

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

75-374

CHEMISTRY REVIEW(S)

1. CHEMISTRY REVIEW NO. 3
2. ANDA # 75-374
3. NAME AND ADDRESS OF APPLICANT

Altana Inc.
60 Baylis Rd
Melville, NY 11747

4. LEGAL BASIS FOR SUBMISSION

The applicant, Altana Inc., hereby certifies that, in their opinion and to the best of the applicant's knowledge, all listed patents claim in the United States for the reference listed drug psorcon (diflorasone diacetate) ointment, 0.05%, manufactured by Pharmacia & Upjohn have expired, and there is no period of marketing exclusivity for the reference list drug.

- | | |
|-------------------------------|---|
| 5. <u>SUPPLEMENT(s)</u> | 6. <u>PROPRIETARY NAME</u> |
| Original 5/1/98 | N/A |
| 7. <u>NONPROPRIETARY NAME</u> | 8. <u>SUPPLEMENT(s) PROVIDE(s) FOR:</u> |
| Diflorasone Diacetate, USP | N/A |

9. AMENDMENTS AND OTHER DATES:

Amendment 5/15/98
Amendment 10/23/98
Amendment 10/29/98

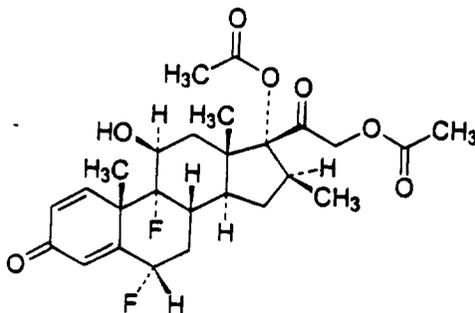
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|-------------------------------------|----------------------|
| 10. <u>PHARMACOLOGICAL CATEGORY</u> | 11. <u>Rx or OTC</u> |
| Anti-inflammatory | Rx |

12. RELATED IND/NDA/DMF(s)

- | | |
|------------------------|--------------------|
| 13. <u>DOSAGE FORM</u> | 14. <u>POTENCY</u> |
| Ointment | 0.05% |

15. CHEMICAL NAME AND STRUCTURE

Diflorasone Diacetate. Pregna-1,4-diene-3,20-dione, 17,21-bis(acetyloxy)-6,9-difluoro-11-hydroxy-16-methyl-, (6 α ,11 β ,16 β)-. C₂₈H₃₂F₂O₇. M.Wt. 494.54. 33564-31-7. Anti-inflammatory, Glucocortic. USP 23, page 508.



16. RECORDS AND REPORTS

17. COMMENTS

18. CONCLUSIONS AND RECOMMENDATIONS

The application is approvable.

19. REVIEWER:

DATE COMPLETED:

Nashed E. Nashed, Ph.D.

4/8/99

Supervisor: Paul Schwartz, Ph.D.

4/9/99

cc:

Endr

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Contain Trade Secret,

Commercial/Confidential

Information and are not

releasable.

*See Page 3
4/9/77*