CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:
NDA 20-441/S011

Trade Name: Pulmicort Turbuhaler

Generic Name: budesonide inhalation powder, 200 mcg

Sponsor: Astra Pharmaceuticals

Approval Date: June 18, 2001

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:
NDA 20-441/S011

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**

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APPLICATION NUMBER:
NDA 20-441/S011

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-441/S-011
NDA 20-746/S-005
NDA 20-929/S-005

AstraZeneca LP
1800 Concorde Pike
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 applications dated January 15, 200, received January 16, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Pulmicort Turbuhaler (budesonide inhalation powder), Rhinocort Aqua (budesonide) Nasal Spray, and Pulmicort Respules (budesonide inhalation suspension).

We acknowledge receipt of your submissions dated May 15, 2001.

These "Changes Being Effected" supplemental new drug applications provide for separate and individual method numbers for drug substance and drug product for each referenced NDA.

We have completed the review of these supplemental applications, and they are 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
6/18/01 03:33:34 PM

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 20-441/S011

CHEMISTRY REVIEW(S)

CHEMIST'S REVIEW #1

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

3. NAME AND ADDRESS OF APPLICANT *(City and State)*
AstraZeneca LP
725 Chesterbrook Blvd
Wayne, PA 19087-5677

4. AF NUMBER

5. SUPPLEMENT(S)
NUMBER(S) DATES(S)
SCS-011 1/15/01

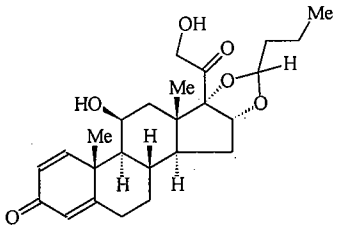
6. NAME OF DRUG	7. NONPROPRIETARY NAME
Pulmicort® Turbuhaler®	budesonide inhalation powder

8. SUPPLEMENT PROVIDES FOR: Separate and individual method numbers for drug substance for each of the related applications for the firm's products containing the budesonide API (Rhinocort Aqua, N 20-746; Pulmicort Respules, N20-929; Pulmicort Turbuhaler, N20-441).

9. AMENDMENT(S), REPORT(S), ETC.
SCS-011 (BC) 5/15/01

10. PHARMACOLOGICAL CATEGORY	11. HOW DISPENSED	12. RELATED IND/NDA/DMF
steroid anti-inflammatory	RX X OTC __	NDA 20-746/S-005 NDA 20-929/S-005
13. DOSAGE FORM(S) inhalation powder	14. POTENCY 200 mcg metered; as noted in S-009.	

15. CHEMICAL NAME AND STRUCTURE



Budesonide or (*RS*)-11β,16α,17,21-tetrahydroxypregna-1,4-diene-3,20-dione cyclic 16,17-acetal with butyraldehyde

16. RECORDS AND REPORTS
CURRENT YES__NO__
REVIEWED YES__NO__

17. COMMENTS: See review notes attached.

cc:
Orig. NDA 20-441
HFD-570/div. File
HFD-570/CBertha/5/24/01
HFD-570/GPoochikian
HFD-570/CKim
HFD-570/KSwiss
HFD-570/GTrout
R/D Init. by:_____
F/T by: CBertha/5/24/01
doc # 01-05-15.rev.doc

18. CONCLUSIONS AND RECOMMENDATIONS: From the CMC perspective, the supplement should be **approved (AP)**.

19. REVIEWER NAME:	SIGNATURE	DATE COMPLETED
Craig M. Bertha, Ph.D.		5/24/01

1 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
S011

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/s/

Craig Bertha
6/18/01 09:30:52 AM
CHEMIST

Guiragos Poochikian
6/18/01 10:45:54 AM
CHEMIST

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 20-441/S011

ADMINISTRATIVE and CORRESPONDENCE DOCUMENTS

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-441/S-011
NDA 20-746/S-005
NDA 20-929/S-005

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 applications submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following:

NDA Number	Supplement Number	Drug Name
20-441	S-011	Pulmicort Turbuhaler (budesonide inhalation powder)
20-746	S-005	Rhinocort Aqua (budesonide) Nasal Spray
20-929	S-005	Pulmicort Respules (budesonide inhalation suspension)

Date of Supplements: January 15, 2001

Date of Receipt: January 16, 2001

These supplemental applications, submitted as "Supplement - Changes Being Effected" supplements, propose the following change(s): revised testing monographs with individual method numbers.

Unless we notify you within 60 days of our receipt date that the applications are not sufficiently complete to permit a substantive review, these applications will be filed under section 505(b) of the Act on March 27, 2001 in accordance with 21 CFR 314.101(a). If the applications are filed, the user fee goal date will be July 16, 2001.

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

U.S. Postal/Courier/Overnight Mail:

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

If you have any questions, call me at (301) 827-1058.

Sincerely yours,

{See appended electronic signature page}

Gretchen Trout
Project Manager
Division of Pulmonary and Allergy Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

/s/

Gretchen Trout
1/26/01 03:51:19 PM