CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

14-901 / S-010

Trade Name: **Kenalog - 40**

Generic Name: **Triamcinolone acetonide**

Sponsor: **Apothecon Inc.**

Approval Date: **April 7, 1978**

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APPLICATION NUMBER:

14-901 / S-010

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APPLICATION NUMBER:

14-901 / S-010

APPROVAL LETTER

APR 7 1978

NDA 14-901/S-010

E. R. Squibb & Sons, Inc.
Attention: Norman W. Lavy, M.D.
P.O. Box 191
New Brunswick, New Jersey 08903

Gentlemen:

We acknowledge the receipt on December 19, 1977, of your communication dated December 16, 1977, regarding your supplemental new drug application of May 18, 1976, submitted pursuant to section 505(b) of the Federal Food, Drug, and Cosmetic Act for Kenalog-40 (Sterile Triamcinolone Acetonide Suspension U.S.P.) 40 mg per ml in a 5 ml multiple dose vial.

The supplemental application as amended provides for twelve copies of revised carton labeling (L5065D).

We have completed the review of this supplemental application and it is approved in accordance with the provision of this submission.

Sincerely yours,

William J. Gyarfas, M.D.
Director
Division of Oncology and
Radiopharmaceutical Drug Products
Bureau of Drugs

cc: NWK-DO
Orig. NDA
HFD-150
HFD-150/RMPatel/3/15/78/ls/4/5/78
R/D init. by: RHWood/3/24/78

APPROVAL

JUN 14 1976

MEDICAL OFFICER REVIEW OF NDA SUPPLEMENT

NDA: 14-901/S-010 June 8, 1976

Applicant: E. R. Squibb & Sons, Inc.
Georges Road
New Brunswick, New Jersey 08903

Original Approval Date: September 30, 1964.

Name of Drug: Trade: Kenalog-40 Injection

Generic: Triamcinolone Acetonide Suspension U.S.P.

Dosage Form and Route of Administration: Kenalog-40 Injection provides 40 mg/ml; Kenalog-10 Injection provides 10 mg/ml of triamcinolone acetonide for I.M.; I.A., intrabursal injection or injection into tendon sheats.

Category: Parenteral Glucocorticoid

Date of Supplement: May 18, 1976.

Reason for Supplement:

1. Leading zeros have been added to the National Drug Code numbers; 3-0293-05 and 3-0293-20 have been changed to read 0003-0293-05 and 0003-0293-20 particularly for the 1 ml and 5-ml packages, respectively.
2. The unit volume is expressed as 'ml' instead of 'cc'.
3. The compendial designation (U.S.P.) now appears on the vial labels as well as on the cartons.
4. The mailing address is changed from New York, N.Y. to Princeton, N.J.
5. The control number and expiration date is to be imprinted during the packaging operation and each package will contain a copy of the latest approved package insert.

Material Reviewed: The above changes.

Clinical Evaluation: There is no objection to the above changes.

Recommendations: Inform the sponsor as follows:
We have no objection to your initiation of the changes indicated in this supplement.

Albert R. Norris, M.D.

cc:
NDA 14-901 Orig
HFD-108 ~~HFD-150~~
HFD-150/ARNorris:6/8/76
Final typed by deg:6/14/76

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

14-901 / S-010

CHEMISTRY REVIEW(S)

CHEMIST VIEW
(If necessary, continue any ...n on 8" x 10½" paper. Key continuation to item by number.)

1. ORGANIZATION: DORDP/HFD-1

2. NDA NUMBER: 14-901

3. NAME AND ADDRESS OF APPLICANT *(City and State)*
E.R. Squibb and Sons, Incorporated
Georges Road, New Brunswick, New Jersey, 08903

4. AF NUMBER: JUL 13 1976

5. SUPPLEMENT (S)

NUMBER(S)	DATE(S)
S-010	5/18/76

6. NAME OF DRUG: Kenalog-40(R)

7. NONPROPRIETARY NAME: Triamcinolone acetonide

8. SUPPLEMENT(S) PROVIDES FOR:
Three copies each of container and carton labels for the 1 and 5 ml sizes of Kenalog-40.

9. AMENDMENTS AND OTHER *(Reports, etc.)* DATES
R14 dated 9/1/75

10. PHARMACOLOGICAL CATEGORY: Glucocorticoid

11. HOW DISPENSED: [X] RX [ ] OTC

12. RELATED IND/NDA/DMF(S)

13. DOSAGE FORM (S): Sterile aqueous suspension

14. POTENCY *(ies)*: 40 mg/ml (also 10 mg/ml)

15. CHEMICAL NAME AND STRUCTURE

16. RECORDS AND REPORTS
CURRENT: [X] YES [ ] NO
REVIEWED: [X] YES [ ] NO

17. COMMENTS
R14 dated 9/1/75 shows some revision for container, carton and box labels for Kenalog-40, (10 ml). ▲ However, their cover letter did not specify this change.

FD form 356 H is not enclosed for S-010.

Only 3 instead of 12 copies are enclosed for container and carton of Kenalog-40, 1 and 5 ml vials. (▲No labels are enclosed for 10 ml vials).

No labels are shown for Kenalog-10 dosage forms. This should be up-dated.

The mailing address is changed to Princeton, N. J. from New York, N.Y., but the stationary shows New Brunswick, N.J. as an address. Thus, explanation is necessary whether or not New Brunswick, N.J., should be used as a mailing address for correspondence.

18. CONCLUSIONS AND RECOMMENDATIONS

Issue a Rev/w.f. letter (controls related deficiency).

(Note: M.O. review dated 6/8/76 indicated no objection.)

19. B. Kagan:6/24/76 REVIEWER

NAME	SIGNATURE	DATE COMPLETED
Rashmikant M. Patel, Ph.D.		6/21/76

DISTRIBUTION [ ] ORIGINAL JACKET [ ] REVIEWER [✓] DIVISION FILE

FORM FDH 2266 (7/75) PREVIOUS EDITION MAY BE USED UNTIL SUPPLY IS EXHAUSTED.

CHEMIST'S REVIEW, Page 2

Enter evaluation or comments for each item. If necessary, continue on 8" x 10½" paper. Key continuation to item by number. Enter "NC" if no change or "NA" if not applicable.

NDA NUMBER 14-901/S-010

20. COMPONENTS AND COMPOSITION *(6, 7)*

21. FACILITIES AND PERSONNEL *(8a,b)*

22. SYNTHESIS *(8c)*

23. RAW MATERIAL CONTROLS *(8d,e)*
a. NEW DRUG SUBSTANCE

b. OTHER INGREDIENTS

24. OTHER FIRM(S) *(8f)*

25. MANUFACTURING AND PROCESSING *(8g,h,j,k)*

26. CONTAINER *(8i)*

27. PACKAGING AND LABELING *(8l,m)*

28. LABORATORY CONTROLS *(In-Process and Finished Dosage Form) (8n)*

29. STABILITY *(8p)*

30. CONTROL NUMBERS *(8c)*

31. SAMPLES AND RESULTS *(9)*

a. VALIDATION

b. MARKET PACKAGE

32. LABELING *(4)*

1. 1 cc and 5 cc have been changed to 1 ml and 5 ml.
2. NDC number shows a 000 prefix.
3. The mailing address is changed from New York, N.Y., to Princeton, N.J. for Kenalog-40, 1 ml and 5 ml container and carton labels.
4. U.S.P. designation is used with the chemical name.

CHEMIST[illegible]VIEW

(If [illegible] on 8" x 10½" paper. [illegible])

1. ORGANIZATION: DORDP/HFD-150

2. NDA NUMBER: 14-901

3. NAME AND ADDRESS OF APPLICANT (City and State)

E.R. Squibb & Sons, Incorporated
Georges Road, New Brunswick, New Jersey 08903

4. AF NUMBER: OCT 13 1976

5. SUPPLEMENT (S)

NUMBER(S)	DATE(S)
S-010	5/18/76
S-011	7/20/76

6. NAME OF DRUG: Kenalog(R)-40

7. NONPROPRIETARY NAME: Sterile Triamcinolone Acetonide Suspension, U.S.P.

8. SUPPLEMENT(S) PROVIDES FOR:

S-010AM: Twelve copies of the immediate container and carton labels for 1 and 5 ml packages, and container carton and box labels for the 10 ml vial of the product.

9. AMENDMENTS AND OTHER (Reports, etc.) DATES

S-010 AM 7/23/76

[redacted] b(4)

10. Glucocorticoid

☒ RX ☐ OTC

12. REFERENCE(S)/DMF(S)

[redacted]

13. DOSAGE FORM (S): Sterile aqueous suspension

14. POTENCY (ies): 40 mg/ml (also, 10 mg/ml)

15. CHEMICAL NAME AND STRUCTURE

16. RECORDS & REPORTS

CURRENT ☐ YES ☐ NO

REVIEWED ☐ YES ☐ NO

17. COMMENTS

S-010 AM is provided in response to our Rev/W.F. letter of July 13, 1976. It is stated that Kenalog(R)-10 is the subject of a separate NDA and labeling will be provided as soon as the revised copies are available. The amendment is adequate for S-010.

The changes proposed for S-011 are adequate for Kenalog-40.

18. CONCLUSIONS AND RECOMMENDATIONS

Issue a PE letter applicable to glucocorticoids for S-010 AM and S-011.

10/13/76

Final typed:mvb:10/7/76

19. B.Kagan:9/30/76

REVIEWER

NAME	SIGNATURE	DATE COMPLETED
Rashmikant M. Patel, Ph.D.	RM Patel 10/13/76	9/28/76

DISTRIBUTION ☐ ORIGINAL JACKET ☐ REVIEWER ☒ DIVISION FILE

FORM FDH 2266 (7/75) PREVIOUS EDITION MAY BE USED UNTIL SUPPLY IS EXHAUSTED.

2 Page(s) Withheld

1 Trade Secret / Confidential (b4)

_____ Draft Labeling (b4)

_____ Draft Labeling (b5)

_____ Deliberative Process (b5)

Withheld Track Number: Chemistry-_____

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

14-901 / S-010

ADMINISTRATIVE and CORRESPONDENCE DOCUMENTS

OCT 13 1976

NDA 14-901/S-010, S-011

E. R. Squibb & Sons, Inc.
Attention: Norman W. Lavy, M.D.
Georges Road
New Brunswick, New Jersey 08903

Gentlemen:

We acknowledge the receipt on July 27, 1976, of your communication dated July 23, 1976, regarding your supplemental new drug application of May 18, 1976, submitted pursuant to section 505(b) of the Federal Food, Drug, and Cosmetic Act for Kenalog-40 (Sterile Triamcinolone Acetonide Suspension U.S.P.) 40 mg per ml.

The supplemental application as amended provides for twelve printed copies of the immediate container and carton labels for the 1, 5 and 10 ml vials, and (box) "labels" for the 25 unit (10 ml vials) of Kenalog-40 (S-010).

We also acknowledge the receipt on July 23, 1976, of your supplemental new drug application dated July 20, 1976, submitted pursuant to section 505(b) of the Federal Food, Drug, and Cosmetic Act for this product

[redacted] b(4)

We have completed the review of these supplemental applications. Approvals of supplemental applications for the drug are being withheld. In the interim, the changes proposed in the supplemental applications will be permitted without approval.

cc: NWK-DO
Orig. NDA
HFD-150
HFD-150/CWilkes
HFD-150/RMPatel/9/28/76/jmb/10/5/76
R/D init. by: BKagan/9/30/76

Sincerely yours,

William J. Gyarfas, M.D.
Director
Division of Oncology and
Radiopharmaceutical Drug Products
Bureau of Drugs

JUN 10 1976

NDA 14-901

E. R. Squibb & Sons, Incorporated
Attention: Norman W. Lavy, M.D.
Georges Road
New Brunswick, New Jersey 08903

Gentlemen:

We acknowledge receipt of your supplemental application for the following:

Name of Drug: Kenalog-40

NDA Number: 14-901

Supplement Number: S-010

Date of Supplement: May 18, 1976

Date of Receipt: May 20, 1976

All communications concerning this NDA should be addressed as follows:

Bureau of Drugs HFD-150
Attention: DOCUMENT CONTROL ROOM #17B-34
5600 Fishers Lane
Rockville, Maryland 20852

Sincerely yours,

cc: NWK-DO
NDA Orig.
HFD-150
HFD-150/BArmstrong/rab/6/10/76

SUPPLEMENT ACKNOWLEDGEMENT

William J. Gyarfas, M.D.
Director
Division of Oncology and
Radiopharmaceutical Drug Products
Bureau of Drugs