

**CENTER FOR DRUG EVALUATION AND RESEARCH**

**APPLICATION NUMBER:**

**MEDICAL REVIEW(S)**

Medical Officer Review  
October 20, 1998

ANDA 75-264  
Drug Product: Tretinoin Cream USP 0.025%  
Sponsor: Spear Pharmaceuticals, Inc.

The Medical Officer Review, Statistical Review and Secondary Medical Review have been completed.

Recommendation: This study has been found to show bioequivalence between the reference listed drug and the Spear Tretinoin Cream USP, 0.025%. Therefore, the product can be approved from this point of view provided that all other relevant aspects of the application are also approvable.

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10/21/98

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