

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

ANDA 75-570

CHEMISTRY REVIEW(S)

1. CHEMISTRY REVIEW NO. 1 (one)

2. ANDA # 75570

3. NAME AND ADDRESS OF APPLICANT

Clay-Park Labs, Inc
1700 Bathgate Ave
Bronx, NY 10457

4. LEGAL BASIS FOR SUBMISSION

Basis for ANDA Submission [314.94 (a) (3)]
The listed drug is Lac-Hydrin® 12% (ammonium lactate) Lotion, the subject of NDA # 019155, approved April 1985, held by Westwood-Squibb Pharmaceuticals Inc.
Lac-Hydrin® 12% (ammonium lactate) Lotion is listed in the Electronic Orange Book, Approved Drug Products with Therapeutic Equivalence Evaluations, current through September 1998.

Innovator Product: Lac-Hydrin 12% (ammonium lactate) Lotion

Innovator Company: Westwood-Squibb Pharmaceuticals Inc.

Patent Expiration Date:

Patent Certification [314.94 (a) (12)]

There is no unexpired patent for Lac-Hydrin® 12% (ammonium lactate) Lotion, manufactured by Westwood-Squibb Pharmaceuticals Inc. Lac-Hydrin® 12% (ammonium lactate) Lotion is not entitled to a period of marketing exclusivity under Section 505(j) (4) (D) of the Act.

Exclusivity Statement [314.94 (a) (3)] There is no unexpired exclusivity for Lac-Hydrin® 12% (ammonium lactate) Lotion which is a subject of NDA# N19155.

5. SUPPLEMENT(s)

None

6. PROPRIETARY NAME

Ammonium Lactate Lotion, 12%

7. NONPROPRIETARY NAME

Ammonium Lactate Lotion, 12%

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

none

9. AMENDMENTS AND OTHER DATES:

| Submission date | Submission type |
|-----------------|-----------------|
| 01/27/99 | original |

10. PHARMACOLOGICAL CATEGORY

Humectant

11. Rx or OTC

Rx

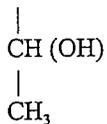
12. RELATED IND/NDA/DMF(s)
NDA # 019155: Lac-Hydrin® 12% (ammonium lactate) Lotion, approved April 1985, held by Westwood-Squibb Pharmaceuticals Inc.

| DMF number | DMF type | DMF holder |
|------------|---------------------|------------|
| _____ | I: _____ _____ | _____ |
| _____ | II: _____ _____ | _____ |
| _____ | III: _____ _____ | _____ |

13. DOSAGE FORM
lotion

14. POTENCY
12%

15. CHEMICAL NAME AND STRUCTURE
DL-Lactic acid ammonium salt, C₃H₇NO₃, CH₃CH(OH)COONH₄
Chemical Structure: COONH₄



16. RECORDS AND REPORTS
None

17. COMMENTS
This application is not approvable.

18. CONCLUSIONS AND RECOMMENDATIONS
This application is not approvable.

19. REVIEWER:
Liang-Lii Huang, Ph.D
Endorsed by Paul Schwartz, Ph.D./July 28, 1999

DATE COMPLETED:
July 28, 1999

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17. COMMENTS

This application is approvable.

Bio is acceptable 6/9/04 by C. Kim.

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18. CONCLUSIONS AND RECOMMENDATIONS

This application is approvable.

19. REVIEWER:

Liang-Lii Huang, Ph.D.
Endorsed by James Fan

DATE COMPLETED:

June 17, 2004
June 17, 2004

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ANDA APPROVAL SUMMARY

ANDA: 75-570

DRUG PRODUCT: Ammonium Lactate Lotion, 12%

FIRM: Clay-Park Labs, Inc.

DOSAGE FORM: Lotion

STRENGTH: 12%

CGMP: Statement/EIR Update Status:

EER is acceptable (OC recommendation, 11/25/03)

BIO: The bioequivalent study was found acceptable.
(reviewed by C. Kim, 6/9/04).

VALIDATION - (DESCRIPTION OF DOSAGE FORM SAME AS FIRM'S):

Method validation is not required.

STABILITY: (Are containers used in study identical to those in
container section?)

The containers used in the stability study are identical to
those described in the container section.

LABELING:

Container, carton and insert labeling have been found
satisfactory (4/21/03)

STERILIZATION VALIDATION (IF APPLICABLE):

N/A

SIZE OF BIO BATCH (FIRM'S SOURCE OF NDS OK?):

The size of the exhibit batch for the Ammonium Lactate
Lotion, 12% was _____
DMF _____ was found
adequate (1/16/04, reviewed by Liang-Lii Huang)

SIZE OF STABILITY BATCHES- (IF DIFFERENT FROM BIO BATCH, WERE
THEY MANUFACTURED VIA THE SAME PROCESS?):

The exhibit batch of the Ammonium Lactate Lotion, 12% was
the stability batch.

PROPOSED PRODUCTION BATCH - MANUFACTURING PROCESS THE SAME?:

The manufacturing process for the proposed production batch will be the same as was used for the exhibit batch.

CHEMIST: Liang-Lii Huang, Ph.D. *LLH 6/17/04* DATE: June 17, 2004

SUPERVISOR: James M Fan, Team Leader DATE: June 17, 2004

JM Fan 6/17/04

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