

CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

20-468/S001

Trade Name: Nasacort AQ

Generic Name: triamcinolone acetonide

Sponsor: Rhone -Poulenc Rorer Pharmaceuticals

Approval Date: August 23, 1996

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

20-468/S001

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APPLICATION NUMBER:

20-468/S001

APPROVAL LETTER

NDA 20-468/S-001

Rhone-Poulenc Rorer Pharmaceuticals Inc.
500 Arcola Road
P.O. Box 1200
Collegeville, PA 19426-0107

AUG 23 1996

Attention: Judith R. Plon
Director
Regulatory Affairs

Dear Ms. Plon:

Please refer to your August 22, 1996 supplemental new drug application submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Nasacort AQ (triamcinolone acetonide) Nasal Spray.

This supplemental application provides for revised specifications for ~~the pump components~~ and ~~the pump components~~ for the ~~the pump components~~ pump components.

We have completed the review of this supplemental application, and it is approved effective on the date of this letter.

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, please contact:

Sandy Barnes
Project Manager
(301) 827-1075

Sincerely yours,

Guirag Poochikian, Ph.D.
Chemistry Team Leader, DNDC II
Division of Pulmonary Drug Products (HFD-570)
Office of Drug Evaluation II
Center for Drug Evaluation and Research

NDA 20-468/S-001

Page 2

cc:

Original NDA 20-468/S-001

HFD-570/Div. Files/NDA 20-468

HFD-570/S. Barnes

HFD-570/B. Rogers

HFD-80

DISTRICT OFFICE

HFD-232

*ResubP
8/23/96*

drafted: SBarnes/August 23, 1996/N:\Staff\Barness\N20468S1.AP

R/D Initials By: BKuzmik/8-23-96

ACSchroeder for GPoochikian/8-23-96

Final By: LGrimshaw/8-23-96

APPROVAL

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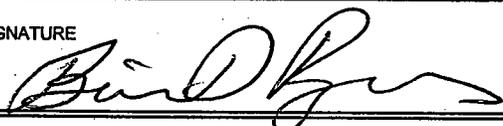
APPLICATION NUMBER:

20-468 /S001

CHEMISTRY REVIEW(S)

ORIGINAL

AUG 23 1996

CHEMIST'S REVIEW		1. ORGANIZATION HFD-570 DPDP	2. NDA NUMBER 20-468
3. NAME AND ADDRESS OF APPLICANT (City and State) Rhône-Poulenc Rorer Pharmaceuticals Inc. Collegeville, PA 19426-0107		4. AF NUMBER	
6. NAME OF DRUG Nasacort® AQ Nasal Spray	7. NONPROPRIETARY NAME triamcinolone acetonide nasal suspension	5. SUPPLEMENT(S) NUMBER(S) DATES(S) SCS-001 8/22/96	
8. SUPPLEMENT PROVIDES FOR: Changes in the specifications for _____ and _____ of the _____ pump components.		9. AMENDMENT(S), REPORT(S), ETC.	
10. PHARMACOLOGICAL CATEGORY glucocorticosteroid with anti-inflammatory and anti-allergic properties for treatment of seasonal and perennial allergic rhinitis	11. HOW DISPENSED RX <input checked="" type="checkbox"/> OTC <input type="checkbox"/>	12. RELATED IND/NDA/DMF DMF <input checked="" type="checkbox"/>	
13. DOSAGE FROM(S) Metered nasal pump spray (suspension)	14. POTENCY 55 µg of triamcinolone acetonide per actuation from the nasal adapter		
15. CHEMICAL NAME AND STRUCTURE 9-Fluoro-11β,16α,17,21-tetrahydroxypregna-1,4-diene-3,20-dione cyclic 16,17-acetal with acetone (for structure see USAN)		15. RECORDS AND REPORTS CURRENT YES ___ NO ___ REVIEWED YES ___ NO ___	
16. COMMENTS: See attached cc: Orig. NDA #20-468 HFD-570/div. File HFD-570/BRogers/8/23/96 HFD-570/GPoochikian HFD-570/SBarnes HFD-570/CKwong R/D Init. by: <u>ACS for GP 8/23/96</u> F/T by: BRogers/8/23/96 doc # 20468.S01			
17. CONCLUSIONS AND RECOMMENDATIONS: The supplement is APPROVABLE from a CMC viewpoint. The PM should send an approval letter to the applicant.			
18. REVIEWER NAME: Brian D. Rogers, Ph.D.	SIGNATURE 		DATE COMPLETED 8/23/96

2 Page(s) Withheld

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

 § 552(b)(4) Draft Labeling

 § 552(b)(5) Deliberative Process

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**ADMINISTRATIVE and CORRESPONDENCE
DOCUMENTS**



RHÔNE-POULENC RORER

ORIGINAL

RHÔNE-POULENC RORER PHARMACEUTICALS INC.

500 ARCOLA ROAD
P.O. BOX 1200
COLLEGEVILLE, PA 19426-0107

JUDITH R. PLON
DIRECTOR
REGULATORY AFFAIRS

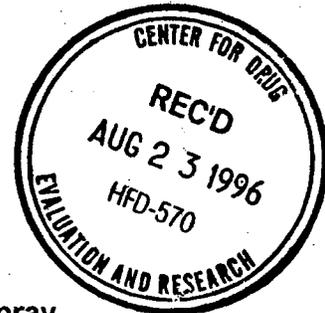
TEL: 610-454-3024
FAX: 610-454-5299
VM# 610-454-8666, BOX 3024

NDA NO. 20468 REF. NO. 001

NDA SUPPL FOR 865

August 22, 1996

John K. Jenkins, M.D., Director
Division of Pulmonary Drug Products (HFD-570)
Center for Drug Evaluation and Research - ODE II
Room 10B-03
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857



NDA #20-468
Nasacort® AQ Nasal Spray
(triamcinolone acetonide)

RE: SUPPLEMENT - EXPEDITED
REVIEW REQUESTED

Dear Dr. Jenkins:

Reference is made to the above-mentioned Notice for our NDA #20-468, and further reference is made to the May 20, 1996, Approval Letter for this application which referred to the Phase IV Commitments agreed to by the Division and Rhône-Poulenc Rorer on May 16, 1996, for this product.

As part of the above-referenced Phase IV Commitments, RPR agreed to evaluate at

~~_____~~ 7
~~_____~~)

In support of these commitments, RPR provided the Division initial data on August 7, 1996. This was followed with a complete package on August 20, 1996, in which widened specifications for _____ and _____ or both the pump componentry _____. Today, August 22, 1996, your representative, Dr. Brian Rogers, called to relay that the Division did agree with RPR's proposals concerning the pump componentry; I _____

Furthermore, he noted that this information must be filed as a supplemental application requiring pre-approval by the Division.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
**APPLICATION TO MARKET A NEW DRUG FOR HUMAN USE
OR AN ANTIBIOTIC DRUG FOR HUMAN USE**
(Title 21, Code of Federal Regulations, 314)

Form Approved: OMB No. 0910-0001.
Expiration Date: April 30, 1994.
See OMB Statement on Page 3.

FOR FDA USE ONLY

DATE RECEIVED	DATE FILED
DIVISION ASSIGNED	NDA/ANDA NO. ASS.

NOTE: No application may be filed unless a completed application form has been received (21 CFR Part 314).

NAME OF APPLICANT Rhone-Poulenc Rorer Pharmaceuticals Inc.	DATE OF SUBMISSION August 22, 1996
ADDRESS (Number, Street, City, State and Zip Code) 500 Arcola Road Collegeville, PA 19426	TELEPHONE NO. (Include Area Code) (610) 454-3024
	NEW DRUG OR ANTIBIOTIC APPLICATION NUMBER (If previously issued) 20-468

DRUG PRODUCT

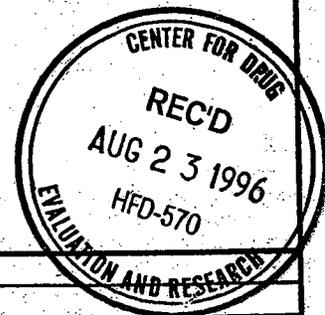
ESTABLISHED NAME (e.g., USPI/USAN) triamcinolone acetonide	PROPRIETARY NAME (If any) Nasacort [®] AQ Nasal Spray
CODE NAME (If any) RG 5029Y	CHEMICAL NAME triamcinolone acetonide
DOSAGE FORM Intranasal Spray	ROUTE OF ADMINISTRATION Intranasal
	STRENGTH(S) 55 mcg/spray

PROPOSED INDICATIONS FOR USE

For treatment of seasonal and perennial allergic rhinitis symptoms

LIST NUMBERS OF ALL INVESTIGATIONAL NEW DRUG APPLICATIONS (21 CFR Part 312), NEW DRUG OR ANTIBIOTIC APPLICATIONS (21 CFR Part 314), AND DRUG MASTER FILES (21 CFR 314.420) REFERRED TO IN THIS APPLICATION:

IND / _____
IND / _____
NDA 19-798 - Nasacort[®] Nasal Inhaler
NDA 18-117 - Azmacort[®] Oral Inhaler
DMF / _____
DMF / _____
DMF / _____



INFORMATION ON APPLICATION

TYPE OF APPLICATION (Check one)

THIS SUBMISSION IS A FULL APPLICATION (21 CFR 314.50) THIS SUBMISSION IS AN ABBREVIATED APPLICATION (ANDA) (21 CFR 314.55)

IF AN ANDA, IDENTIFY THE APPROVED DRUG PRODUCT THAT IS THE BASIS FOR THE SUBMISSION

NAME OF DRUG	HOLDER OF APPROVED APPLICATION
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TYPE SUBMISSION (Check one)

PRESUBMISSION AN AMENDMENT TO A PENDING APPLICATION SUPPLEMENTAL APPLICATION
 ORIGINAL APPLICATION RESUBMISSION

SPECIFIC REGULATION(S) TO SUPPORT CHANGE OF APPLICATION (e.g., Part 314.70(b)(2)(iv))

PROPOSED MARKETING STATUS (Check one)

APPLICATION FOR A PRESCRIPTION DRUG PRODUCT (Rx) APPLICATION FOR AN OVER-THE-COUNTER PRODUCT (OTC)