

CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

14-901 / S-009

Trade Name: Kenalog - 40

Generic Name: Triamcinolone acetonide

Sponsor: Apothecon Inc.

Approval Date: July 27, 1979

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

14-901 / S-009

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APPLICATION NUMBER:

14-901 / S-009

APPROVAL LETTER

JUL 27 1979

NDA 14,901/S-009

E. R. Squibb & Sons, Inc.
Attention: Dr. C. L. Kroll
P.O. Box 191
New Brunswick, New Jersey 08903

Gentlemen:

We acknowledge the receipt on February 26, 1979 of your communication dated February 23, 1979 regarding your supplemental new drug application of February 25, 1976 submitted pursuant to section 505(b) of the Federal Food, Drug, and Cosmetic Act for Kenalog-40 (Triamcinolone Acetonide) Injection, 40 mg per ml.

We also acknowledge receipt of your additional communication dated August 4, 1978 providing stability data of the drug product.

The supplemental application as amended provides for a 36 month expiration dating of the drug product packaged in both 5 and 10 ml multiple-dose glass vials.

We have completed the review of this supplemental application and it is approved. The conditions relating to the approval of this application have previously been forwarded to you.

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/5/22/79/1s/6/12/79/7/18/79
R/D init. by: RHWood/5/25/79

APPROVED

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

14-901 / S-009

MEDICAL REVIEW(S)

Medical Officer's Review to NDA 14-901/S-009

SEP 27 1976

NDA 14-901/S-009

Sponsor: E. R. Squibb & Sons, Inc.

Type of Submission: Supplement, labeling revision

Date of Submission: May 18, 1976

Date of Review: June 22, 1976

Supplemental Review to Dr. Norris's Review of June 7, 1976

Reviewer: John G. Harter, M.D.

A. Resume:

In response to our letter of November 11, 1975 in which we reviewed an annual report. We advised the sponsor that the package insert should be revised to conform with the Federal Register Statement dated February 19, 1972 concerning glucocorticoids for parenteral use.

The sponsor submitted a new package insert on February 25, 1976. This was reviewed and on April 15, 1976 we sent them a letter asking them to revise the DOSAGE ADMINISTRATION section and the INDICATIONS section.

This submission is in response to the letter dated April 15, 1976.

The changes in labeling that they proposed in both package inserts are not documented by any clinical or other data. Our policy on changes in the corticoid labeling have been to review them and to allow changes which seem reasonable to whoever reviewed it but not to approve the changes pending the class labeling revision of all corticoid labeling.

B. Conclusions:

1. The submission is adequate to fill the requirement for which it was submitted.

2. The submission does raise a safety question which requires FDA action.
3. This submission does not resolve any efficacy questions which require FDA action.
4. The submission does satisfy questions on deficiencies previously referred to the sponsor.
5. The submission does require the FDA to point out one or more deficiencies in this submission.

C. Recommendations:

That we write Squibb and ask them to make several additional changes in their proposed package insert. If they make those changes, we will allow the rest of the package insert to be allowed but not approved. At the same time, we should request the basis upon which they have deviations in their package insert from the February 19, 1972, Federal Register Statement.

These items, in both categories, are listed under deficiencies.

D. Deficiency List:

1. The following changes should be made in the current labeling at this time.

[

]

b(4)

6 Page(s) Withheld

 Trade Secret / Confidential (b4)

Draft Labeling (b4)

 Draft Labeling (b5)

 Deliberative Process (b5)



b(4)

d. SUGGESTIONS:

See RECOMMENDATIONS and DEFICIENCY LIST.

John G. Harter, M.D.
Medical Officer, HFD-150

cc:
Orig NDA
HFD-150
HFD-108
HFD-150/JGHarter
Final typed by: mab/9:17:76

MEDICAL OFFICER'S REVIEW OF NDA SUPPLEMENT

JUN 14 1976

NDA: 14-901/S-009

Date Completed: June 7, 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 of triamcinolone acetonide for I.M., I.A., intrabursal injection or injection into tendon sheaths.

CATEGORY: Parenteral Glucocorticoid.

DATE OF SUPPLEMENT: May 18, 1976.

REASON FOR SUPPLEMENT:

To provide a revised draft form of draft package insert which was submitted on February 25, 1976.

MATERIAL REVIEWED:

Draft form dated May 12, 1976 of revised package insert.

CLINICAL EVALUATION:

The revised package insert draft appears to conform with the Federal Register publication dated February 19, 1972 regarding certain glucocorticoids for parenteral use.

RECOMMENDATIONS:

Inform the sponsor as follows: Since glucocorticoid labeling is currently under review, the revised draft dated May 12, 1976 of the package insert submitted with the supplement (009) dated May 18, 1976 will be permitted without approval pending completion of the review of glucocorticoid labeling.

NDA 14-901

2

Albert R. Norris, M.D.

cc:

NDA 14-901 Orig.

HFD-108

HFD-150

HFD-150/ARNorris

Final typed:mvb:6/12/76

APR 2 1976

Medical Officer Review of NDA Supplement

April 2, 1976

NDA: 14-901/S-009

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; and Kenalog-10 provides 10mg/ml of triamcinolone acetonide for I.M., I.A., intrabursal or injection into tendon sheaths.

Category: Patenteral Glucocorticoid

Date of Supplement: February 25, 1976.

Reason for Supplement: To submit draft copies of a revised package insert to conform with the Federal Register statement of February 19, 1972.

Material Review: Revised draft copy of package insert.

Clinical Evaluation:

With the exceptions of Dosage and Administration section the package insert appears to reasonably conform with the Federal Register Publication of February 19, 1972.

Recommendations:

Inform the sponsor as follows:

The DOSAGE AND ADMINISTRATION section should be further revised. All indications utilized under Administration should conform with those presently under INDICATIONS in the revised package insert.

If the INDICATIONS section of the revised package insert is changed from its present form to contain indications which were considered less than effective in the Federal Register publication dated February 19, 1972 concerning glucocorticoids for parenteral use, then the revised package insert should also conform with CFR 21 section 201.200.

Albert R. Norris, M.D.

cc:
NDA 14-901 Orig.
HFD-108, HFD-150
HFD-150/ARNorris:4/2/76
Final typed by deg:4/2/76

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

14-901 / S-009

CHEMISTRY REVIEW(S)

MAY 10 1976

CHEMIS REVIEW <i>(If necessary, continue any item on 8" x 10 1/2" paper. Key continuation to item by number.)</i>		1. ORGANIZATION DORDP/HFD-150	2. NDA NUMBER 14-901				
3. NAME AND ADDRESS OF APPLICANT (City and State) E. R. Squibb & Sons, Inc. Georges Road New Brunswick, N.J. 08903		4. AF NUMBER 9-561					
6. NAME OF DRUG Kenalog- 40		7. NONPROPRIETARY NAME Triamcinolone Acetonide Suspension U.S.P.	5. SUPPLEMENT (S) <table border="1"> <tr> <th>NUMBER(S)</th> <th>DATE(S)</th> </tr> <tr> <td>S009</td> <td>2-25-76</td> </tr> </table>	NUMBER(S)	DATE(S)	S009	2-25-76
NUMBER(S)	DATE(S)						
S009	2-25-76						
8. SUPPLEMENT(S) PROVIDES FOR: Revision of package insert to conform with the F. R. statement dated 2/19/72 (A draft copy)		9. AMENDMENTS AND OTHER (Reports, etc) DATES NC 1-28-76					
10. PHARMACOLOGICAL CATEGORY Glucocorticoid	11. HOW DISPENSED <input checked="" type="checkbox"/> RX <input type="checkbox"/> OTC		12. RELATED IND/NDA/DMF(S)				
13. DOSAGE FORM (S) Injectable (Not for IV or ID use)	14. POTENCY (ies) 40 mg/ml (also 10 mg/ml)		16. RECORDS AND REPORTS CURRENT <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO REVIEWED <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO				
15. CHEMICAL NAME AND STRUCTURE			17. COMMENTS The "Charge and History" card necessary to confirm the supplement/number assigned by Squibb, in their SNC dated 1/28/76, is missing (#3, old cards), therefore, assignment of <u>S009</u> may be incorrect.				
<p style="text-align: right;">b(4)</p>							
18. CONCLUSIONS AND RECOMMENDATIONS Rev/w/f/ letter to be issued as per M.O.'s recommendations (C.S.O. has prepared a draft for circulation)							
19. R/D Endorsed by BKagan 4/7/76							
NAME R. M. Patel	SIGNATURE	DATE COMPLETED 4/7/76					
DISTRIBUTION <input type="checkbox"/> ORIGINAL JACKET <input type="checkbox"/> REVIEWER		<input checked="" type="checkbox"/> DIVISION FILE					

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APPLICATION NUMBER:

14-901 / S-009

ADMINISTRATIVE and CORRESPONDENCE
DOCUMENTS

MAR 10 1976

NDA 14-901

E. R. Squibb and Sons, Inc.
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 Injection

NDA Number: 14-901

Supplement Number: S-009

Date of Supplement: February 25, 1976

Date of Receipt: February 27, 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,

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

cc: NWK-DO
NDA Orig.
HFD-150
HFD-150/BArmstrong/cg/3/8/76

SUPPLEMENT ACKNOWLEDGEMENT

APR 15 1976

NDA 14-901/S-009

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

Gentlemen:

Reference is made to your supplemental amendment to the New Drug Application of February 25, 1976, submitted pursuant to section 505(b) of the Federal Food, Drug, and Cosmetic Act for Kenalog-40 (triamcino-lone acetonide suspension) Injection.

The supplemental amendment provides for revised labeling.

We have reviewed your package circular and offer the following recommendations:

1. The DOSAGE AND ADMINISTRATION section should be further revised. All indications utilized under Administration should conform with those presently under INDICATIONS in the revised package insert.
2. If the INDICATIONS section of the revised package insert is changed from its present form to contain indications which were considered less than effective in the FEDERAL REGISTER publication dated February 19, 1972, concerning glucocorticoids for parenteral use, then the revised package insert should also conform with CFR 21 section 201.200.

We may communicate with you further should any questions arise as a result of a comprehensive review of your application.

Sincerely yours,

cc: NWK-DO

Orig. NDA

HFD-150

CEWTKes/4/6/76/vha/4/8/76

R/D init. by: ARNorris/4/6/76

Patel/4/7/76

BKagan/4/7/76

William J. Gyarfás, M.D.

Director

Division of Oncology and

Radiopharmaceutical Drug Products

Bureau of Drugs

REV./W.F.

JUN 16 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 resubmitted supplemental application for the following:

Name of Drug: - Kenalog IM

NDA Number: 14-901

Supplement Number: S-009

Date of Resubmitted 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

cc: NWK-DO
NDA Orig
HFD-150
HFD-150/WJones/ep/6/4/76

Sincerely yours,

RESUBMITTED SUPPLEMENT ACKNOWLEDGEMENT

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