CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

75391

CHEMISTRY REVIEW(S)

ANDA APPROVAL SUMMARY

ANDA: 75-391	CHEMIST: Kathy P. Woodland	DATE: 1/20/99
DRUG PRODUCT: Clobetasol Propionate Topical Solution, USP 0.05%		
FIRM: Altana, Inc.		
DOSAGE FORM: Topical Solution	**STRENGTH:** 0.05%	
cGMP: Acceptable		
BIO: Waiver granted, 10/19/98, N Tran		
VALIDATION - *(Description of dosage form same as firm's):* USP drug substance and product.		
STABILITY: The containers in the stability studies are identical to those in the container section.		
LABELING: Approvable 12/29/98		
STERILIZATION VALIDATION *(If applicable)*: N/A		
SIZE OF BIO BATCH *(Firm's source of NDS ok?)*: Waiver granted		
SIZE OF STABILITY BATCHES *(If different from bio batch, were they Manufactured via the same process?)*: Stability batch kg.		
PROPOSED PRODUCTION BATCH - MANUFACTURING PROCESS THE SAME?: Production batches kg. Same manufacturing process.		
Signature of chemist: /S/	**Signature of supervisor:** P S 1/22/99	

1. CHEMISTRY REVIEW NO. 2

2. ANDA # 75-391

3. NAME AND ADDRESS OF APPLICANT

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

4. LEGAL BASIS FOR SUBMISSION

Temovate, Clobetasol Propionate Scalp Application, 0.05% (Glaxo), NDA 19-966.
Altana certifies that in their opinion and to the best of their knowledge, all listed patents claimed in the US the reference listed drug have expired.

5. SUPPLEMENT(s)

N/A

6. PROPRIETARY NAME

None

7. NONPROPRIETARY NAME

Clobetasol Propionate, USP

8. SUPPLEMENT(s) PROVIDE(s) FOR:

N/A

9. AMENDMENTS AND OTHER DATES:

Original Submission	May 27, 1998
Amendments	December 9, 1998, January 20, 1999

10. PHARMACOLOGICAL CATEGORY

Anti-inflammatory

11. Rx or OTC

Rx

12. RELATED IND/NDA/DMF(s)

DMF#	Manufacturer	Component
		Drug substance
		Bottle
		Cap
		Bottle Resin
		Bottle Resin
		Dropper plug
		Resin

13. DOSAGE FORM

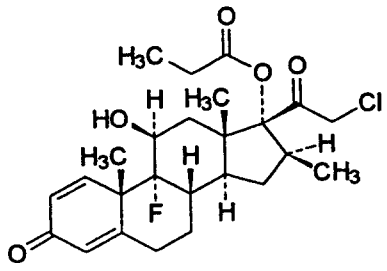
Topical solution

14. POTENCY

0.05%

15. CHEMICAL NAME AND STRUCTURE

$C_{25}H_{32}ClFO_5$. Pregna-1,4-diene-3,20-dione, 21-chloro-9-fluoro-11-hydroxy-16-methyl-17-(1-oxopropoxy)-, (11β,16β)-.



16. RECORDS AND REPORTS

None

17. COMMENTS

None

18. CONCLUSIONS AND RECOMMENDATIONS

The application is approvable.

19. REVIEWER:

Kathy P. Woodland

DATE COMPLETED:

January 20, 1999

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commercial

information

Chem Review #2