

**CENTER FOR DRUG EVALUATION AND RESEARCH**

**APPLICATION NUMBER: 75264**

**ADMINISTRATIVE**

APPROVAL PACKAGE SUMMARY FOR 75-264 AND 75-265

ANDA: 75-264 (0.025%), 75-265 (0.05%)

FIRM: Spear Pharmaceuticals

DRUG: Tretinoin

DOSAGE: Cream

STRENGTH: 0.025%, 0.05%

CGMP STATEMENT/EIR UPDATE STATUS: **EER IS ACCEPTABLE**

BIO STUDY/BIOEQUIVALENCE STATUS: Bio and clinical study is satisfactory  
11/26/98.

METHODS VALIDATION: The drug product is compendial- methods verification by  
SERL

STABILITY: The firm has submitted satisfactory 3 month accelerated stability data at  
RH and 9 months room temperature data at  
in both tube sizes for both strengths.

LABELING REVIEW STATUS: Labeling is satisfactory 8/11/98

STERILIZATION VALIDATION: N/A

BATCH SIZES: The firm has provided a copies of the exhibit batches lot #702700  
for (0.025%) and lot #702710 (0.05%) for  
The firm has submitted the master formula and manufacturing  
procedure for the intended production batch of using the  
same drug substance manufacture, the same equipment and  
procedure as the executed batch.

COMMENTS: The Application are Approvable.

REVIEWER: Nashed E. Nashed, Ph.D.

DATE: 12/3/98

Supervisor: Paul Schwartz, Ph.D.

PS 12/4/98

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