CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

14-901 / S-029

Trade Name: **Kenalog - 40**

Generic Name: **Triamcinolone acetonide**

Sponsor: **Apothecon Inc.**

Approval Date: **July 19, 1991**

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APPLICATION NUMBER:

14-901 / S-029

CONTENTS

Reviews / Information Included in this NDA Review.	
Approval Letter	X
Approvable Letter	
Labeling	X
Summary Review	
Officer/Employee List	
Office Director Memo	
Cross Discipline Team Leader Review	
Medical Review(s)	
Chemistry Review(s)	X
Environmental Assessment	
Pharmacology Review(s)	
Statistical Review(s)	
Microbiology Review(s)	
Clinical Pharmacology/Biopharmaceutics Review(s)	
Risk Assessment and Risk Mitigation Review(s)	
Proprietary Name Review(s)	
Administrative/Correspondence Document(s)	X

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APPLICATION NUMBER:

14-901 / S-029

APPROVAL LETTER

291

JUL 19 1991

NDA 12-041/S025
14-901/S029

Westwood-Squibb Pharmaceuticals, Inc.
100 Forest Avenue
Buffalo, New York 14213

Attention: Kathy B. Schrode, Ph.D.
Manager, Drug Regulatory Affairs

Dear Dr. Schrode:

Please refer to your supplemental new drug applications dated March 4, 1991 (12-041/S025) and March 15, 1991 (14-901/S029) submitted pursuant to section 505(b) of the Federal Food, Drug, and Cosmetic Act for Kenalog 10 and 40 (sterile triamcinolone acetonide) Suspension.

We also refer to your communications dated April 26, 1991 which amended the applications.

The supplemental applications provide for a larger (10 mL) vial with the same [redacted]. b(4)

We have completed the review of these supplemental applications and they are approved effective as of the date of this letter.

We remind you that you must comply with the requirements for an approved NDA as set forth under 21 CFR 314.80 and 314.81.

Should you have any questions, please contact:

Herbert T. Behrens
Project Manager
Pilot Drug Evaluation Staff,
HFD-007
(301) 443-3741

Sincerely yours,

Charlotte A. Yaciw, Chemist
Pilot Drug Evaluation Staff

cc:
Original NDAs
HFD-007/Division file
HFD-007/Chemist/CYaciw
HFD-80
HFD-007/HTBehrens, 7/15/91
HFC 130/J.Allen
R/D init. by: D.Pease 7-18-91
F/T by: M.Beall 7-18-91
Wang # 0516b
SUPPLEMENTS APPROVED

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

14-901 / S-029

CHEMISTRY REVIEW(S)

JUL 15 1991

CHEMIST'S REVIEW	1. Organization HFD-007	2. NDA Number 14-901
3. Name and Address of Applicant (City & State) Westwood-Squibb Pharmaceuticals Inc. 100 Forest Avenue Buffalo, NY 14213		4. AF Number 5. Supplement(s) Number(s): SCP 029 — Date(s): 3-15-91
6. Name of Drug Kenalog 40	7. Nonproprietary Name triamcinolone acetonide	
8. Supplement(s) Provides For: [redacted]		9. Amendments & Other (Reports, etc) Dates AC 4-26-91
10. Pharmacological Category corticosteroid	11. How Dispensed /x/ RX / / OTC	12. Related Documents NDA 12-041 Kenalog 40
13. Dosage Form(s) suspension for injection	14. Potency(ies) 40 mg/mL	
15. Chemical Name and Structure see USP		16. Records & Reports Current / / Yes / / No Reviewed / / Yes / / No

17. Comments

EXPEDITED REVIEW REQUESTED

The Japanese have requested that the product be packaged in 10 ml vials instead of the 5 ml vials used for US distribution. Otherwise the fill and packaging components will be unchanged. Specifications for the new size vial were provided along with three months accelerated stability data which show acceptable stability. The vials will be filled at the current facility and will be shipped in bulk cartons without labels. A copy of the package insert is included in the carton. A COA for the first lot packaged was provided as were shipping labels.

18. Conclusions and Recommendations:

This supplement is approvable. Issue an approval letter.

19. REVIEWER Paul Hillery 7-15-91

Name	Signature	Date Completed
Charlotte A. Yaciw	Charlotte A. Yaciw	7-12-91

/ / NDA # 14-901 / / CYaciw / / Div. File / / HBEHRENS

DOC ID: YACIW/N14901S.029

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APPLICATION NUMBER:

14-901 / S-029

ADMINISTRATIVE and CORRESPONDENCE DOCUMENTS

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

3-22-1991

Westwood-Squibb Pharmaceuticals Inc.
100 Forest Avenue,
Buffalo, NY 14223

Attention: Kathy B. Schrode, Ph.D.
Manager Drug Regulatory Affairs

Dear :

We acknowledge receipt of your supplemental application for the following:

Name of Drug: KENALOG-40

NDA Number: 14901

Supplement Number: S-029

Date of Supplement: 3-15-1991

Date of Receipt: 3-18-1991

Should you have any questions, please contact:

Herb Behrens
Project Manager
(301) 443-3741

Sincerely yours,

For Project Manager
Center for Drug Evaluation and Research

cc:
Original NDA
HFN-007/150
HFN-007/150/CSO

SUPPLEMENT ACKNOWLEDGEMENT