CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

ANDA 76-422

CHEMISTRY REVIEW(S)

ANDA 76-422

Ciclopirox Olamine Topical Suspension USP, 0.77%

Altana, Inc.

Liang-Lii Huang, Ph.D.

OGD/DC1

Table of Contents

APPEARS THIS WAY
ON ORIGINAL

Chemistry Review Data Sheet

1. ANDA 76-422

2. REVIEW #:1

3. REVIEW DATE: 23-Aug-2002

4. REVIEWER: Liang-Lii Huang, Ph.D.

5. PREVIOUS DOCUMENTS:

Previous Documents	Document Date
None	

6. SUBMISSION(S) BEING REVIEWED:

Submission(s) Reviewed	Document Date
Original	28-May-2002
Response to "refuse to receive" letter	05-Aug-2002
Acceptable for filing	06-Aug-2002
New Correspondence	08-Aug-2002

7. NAME & ADDRESS OF APPLICANT:

Name	Altana Inc.
Address	60 Baylis Road, Melville, NY 11747
representative	Robert J. Anderson
Telephone	631-454-7677
Fax	631-756-5114

8. DRUG PRODUCT NAME/CODE/TYPE:

a) Proprietary Name: N/A
b) Non-Proprietary Name (USAN):
Ciclopirox Lotion 0.77%
(Ciclopirox Olamine Topical Suspension USP)

9. LEGAL BASIS FOR SUBMISSION:
RLD: NDA 19-824 Loprox® Lotion 0.77%
Medicis, The dermatology company
Manufactured by West Pharmaceutical Services

Patent certification [21 CFR 314.94 (a)(12)]
Paragraph II certification:
Altana certifies that all listed patents claimed in US for RLD have expired.
Exclusivity statement [21 CFR 314.94 (a)(3)]
There is no unexpired exclusivity for the RLD.

10. PHARMACOL. CATEGORY:
for the topical treatment of the following dermal infections: tinea pedis, tinea cruris, and tinea corporis

11. DOSAGE FORM:
lotion

12. STRENGTH/POTENCY:
0.77%

13. ROUTE OF ADMINISTRATION:
topical

14. Rx/OTC DISPENSED: _X_ Rx ___ OTC

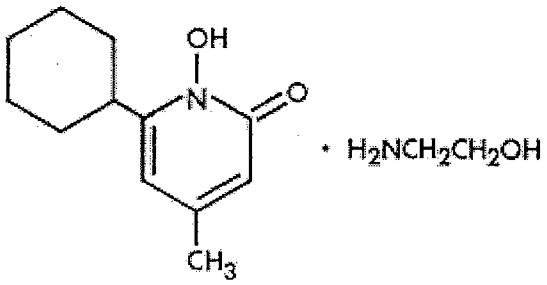
15. SPOTS (SPECIAL PRODUCTS ON-LINE TRACKING SYSTEM)[Note23]:

_____SPOTS product – Form Completed

___X___Not a SPOTS product

16. CHEMICAL NAME, STRUCTURAL FORMULA, MOLECULAR FORMULA, MOLECULAR WEIGHT:

6-cyclohexyl-1-hydroxy-4-methyl-2(1 *H*)-pyridone, 2-aminoethanol salt.
The CAS Registry Number is 41621-49-2.



17. RELATED/SUPPORTING DOCUMENTS:

APPEARS THIS WAY
ON ORIGINAL

A. DMFs:

DMF #	TYPE	HOLDER	ITEM REFERENCED	CODE[1]	STATUS[2]	DATE REVIEW COMPLETED	COMMENTS
	II			1	inadequate	8/23/02	Reviewed by Liang-Lii Huang, Ph.D.
	III			4			
	III			4			
	III			4			
	III			4			
	III			4			
	III			4			

[1] Action codes for DMF Table:
1 – DMF Reviewed.
Other codes indicate why the DMF was not reviewed, as follows:
2 –Type 1 DMF
3 – Reviewed previously and no revision since last review
4 – Sufficient information in application
5 – Authority to reference not granted
6 – DMF not available
7 – Other (explain under "Comments")

[2] Adequate, Inadequate, or N/A (There is enough data in the application, therefore the DMF did not need to be reviewed)

B. Other Documents:

DOCUMENT	APPLICATION NUMBER	DESCRIPTION
NDA	19-824	Loprox® Lotion 0.77%

18. STATUS:

CONSULTS/ CMC RELATED REVIEWS	RECOMMENDATION	DATE	REVIEWER
Microbiology	N/A		
EES	pending		
Methods Validation	Not required		
Labeling	pending		
Bioequivalence	pending		
EA	EA is not required.		
Radiopharmaceutical	N/A		

19. ORDER OF REVIEW

The application submission(s) covered by this review was taken in the date order of receipt. ___X_ Yes _____ No If no, explain reason(s) below:

APPEARS THIS WAY
ON ORIGINAL

The Chemistry Review for ANDA 76-422

The Executive Summary

I. Recommendations

A. Recommendation and Conclusion on Approvability

This application ANDA 76-422 is not approvable.

B. Recommendation on Phase 4 (Post-Marketing) Commitments, Agreements, and/or Risk Management Steps, if Approvable

N/A

II. Summary of Chemistry Assessments

A. Description of the Drug Product(s) and Drug Substance(s)

Drug product

The Ciclopirox Lotion 0.77% (Ciclopirox Olamine Topical Suspension USP) is indicated for the topical treatment of the following dermal infections: tinea pedis, tinea cruris, and tinea corporis

The Ciclopirox Lotion is a smooth and homogeneous liquid dispersion intended for external application to the body. It is prepared using the ——— to achieve the smooth texture. The lotion is then packaged into 30 mL (2 oz) and 60 mL (3 oz) ——— bottles with white ——— caps.

Drug substance

Ciclopirox Olamine USP is a white or pale yellow crystalline powder, odorless. Ciclopirox Olamine is very soluble in ethanol and dichloromethane, slightly soluble in water and ethylacetate, practically insoluble in cyclohexane.

B. Description of How the Drug Product is Intended to be Used

The drug product is intended to be used for the treatment of dermal infections: tinea pedis, tinea cruris, and tinea corporis

C. Basis for Approvability or Not-Approval Recommendation

This application is not approvable due to the deficiencies found in the following areas.

(1) DMF deficient, (2) residual solvents and OVI for drug substance, (3) stability specifications for degradation products (4) RLD data at expiry date.

III. Administrative

A. Reviewer's Signature

Liang-Lii Huang, Ph.D.

B. Endorsement Block

Liang-Lii Huang, Ph.D./ 8/29/02
James Fan, Team Leader/8/29/02
Sarah Ho, Project Manager/8/29/02

C. CC Block

ANDA 76-422
ANDA DUP 76-422
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August 29, 2002

Redacted 15 page(s)

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CHEMISTRY REVIEW #1

3. Information related to labeling and bioequivalency is pending review. After the reviews are completed, any deficiencies found will be communicated to you under separate covers.

4. The firms referenced in your ANDA application relative to the manufacturing and testing of the product must be in compliance with cGMP's at the time of approval.

Sincerely yours,

Rashmikant M. Patel, Ph.D.
Director
Division of Chemistry I
Office of Generic Drugs
Center for Drug Evaluation and Research

APPEARS THIS WAY
ON ORIGINAL

cc: ANDA 76-422
ANDA DUP 76-422
DIV FILE
Field Copy

Endorsements (Draft and Final with Dates):

HFD-627 /Liang-Lii Huang, Ph.D. /9/26/02 L. Huang 10/17/02

HFD-627/James Fan, Team Leader/ 9/26/02 10/17/02

HFD-617/Sarah Ho, Project Manager/9/30/02 10/17/02

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October 11, 2002

TYPE OF LETTER: NOT APPROVABLE -MINOR/

ANDA 76-422

Ciclopirox Olamine Topical Suspension USP, 0.77%

Altana, Inc.

Liang-Lii Huang, Ph.D.

OGD/DC1

Table of Contents

Chemistry Review Data Sheet

1. ANDA 76-422

2. REVIEW #:2

3. REVIEW DATE: 21-Mar-2003

4. REVIEWER: Liang-Lii Huang, Ph.D.

5. PREVIOUS DOCUMENTS:

Previous Documents	Document Date
None	

6. SUBMISSION(S) BEING REVIEWED:

Submission(s) Reviewed	Document Date
Original	28-May-2002
Response to "refuse to receive" letter	05-Aug-2002
Acceptable for filing	06-Aug-2002
New Correspondence	08-Aug-2002
Minor amendment	20- Dec- 2002

7. NAME & ADDRESS OF APPLICANT:

Name	Altana Inc.
Address	60 Baylis Road, Melville, NY 11747
representative	Robert J. Anderson
Telephone	631-454-7677
Fax	631-756-5114

8. DRUG PRODUCT NAME/CODE/TYPE:

a) Proprietary Name: N/A
b) Non-Proprietary Name (USAN):
Ciclopirox Lotion 0.77%
(Ciclopirox Olamine Topical Suspension USP)

9. LEGAL BASIS FOR SUBMISSION:
RLD: NDA 19-824 Loprox® Lotion 0.77%
Medicis, The dermatology company
Manufactured by West Pharmaceutical Services

Patent certification [21 CFR 314.94 (a)(12)]
Paragraph II certification:
Altana certifies that all listed patents claimed in US for RLD have expired.
Exclusivity statement [21 CFR 314.94 (a)(3)]
There is no unexpired exclusivity for the RLD.

10. PHARMACOL. CATEGORY:
for the topical treatment of the following dermal infections: tinea pedis, tinea cruris, and tinea corporis

11. DOSAGE FORM:
lotion

12. STRENGTH/POTENCY:
0.77%

13. ROUTE OF ADMINISTRATION:
topical

14. Rx/OTC DISPENSED: _X_ Rx ___ OTC

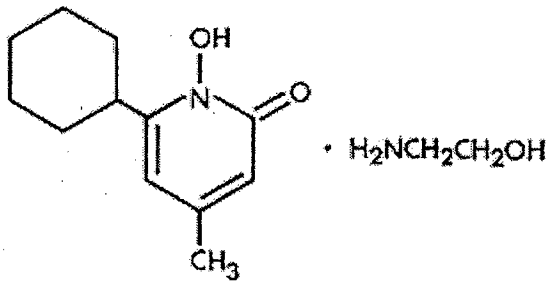
15. SPOTS (SPECIAL PRODUCTS ON-LINE TRACKING SYSTEM)[Note23]:

_____SPOTS product – Form Completed

___X___Not a SPOTS product

16. CHEMICAL NAME, STRUCTURAL FORMULA, MOLECULAR FORMULA, MOLECULAR WEIGHT:

6-cyclohexyl-1-hydroxy-4-methyl-2(1 *H*)-pyridone, 2-aminoethanol salt.
The CAS Registry Number is 41621-49-2.



17. RELATED/SUPPORTING DOCUMENTS:

A. DMFs:

DMF #	TYPE	HOLDER	ITEM REFERENCED	CODE[1]	STATUS[2]	DATE REVIEW COMPLETED	COMMENTS
	II			1	inadequate	4/17/03	Reviewed by Liang-Lii Huang, Ph.D.
	III			4			
	III			4			
	III			4			
	III			4			
	III			4			
	III			4			

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5 – Authority to reference not granted
6 – DMF not available
7 – Other (explain under "Comments")

[2] Adequate, Inadequate, or N/A (There is enough data in the application, therefore the DMF did not need to be reviewed)

B. Other Documents:

DOCUMENT	APPLICATION NUMBER	DESCRIPTION
NDA	19-824	Loprox® Lotion 0.77%

18. STATUS:

CONSULTS/ CMC RELATED REVIEWS	RECOMMENDATION	DATE	REVIEWER
Microbiology	N/A		
EES	Acceptable	12/19/02	
Methods Validation	Not required		
Labeling	pending		
Bioequivalence	pending		
EA	EA is not required.		
Radiopharmaceutical	N/A		

19. ORDER OF REVIEW

The application submission(s) covered by this review was taken in the date order of receipt. __X_ Yes ____ No If no, explain reason(s) below:

APPEARS THIS WAY
ON ORIGINAL

The Chemistry Review for ANDA 76-422

The Executive Summary

I. Recommendations

A. Recommendation and Conclusion on Approvability

This application ANDA 76-422 is not approvable.

B. Recommendation on Phase 4 (Post-Marketing) Commitments, Agreements, and/or Risk Management Steps, if Approvable

N/A

II. Summary of Chemistry Assessments

A. Description of the Drug Product(s) and Drug Substance(s)

Drug product

The Ciclopirox Lotion 0.77% (Ciclopirox Olamine Topical Suspension USP) is indicated for the topical treatment of the following dermal infections: tinea pedis, tinea cruris, and tinea corporis

The Ciclopirox Lotion is a smooth and homogeneous liquid dispersion intended for external application to the body. It is prepared using [redacted] to achieve the smooth texture. The lotion is then packaged into 30 mL (2 oz) and 60 mL (3 oz) [redacted] bottles with white [redacted] caps.

Drug substance

Ciclopirox Olamine USP is a white or pale yellow crystalline powder, odorless. Ciclopirox Olamine is very soluble in ethanol and dichloromethane, slightly soluble in water and ethylacetate, practically insoluble in cyclohexane.

B. Description of How the Drug Product is Intended to be Used

The drug product is intended to be used for the treatment of dermal infections: tinea pedis, tinea cruris, and tinea corporis

C. Basis for Approvability or Not-Approval Recommendation

This application is not approvable due to the deficiencies found in the following areas.

(1) LOD and LOQ for HPLC to determine drug substance related substance (2) individual known and unknown impurities for the drug product release and stability.

III. Administrative

A. Reviewer's Signature

Liang-Lii Huang, Ph.D.

B. Endorsement Block

Liang-Lii Huang, Ph.D./ 3/21/03
James Fan, Team Leader/3/21/03

C. CC Block

ANDA 76-422
ANDA DUP 76-422
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March 21, 2003

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ON ORIGINAL

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information from

CHEMISTRY REVIEW #2

cc: ANDA 76-422
ANDA DUP 76-422
DIV FILE
Field Copy

Endorsements (Draft and Final with Dates):

HFD-627 /Liang-Lii Huang, Ph.D. /3/21/03;4/15/03;4/24/03 L. Huang 4/24/03

HFD-627/James Fan, Team Leader/3/21/03;4/16/03;4/24/03 4/26/03

HFD-617/Ann Vu, Project Manager/4/15/03;4/24/03 5/1/03

F/T:ard/4/17/03
\\CDS013\OGDS11\FIRMSAM\ALTANA\LTRS&REV\76422 rev2.doc
April 24, 2003

TYPE OF LETTER: NOT APPROVABLE -MINOR/

APPEARS THIS WAY
ON ORIGINAL

ANDA 76-422

Ciclopirox Olamine Topical Suspension USP, 0.77%

Altana, Inc.

Liang-Lii Huang, Ph.D.

OGD/DC1

Table of Contents

Chemistry Review Data Sheet

1. ANDA 76-422

2. REVIEW #:3

3. REVIEW DATE:
   21-Oct-2003

4. REVIEWER:
   Liang-Lii Huang, Ph.D.

5. PREVIOUS DOCUMENTS:

Previous Documents	Document Date
None	

6. SUBMISSION(S) BEING REVIEWED:

Submission(s) Reviewed	Document Date
Original	28-May-2002
Response to "refuse to receive" letter	05-Aug-2002
Acceptable for filing	06-Aug-2002
New Correspondence	08-Aug-2002
Minor amendment	20- Dec- 2002
Bio amendment	24-Apr-2003
Minor amendment	20-May-2003
Telephone amendment	09-October-2003

7. NAME & ADDRESS OF APPLICANT:

Name	Altana Inc.
Address	60 Baylis Road, Melville, NY 11747
representative	Andrey Zaweski
Telephone	631-454-7677
Fax	631-756-5114

8. DRUG PRODUCT NAME/CODE/TYPE:

a) Proprietary Name: N/A
b) Non-Proprietary Name (USAN):
Ciclopirox Lotion 0.77%
(Ciclopirox Olamine Topical Suspension USP)

9. LEGAL BASIS FOR SUBMISSION:

RLD: NDA 19-824 Loprox® Lotion 0.77%
Medicis, The dermatology company
Manufactured by West Pharmaceutical Services

Patent certification [21 CFR 314.94 (a)(12)]
Paragraph II certification:
Altana certifies that all listed patents claimed in US for RLD have expired.
Exclusivity statement [21 CFR 314.94 (a)(3)]
There is no unexpired exclusivity for the RLD.

10. PHARMACOL. CATEGORY:

for the topical treatment of the following dermal infections: tinea pedis, tinea cruris, and tinea corporis

11. DOSAGE FORM:

lotion

12. STRENGTH/POTENCY:

0.77%

13. ROUTE OF ADMINISTRATION:

topical

14. Rx/OTC DISPENSED: _X_ Rx ___ OTC

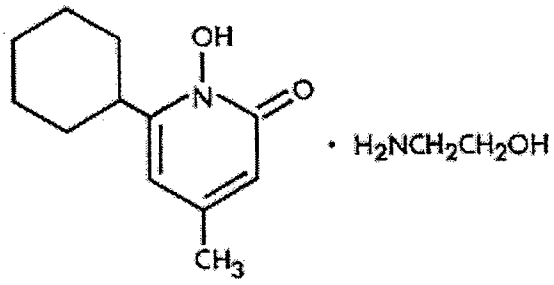
15. SPOTS (SPECIAL PRODUCTS ON-LINE TRACKING SYSTEM)[Note22]:

_____SPOTS product – Form Completed

___X___Not a SPOTS product

16. CHEMICAL NAME, STRUCTURAL FORMULA, MOLECULAR FORMULA, MOLECULAR WEIGHT:

6-cyclohexyl-1-hydroxy-4-methyl-2(1 *H*)-pyridone, 2-aminoethanol salt.
The CAS Registry Number is 41621-49-2.



17. RELATED/SUPPORTING DOCUMENTS:

APPEARS THIS WAY
ON ORIGINAL

A. DMFs:

DMF #	TYPE	HOLDER	ITEM REFERENCED	CODE[1]	STATUS[2]	DATE REVIEW COMPLETED	COMMENTS
	II			1	adequate	9/5/03	Liang-Lii Huang, Ph.D.
	III			4			
	III			4			
	III			4			
	III			4			
	III			4			
	III			4			

[1] Action codes for DMF Table:
1 – DMF Reviewed.
Other codes indicate why the DMF was not reviewed, as follows:
2 –Type 1 DMF
3 – Reviewed previously and no revision since last review
4 – Sufficient information in application
5 – Authority to reference not granted
6 – DMF not available
7 – Other (explain under "Comments")

[2] Adequate, Inadequate, or N/A (There is enough data in the application, therefore the DMF did not need to be reviewed)

B. Other Documents:

DOCUMENT	APPLICATION NUMBER	DESCRIPTION
NDA	19-824	Loprox® Lotion 0.77%

18. STATUS:

CONSULTS/ CMC RELATED REVIEWS	RECOMMENDATION	DATE	REVIEWER
Microbiology	N/A		
EES	Acceptable	12/19/02	
Methods Validation	Not required		
Labeling	pending		
Bioequivalence	pending		
EA	EA is not required.		
Radiopharmaceutical	N/A		

19. ORDER OF REVIEW

The application submission(s) covered by this review was taken in the date order of receipt. ___X_ Yes ____ No If no, explain reason(s) below:

APPEARS THIS WAY
ON ORIGINAL

The Chemistry Review for ANDA 76-422

The Executive Summary

I. Recommendations

A. Recommendation and Conclusion on Approvability

This application ANDA 76-422 is not approvable due to labeling deficiencies 12/31/03 and pending Bio review.

B. Recommendation on Phase 4 (Post-Marketing) Commitments, Agreements, and/or Risk Management Steps, if Approvable

N/A

II. Summary of Chemistry Assessments

A. Description of the Drug Product(s) and Drug Substance(s)

Drug product

The Ciclopirox Lotion 0.77% (Ciclopirox Olamine Topical Suspension USP) is indicated for the topical treatment of the following dermal infections: tinea pedis, tinea cruris, and tinea corporis

The Ciclopirox Lotion is a smooth and homogeneous liquid dispersion intended for external application to the body. It is prepared using the ——————to achieve the smooth texture. The lotion is then packaged into 30 mL (2 oz) and 60 mL (3 oz) —— bottles with white —————— caps.

Drug substance

Ciclopirox Olamine USP is a white or pale yellow crystalline powder, odorless. Ciclopirox Olamine is very soluble in ethanol and dichloromethane, slightly soluble in water and ethylacetate, practically insoluble in cyclohexane.

B. Description of How the Drug Product is Intended to be Used

The drug product is intended to be used for the treatment of dermal infections: tinea pedis, tinea cruris, and tinea corporis

C. Basis for Approvability or Not-Approval Recommendation

This application is not approvable due to labeling deficiencies 12/31/03 and pending Bio review.

III. Administrative

A. Reviewer's Signature

Liang-Lii Huang, Ph.D.

B. Endorsement Block

Liang-Lii Huang, Ph.D./ 10/21/03 L Huang 1/15/04
James Fan, Team Leader/10/17/03 1/15/04

C. CC Block

ANDA 76-422
ANDA DUP 76-422
DIV FILE
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ON ORIGINAL

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information from

CHEMISTRY REVIEW #3

Please see the above new proposed specifications in this review item #28.

30. MICROBIOLOGY

N/A

31. SAMPLES AND RESULTS/METHODS VALIDATION STATUS

Method validation is not required per OGD MV policy.

32. LABELING

Not acceptable by B. Weitzman on 12/31/03.

33. ESTABLISHMENT INSPECTION

EER: Acceptable (12/19/02)

34. BIOEQUIVALENCY/MICROBIOLOGY STATUS

Pending review

35. ENVIRONMENTAL IMPACT CONSIDERATIONS/CATEGORICAL EXCLUSION:

satisfactory as review #1

36. CHEMISTRY COMMENTS TO BE PROVIDED TO THE APPLICANT

ANDA: 76-422 APPLICANT: Altana, Inc.

DRUG PRODUCT: Ciclopirox Olamine Topical Suspension USP, 0.77%

The deficiency presented below represents a MINOR deficiency.

A. Deficiency:

Labeling deficiencies were communicated to you via facsimile on December 31, 2003. You should address the issues in the December 31 communication prior to or concurrent with your response to this communication.

Sincerely yours,

1/15/04

Rashmikant M. Patel, Ph.D.
Director
Division of Chemistry I
Office of Generic Drugs
Center for Drug Evaluation and Research

cc: ANDA 76-422
ANDA DUP 76-422
DIV FILE
Field Copy

Endorsements (Draft and Final with Dates):

HFD-627 /Liang-Lii Huang, Ph.D. /10/21/03 L Huang 1/15/04

HFD-627/James Fan, Team Leader/10/21/03 1/15/04

HFD-617/Ann Vu, Project Manager/1/13/04 1/16/04

F/T:ard/1/14/04
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TYPE OF LETTER: CMC APPROVABLE

APPEARS THIS WAY
ON ORIGINAL

ANDA 76-422

Ciclopirox Olamine Topical Suspension USP, 0.77%

Altana, Inc.

Liang-Lii Huang, Ph.D.

OGD/DC1

Table of Contents

Chemistry Review Data Sheet

1. ANDA 76-422

2. REVIEW #:4

3. REVIEW DATE:
   5/25/04

4. REVIEWER:
   Liang-Lii Huang, Ph.D.

5. PREVIOUS DOCUMENTS:

Previous Documents	Document Date
None	

6. SUBMISSION(S) BEING REVIEWED:

Submission(s) Reviewed	Document Date
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Response to "refuse to receive" letter	05-Aug-2002
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Minor amendment	20- Dec- 2002
Bio amendment	24-Apr-2003
Minor amendment	20-May-2003
Telephone amendment	09-October-2003
Bio amendment	2-Feb-2004

7. NAME & ADDRESS OF APPLICANT:

Name	Altana Inc.
Address	60 Baylis Road, Melville, NY 11747
representative	Robert J. Anderson
Telephone	631-454-7677
Fax	631-756-5114

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a) Proprietary Name: N/A
b) Non-Proprietary Name (USAN):
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for the topical treatment of the following dermal infections: tinea pedis, tinea cruris, and tinea corporis

11. DOSAGE FORM:
lotion

12. STRENGTH/POTENCY:
0.77%

13. ROUTE OF ADMINISTRATION:
topical

14. Rx/OTC DISPENSED: _X__Rx ___OTC

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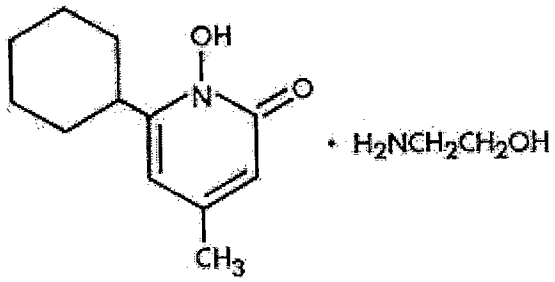

17. RELATED/SUPPORTING DOCUMENTS:

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ON ORIGINAL

A. DMFs:

DMF #	TYPE	HOLDER	ITEM REFERENCED	CODE[1]	STATUS[2]	DATE REVIEW COMPLETED	COMMENTS
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6 – DMF not available
7 – Other (explain under "Comments")

[2] Adequate, Inadequate, or N/A (There is enough data in the application, therefore the DMF did not need to be reviewed)

B. Other Documents:

DOCUMENT	APPLICATION NUMBER	DESCRIPTION
NDA	19-824	Loprox® Lotion 0.77%

18. STATUS:

CONSULTS/ CMC RELATED REVIEWS	RECOMMENDATION	DATE	REVIEWER
Microbiology	N/A		
EES	Acceptable	12/19/02	
Methods Validation	Not required		
Labeling	acceptable	2/9/04	Beverly Weitzman
Bioequivalence	Acceptable	6/4/04	C. Kim
EA	EA is not required.		
Radiopharmaceutical	N/A		

19. ORDER OF REVIEW

The application submission(s) covered by this review was taken in the date order of receipt. ___X_ Yes ____ No If no, explain reason(s) below:

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The Chemistry Review for ANDA 76-422

The Executive Summary

I. Recommendations

A. Recommendation and Conclusion on Approvability

This application ANDA 76-422 is approvable.

B. Recommendation on Phase 4 (Post-Marketing) Commitments, Agreements, and/or Risk Management Steps, if Approvable

N/A

II. Summary of Chemistry Assessments

A. Description of the Drug Product(s) and Drug Substance(s)

Drug product

The Ciclopirox Lotion 0.77% (Ciclopirox Olamine Topical Suspension USP) is indicated for the topical treatment of the following dermal infections: tinea pedis, tinea cruris, and tinea corporis

The Ciclopirox Lotion is a smooth and homogeneous liquid dispersion intended for external application to the body. It is prepared using [redacted] to achieve the smooth texture. The lotion is then packaged into 30 mL (2 oz) and 60 mL (3 oz) [redacted] bottles with white [redacted] caps.

Drug substance

Ciclopirox Olamine USP is a white or pale yellow crystalline powder, odorless. Ciclopirox Olamine is very soluble in ethanol and dichloromethane, slightly soluble in water and ethylacetate, practically insoluble in cyclohexane.

B. Description of How the Drug Product is Intended to be Used

The drug product is intended to be used for the treatment of dermal infections: tinea pedis, tinea cruris, and tinea corporis

C. Basis for Approvability or Not-Approval Recommendation

This application is approvable.

III. Administrative

A. Reviewer's Signature

Liang-Lii Huang, Ph.D.

B. Endorsement Block

Liang-Lii Huang, Ph.D./ 5/25/04 L Huang 6/15/04
James Fan, Team Leader/5/30/04 6/15/04 7/8/04

C. CC Block

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of trade secret and/or

confidential commercial

information from

CHEMISTRY REVIEW #4

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Endorsements (Draft and Final with Dates):

HFD-627 /Liang-Lii Huang, Ph.D. /5/25/04;6/15/04

HFD-627/James Fan, Team Leader/5/30/04;6/15/04

HFD-617/Ann Vu, Project Manager/6/8/04;6/15/04

F/T:ard/6/10/04
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June 15, 2004

TYPE OF LETTER: APPROVABLE

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