

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

75-374

ADMINISTRATIVE DOCUMENTS

APPROVAL PACKAGE SUMMARY FOR 75-374

ANDA: 75-374

FIRM: Altana Inc.

DRUG: Diflorasone Diacetate

DOSAGE: Ointment

STRENGTH: 0.05%

CGMP STATEMENT/EIR UPDATE STATUS: EER is acceptable
6/15/98.

BIO STUDY/BIOEQUIVALENCE STATUS: Bio satisfactory
10/1/98

METHODS VALIDATION: The drug product is compendial

STABILITY: The firm has provided satisfactory 3 months accelerated stability data at 40°C/75%RH and 18 months room temperature stability data at 25°C/60%RH for 15g, 30g and 60g tubes. Also submitted 8 weeks cycle study.

LABELING REVIEW STATUS: Labeling is satisfactory
3/31/99

STERILIZATION VALIDATION: N/A

BATCH SIZES: The firm has provided a copy of the master formula and manufacturing procedure for maximum batch. Also provided a copy of the executed batch lot #9368 for . The firm will be using the same drug substance manufacturer 17, same equipment and same procedure.

COMMENTS: The application is approvable.

REVIEWER: Nashed E. Nashed, Ph.D. DATE: 4/8/99

SUPERVISOR: Paul Schwartz, Ph.D.

PS 4/9/99