4-8-99

final: Lgrimshaw/4-9-99

filename: n:\staff\troutg\20441let

APPROVAL (AP)

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 20-441/S003

CHEMISTRY REVIEW(S)

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
Astra Pharmaceuticals 725 Chesterbrook Blvd. Wayne, PA 19097-5677		003	17-DEC-98

6. NAME OF DRUG	7. NONPROPRIETARY NAME
Pulmicort Turbuhaler	budesonide

8. SUPPLEMENT PROVIDES FOR:	9. AMENDMENT(S), REPORT(S), ETC.
addition of a newly constructed laboratory within the existing facility at the Westborough Massachusetts site of Astra Pharmaceuticals for analytical testing of sub-batches and final batches of Pulmicort Turbuhaler Inhalers.	

10. PHARMACOLOGICAL CATEGORY	11. HOW DISPENSED	12. RELATED IND/NDA/DMF
steroidal 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:

Note: S-005 submitted 08-FEB-99 provides for updated specifications (change in delivered dose specification for sub-batches, addition of specifications and methods for microscopic quality and foreign particles) as compared to the approved specifications (attachment I to this review).

cc:
Orig. NDA # 20-441
HFD-570/div. File
HFD-570/Dkoble
HFD-570/Gpoochikian
HFD-570/Gtrout
R/D Init. By:_____
F/T by: B. Dkoble
doc # 3n20441.cr1

18. CONCLUSIONS AND RECOMMENDATIONS:

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

19. REVIEWER NAME	20. SIGNATURE	21. DATE COMPLETED
Dale L. Koble Ph.D.		4/6/99

3 Page(s) Withheld

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

_____ § 552(b)(4) Draft Labeling

_____ § 552(b)(5) Deliberative Process

Withheld Track Number: Chemistry- 20-441 / S003

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 20-441/S003

ADMINISTRATIVE and CORRESPONDENCE DOCUMENTS

NDA 20-441/S-003

Astra Pharmaceuticals
725 Chesterbrook Blvd.
Wayne PA 19087-5677

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

Dear Dr. Elia:

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

Name of Drug Product: Pulmicort (budesonide) Turbuhaler

NDA Number: 20-441

Supplement Number: S-003

Date of Supplement: December 17, 1998

Date of Receipt: December 18, 1998

This supplement proposes the following change(s): addition of a new testing laboratory to provide additional capacity for analytical testing of both sub-batches and final batches of Pulmicort Turbuhaler. Your submission stated January 16, 1999, as the implementation date for the change(s).

This supplement was submitted under 21 CFR 314.70(c), Special Supplement - Changes Being Effected, and the Post-Approval Changes (PAC) for Analytical Testing Laboratory Sites.

We have determined that this supplement qualifies for submission under PAC for changes being effected [21 CFR 314.70(c)].

Unless we notify you within 60 days of our 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 February 17, 1999, in accordance with 21 CFR 314.101(a). If the application is filed, the user fee goal date will be June 18, 1999.

Please cite the application number listed above at the top of the first page of any communications concerning this application. All communications concerning this supplemental application should be addressed as follows:

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

If you have any questions, contact Mrs. Gretchen Trout, Project Manager, at (301) 827-1058.

Sincerely yours,

Cathie Schumaker, R.Ph.
Chief, Project Management Staff
Division of Pulmonary Drug Products
Office of Drug Evaluation II
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-357
HFD-358
DISTRICT OFFICE

Drafted by: GST/January 7, 1999
Initialed by: Schumaker/1-7-99
final: GST/January 8, 1999
filename: n:\staff\troutg\20441let

SUPAC (CBE) SUPPLEMENT ACKNOWLEDGEMENT (AC)