CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: 75213

CHEMISTRY REVIEW(S)
1. **CHEMISTRY REVIEW NO. 3**

2. **ANDA # 75-213**

3. **NAME AND ADDRESS OF APPLICANT**
   Spear Pharmaceuticals  
   13100 Ponderosa way  
   Fort Myers, FL 33907

4. **LEGAL BASIS FOR SUBMISSION**
   The firm certify that to in their opinion and to the best of their knowledge the patents have expired.

5. **SUPPLEMENT(s)**
6. **PROPRIETARY NAME**

7. **NONPROPRIETARY NAME**
   Tretinoïn

8. **SUPPLEMENT(s) PROVIDE(s) FOR:**
   N/A

9. **AMENDMENTS AND OTHER DATES:**
   Original 9/30/97  
   Amendment 11/24/97  
   Amendment 9/14/98  
   Amendment 8/5/98  
   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**
    0.1% w/w
15. **CHEMICAL NAME AND STRUCTURE**

Retinoic acid

16. **RECORDS AND REPORTS**

17. **COMMENTS**

18. **CONCLUSIONS AND RECOMMENDATIONS**

The application is approvable -

19. **REVIEWER:** Nashed E. Nashed, Ph.D. **DATE COMPLETED:** 12/3/98

        Supervisor: Paul Schwartz, Ph.D. 12/4/98
Contain Trade Secret,
Commercial/Confidential
Information and are not releasable.