

**CENTER FOR DRUG EVALUATION AND RESEARCH**

**Approval Package for:**

***APPLICATION NUMBER:***

**14-901 / S-028**

**Trade Name: Kenalog - 40**

**Generic Name: Triamcinolone acetonide**

**Sponsor: Apotthecon Inc.**

**Approval Date: February 14, 1992**

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**14-901 / S-028**

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**APPROVAL LETTER**

NDA 14-981/502B

FEB 14 1992

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

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

Dear Dr. Schrode:

Please refer to your May 1, 1988 supplemental new drug application submitted pursuant to section 505(b) of the Federal Food, Drug, and Cosmetic Act for KEHALOC-40 (triamcinolone acetonide) injection.

The supplemental application provides for an alternate \_\_\_\_\_ for the product.

b(4)

We have completed the review of this supplemental application and it is 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 the undersigned.

Sincerely yours,

Herbert T. Behrens  
Interdisciplinary Scientist  
Pilot Drug Evaluation Staff (HFD-007)  
Center for Drug Evaluation and Research  
(301) 443-3741

cc:  
Original NDA  
HFD-007/division file  
HFD-007/Chemist/HBehrens  
HFD-520/EPappas  
HFD-80  
HFD-730  
HFC-130/JAllen  
HFD-007/HBehrens, 2/11/92  
R/D inf. by: C. Yacht 2/11/92  
F/T by: B. Shokitka 2/12/92  
Nang # 0556b/p2  
SUPPLEMENT APPROVED

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*APPLICATION NUMBER:*

**14-901 / S-028**

**CHEMISTRY REVIEW(S)**

FEB 14 1992

PILOT DRUG EVALUATION STAFF (HFD-007) CHEMIST'S REVIEW

NDA NUMBER/S#: 14-901/S028

DATED: 5/1/89

APPLICANT: E. R. Squibb & Sons

P.O. Box 4000

Princeton, New Jersey 08543-4000

REVIEW NO.: 1

AF NUMBER:

NAME OF DRUG (PROPRIETARY):

KENALOG-40 Injection

DOSAGE FM/STRENGTH (GENERIC):

triamcinolone acetonide

CHEMICAL NAME AND STRUCTURE (only if new): NA

RELATED NDAs, INDs, DMFs, etc.: NA

AMENDMENTS/ADDITIONAL CORRESPONDENCE/TELCOMS: None

SUPP. PROVIDES FOR:

Use of ~~\_\_\_\_\_~~  
alternative closure.

b(4)

DISCUSSION:

~~\_\_\_\_\_~~ does not contain  
as do the two approved stoppers  
Information contained in DMF ~~\_\_\_\_\_~~ is satisfactory. Supplement  
contains ~~\_\_\_\_\_~~

b(4)

Supplement contains stability data on two lots of product using  
the ~~\_\_\_\_\_~~  
at 50°C). Satisfactory.

b(4)

NOTE:

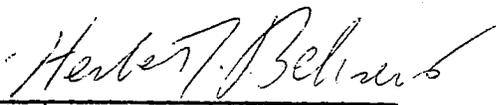
Chemist's Review by Ernie Pappas dated 3/20/90 recommended  
approval. The review was signed off by the HFD-007 Peer  
Reviewer on 3/15/90, but letter never issued and we were unable  
to locate the review.

CONCLUSIONS AND RECOMENDATIONS: Supplement to be approved.

DATE RECEIVED:

DATE COMPLETED: 2/11/92

REVIEWED BY:

  
Herbert T. Behrens  
Interdisciplinary Scientist

cc: Org Jacket( ); Div File ( )

HFD-007/CS0:

HFD-007/HTBehrens/2/11/92

HFD-007/C.Yaciw

R/D Init. by: C.Yaciw 2/11/92

F/T by: B.Shekitka 2/12/92

Wang #: 0556b

*ajaw 2-14-92*