

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**65-049**

**ADMINISTRATIVE DOCUMENTS**

**ANDA APPROVAL SUMMARY**

**ANDA #:** 65-049

**FIRM:** Altana Inc.

**DRUG PRODUCT:** Clindamycin Phosphate Topical Solution USP,  
Pledgets, 1%

**DOSAGE:** Solution                      **STRENGTH:** 1% (as clindamycin)

**CAMP STATEMENT/EIR UPDATE STATUS:** Acceptable 10/27/99

**BIO STUDY:** Acceptable 8/12/99

**METHOD VALIDATION - (DESCRIPTION OF DOSAGE FORM SAME AS  
FIRM'S):** Not requested (USP drug)

**STABILITY - (ARE CONTAINERS USED IN STUDY IDENTICAL TO THOSE  
IN CONTAINER SECTION):** The container/closure system used in  
the stability is the same as those described in the  
container section.

**LABELING:** Acceptable 3/29/00

**STERILIZATION VALIDATION:** N/A

**SIZE OF BIO BATCH (FIRM'S SOURCE OF NDS OK?):** See below

**SIZE OF STABILITY BATCHES - (IF DIFFERENT FROM BIO BATCH,  
WERE THEY MANUFACTURED VIA THE SAME PROCESS?):**

Pilot Batch \_\_\_\_\_ manufactured 11/5/98 with  
actual yield \_\_\_\_\_. The proposed production batch size is

**PROPOSED PRODUCTION BATCH - (MANUFACTURING PROCESS THE SAME  
AS BIO/STABILITY?):** See above

**Specifications for active ingredient:** Under #23A

**Specifications for the finished product:** Under #28 and #29

**CHEMIST:** Maria C. Shih *M.C. Shih* 4/20/00 **DATE:** 4/17/00

**SUPERVISOR:** Richard Adams *R.C. Adams* **DATE:** 4/20/00