

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: 75264

CHEMISTRY REVIEW(S)

1. CHEMISTRY REVIEW NO. 3

2. ANDA # 75-264 (0.025%)
75-265 (0.05%)

3. NAME AND ADDRESS OF APPLICANT

Spear Pharmaceuticals
13100 Ponderosa Way
Fort Myers, FL 33907

4. LEGAL BASIS FOR SUBMISSION

The firm certifies in their opinion and to the best of their knowledge the patents have expired.

5. SUPPLEMENT(s)

N/A

6. PROPRIETARY NAME

N/A

7. NONPROPRIETARY NAME

Tretinoin

8. SUPPLEMENT(s) PROVIDE(s) FOR:

N/A

9. AMENDMENTS AND OTHER DATES:

Original 12/2/97
Amendment 4/29/98
Amendment 9/14/98
Amendment 9/28/98
Amendment 10/14/98
Amendment 11/13/98

10. PHARMACOLOGICAL CATEGORY

Treatment of acne vulgaris

11. Rx or OTC

Rx

12. RELATED IND/NDA/DMF(s)

DMF's

13. DOSAGE FORM

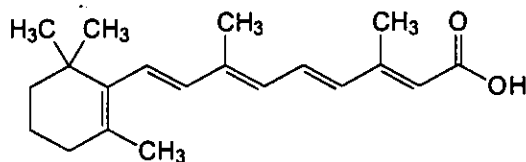
Cream

14. POTENCY

0.025% w/w, 0.05% w/w

15. CHEMICAL NAME AND STRUCTURE

Tretinoin. Retinoic acid. $C_{20}H_{28}O_2$. 300.44. 302-79-4. Keratolytic. USP 23, page 1572.



17. COMMENTS

18. CONCLUSIONS AND RECOMMENDATIONS

The applications are approvable - **PENDING EER**

19. REVIEWER: DATE COMPLETED:

Nashed E. Nashed, Ph.D. 12/3/98

Supervisor: Paul Schwartz, Ph.D. 12/4/98

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releasable.

chemistry