CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:
NDA 20-441/S005

Trade Name: Pulmicort Turbuhaler

Generic Name: budesonide inhalation powder, 200 mcg

Sponsor: Astra Pharmaceuticals

Approval Date: May 21, 1999

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:
NDA 20-441/S005

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/S005

APPROVAL LETTER

NDA 20-441/S-005

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

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

Dear Dr. Elia:

Please refer to your supplemental new drug application dated February 8, 1999, received February 9, 1999, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Pulmicort Turbuhaler (budesonide inhalation powder) 200 mcg and 400 mcg.

We acknowledge receipt of your amendment dated March 2, 1999.

This supplemental new drug application provides for re-centering the sub-batch specification for average delivery dose, and addition of drug product tests and specifications for microscopic quality and foreign particles.

We have completed the review of this supplemental application, as amended, and it is approved effective on the date of this letter. However, we have the following comment.

> Provide characterization studies for the number and type of foreign particles in the drug product in the / ——————— / range via annual report. Depending on the results, a test and specification for the number of foreign particles in the drug product in the / ——————— / ranges may be necessary.

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 for
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
HFD-570/Koble/5-20-99
HFD-570/Poochikian/5-20-99
HFD-570/Schumaker/5-20-99
HFD-820/DNDC Division Director
DISTRICT OFFICE

Drafted by: pj/May 20, 1999
Final: janip/5-21-99
Filename: c:\my documents\n20441ap.005

APPROVAL (AP)

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 20-441/S005

CHEMISTRY REVIEW(S)

MAY 18 1999

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		005 08-FEB-99 Correspond. 23-DEC-97 Correspond. 27-FEB-98

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

8. SUPPLEMENT PROVIDES FOR:	9. AMENDMENT(S), REPORT(S), ETC.
the following changes in the drug product tests and specifications: (1) change of the Pulmicort 200/200 drug product release specifications for average dose delivery of sub-batches from [redacted] (2) addition of drug product tests and specifications for microscopic quality for Pulmicort 200/200 and [redacted] (3) addition of drug product tests and specifications for foreign particles for Pulmicort 200/200 [redacted]	02-MAR-99

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 [redacted]

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

17. COMMENTS:

cc:
Orig. NDA # 20-441
HFD-570/div. File
HFD-570/Dkoble
HFD-570/Gpoochikian
HFD-570/Gtrout
R/D Init. By: 5/18/99
F/T by: B. Dkoble
Doc # 5n20441.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 and include the attached draft comment.

19. REVIEWER NAME	20. SIGNATURE	21. DATE COMPLETED
Dale L. Koble, Ph.D.	Dale L. Koble	14-MAY-99

13 Page(s) Withheld

1 § 552(b)(4) Trade Secret / Confidential

_____ § 552(b)(4) Draft Labeling

_____ § 552(b)(5) Deliberative Process

Withheld Track Number: Chemistry- 20-411 / S005

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 20-441/S005

ADMINISTRATIVE and CORRESPONDENCE DOCUMENTS

ASTRA®
Astra Pharmaceuticals

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

BC
SCS-005
NDA SUPP AMEND
ORIGINAL

March 2, 1999

John Jenkins, M.D., 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. Jenkins:

NDA 20-441
PULMICORT® TURBUHALER® (budesonide inhalation powder)
SUPPLEMENT S-005 – EXPEDITED REVIEW REQUESTED -
FDA Request for Additional CMC Information

Reference is made to the original sNDA submitted February 8, 1999 and to the February 24, 1999 request from Ms. Gretchen Trout to Dr. Michael Elia for an updated version of the specifications for Pulmicort Turbuhaler, 200 µg. Please also refer to the submission of December 23, 1997, which provided a proposed method for Microscopic Quality, and the submission of February 27, 1998 which provided a proposed method for Foreign Particles.

The revised specification sheet ——— and test methods are provided with this submission (Attachments 1 and 2, respectively).

In keeping with our Phase 4 commitments, the methods and specifications for Microscopic Quality and Foreign Particles were developed and submitted previously to the Agency. These methods and specifications have been incorporated into the revised specification that is provided with this submission. Upon approval of this sNDA, which provides for re-centering the sub-batch specification for average delivered dose, the proposed methods and specifications for Microscopic Quality and Foreign Particles will be implemented for routine production as part of ——— of the Pulmicort Turbuhaler specifications. The tests for Microscopic Quality and Foreign Particles have been included in all ongoing stability programs. These data will be included in our Annual Report for Pulmicort Turbuhaler.

MAILING ADDRESS:
Astra Pharmaceuticals, L.P.
725 Chesterbrook Blvd.
Wayne, PA 19087-5677

TEL:
800 236-9933

Please direct any questions on this submission to me at 610-695-1365, or, in my absence, to George Kummeth, Regulatory Project Manager, at 610-578-8415, or Diane Alleva, Ph.D., Director, Product Operations at 610-578-8845.

Sincerely,

M. C. Elia

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

attachments

Federal Express: 808880150742