

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: 75-430

CHEMISTRY REVIEW(S)

1. CHEMISTRY REVIEW NO. 2
2. ANDA # 75-430
3. NAME AND ADDRESS OF APPLICANT

Altana Inc.
 Attention: Virginia Carman
 60 Baylis Road
 Melville, NY 11747

4. LEGAL BASIS FOR SUBMISSION

The applicant certifies that in their opinion and to the best of their knowledge, all listed patents claimed in the United States for the reference listed drug Temovate E, 0.05%, manufactured by Glaxo Wellcome have expired. Exclusivity expires May 3, 1999, and Altana certifies that if approved prior to May 3, 1999, the labeling will contain the dosage limitations of the originally approved Temovate E Emollient labeling.

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| 5. <u>SUPPLEMENT(s)</u> | 6. <u>PROPRIETARY NAME</u> |
| N/A | None |
| 7. <u>NONPROPRIETARY NAME</u> | 8. <u>SUPPLEMENT(s) PROVIDE(s) FOR:</u> |
| Clobetasol Propionate | N/A |

9. AMENDMENTS AND OTHER DATES:

Original Submission	August 5, 1998
Correspondence	September 11, 1998
Amendment	February 12, 1999
Amendment	March 17, 1999
Amendment	March 19, 1999

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

Anti-inflammatory	Rx
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12. RELATED IND/NDA/DMF(s)

DMF	Manufacturer	Component
		Drug Substance
		Tube
		Tube
		Tube

13. DOSAGE FORM

Emollient Cream

m)

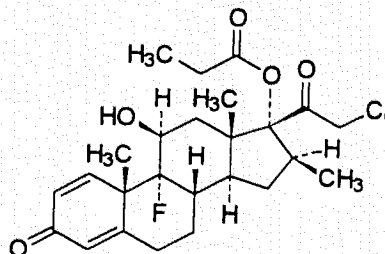
Tube
Cap

14. POTENCY

0.05%

15. CHEMICAL NAME AND STRUCTURE

Pregna-1,4-diene-3,20-dione, 21-chloro-9-fluoro-11-hydroxy-16-methyl-17-(1-oxopropoxy)-, (11 β ,16 β)-. C₂₅H₃₂ClFO₅.



16. RECORDS AND REPORTS

None

17. COMMENTS

None

18. CONCLUSIONS AND RECOMMENDATIONS

The application is approvable.

19. REVIEWER:

Kathy P. Woodland

DATE COMPLETED:

April 6, 1999

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Contain Trade Secret,
Commercial/Confidential
Information and are not
releasable.

Chemistry Review #2