CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

14-901 / S-028

Trade Name: Kenalog - 40

Generic Name: Triamcinolone acetonide

Sponsor: Apothecon Inc.

Approval Date: February 14, 1992
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**Reviews / Information Included in this NDA Review.**

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APPLICATION NUMBER:

14-901 / S-028

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

Attention: Kathy N. Schrock, Ph.D.
Manager, Drug Regulatory Affairs

Dear Dr. Schrock:

Please refer to your May 1, 1989 supplemental new drug application submitted pursuant to section 505(b) of the Federal Food, Drug, and Cosmetic Act for KERALOG-40 (triamcinolone acetonide) Injection.

The supplemental application provides for an alternate (b4) for the product.

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 316.80 and 316.81.

Should you have any questions, please contact the undersigned.

Sincerely yours,

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

cc:
Original NDA
NFD-007/Division file
NFD-007/Chemist/KBehrens
NFD-020/EPappas
NFD-90
NFD-730
HFC-130/JAllen
NFD-007/HTBehrens, 2/11/92
R/D init. by: C.Yasui 2/11/92
F/T by: B.Shelkova 2/12/92
Wang # 0556b/v2
SUPPLEMENT APPROVED
APPLICATION NUMBER:

14-901 / S-028

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

NDA NUMBER/S#: 14-907/5028 DATED: 5/1/89

APPLICANT: E. R. Squibb & Sons
P.O. Box 4000
Princeton, New Jersey 08543-4000

NAME OF DRUG (proprietary): KENALOG-40 Injection
DOSAGE FORM/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.

DISCUSSION: does not contain as do the two approved stoppers. Information contained in DMF is satisfactory. Supplement contains

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

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 RECOMMENDATIONS: 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/CSO:
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