



**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

40310

CHEMISTRY REVIEW(S)

ANDA APPROVAL SUMMARY

ANDA: 40-310	CHEMIST: Kathy P. Woodland	DATE: December 20, 2000
DRUG PRODUCT: Hydrocortisone Ointment USP		
FIRM: Thames Pharmaceutical Co., Inc.		
DOSAGE FORM: Ointment	STRENGTH: 2.5%	
cGMP: Acceptable 12/19/00		
BIO: Waiver granted, J.Kharidia, 7/30/98		
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: Approved by J Barlow, 2/11/00		
STERILIZATION VALIDATION (If applicable): N/A		
SIZE OF BIO BATCH (Firm's source of NDS ok?): Waiver granted, J.Kharidia, 7/30/98		
SIZE OF STABILITY BATCHES (If different from bio batch, were they Manufactured via the same process?): kg batch		
PROPOSED PRODUCTION BATCH - MANUFACTURING PROCESS THE SAME?: Production batch sizes are Manufacturing process is the same.		
Signature of chemist: 	Signature of supervisor: 	

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1. CHEMISTRY REVIEW NO. 4

2. ANDA # 40-310

3. NAME AND ADDRESS OF APPLICANT

Thames Pharmaceutical Co. Inc.
2100 5th Avenue
Ronkonkoma, NY 11779

4. LEGAL BASIS FOR SUBMISSION

HYTONE (Dermik Labs)

The applicant certified that to the best of their knowledge the patent for the listed drug "Hydrocortisone Ointment" has expired.

5. SUPPLEMENT(s)

N/A

6. PROPRIETARY NAME

None

7. NONPROPRIETARY NAME

Hydrocortisone Ointment USP

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

N/A

9. AMENDMENTS AND OTHER DATES:

Amendment	May 15, 1998
Original Submission	April 17, 1998
Amendment	February 1, 1999
Amendment	November 3, 1999
Amendment	November 30, 2000

10. PHARMACOLOGICAL CATEGORY

Glucocorticoid, anti-inflammatory.

11. Rx or OTC

Rx

12. RELATED IND/NDA/DMF(s)

DMF	Manufacturer	Component
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13. DOSAGE FORM

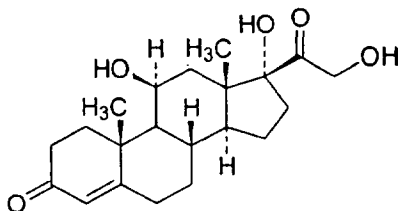
Ointment

14. POTENCY

2.5%

15. CHEMICAL NAME AND STRUCTURE

$C_{21}H_{30}O_5$. Pregn-4-ene-3,20-dione, 11,17,21-trihydroxy-,
(11 β) -



16. RECORDS AND REPORTS

None

17. COMMENTS

None

18. CONCLUSIONS AND RECOMMENDATIONS

The application is approvable.

19. REVIEWER:

Kathy P. Woodland

DATE COMPLETED:

December 20, 2000

Redacted 10

pages of trade

secret and/or

confidential

commercial

information

Manufacturing Controls