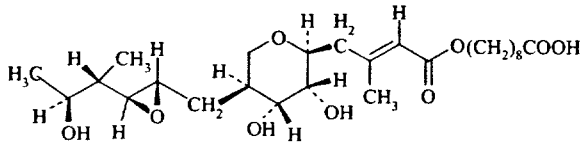
CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number 50-788

CHEMISTRY REVIEW(S)

NDA 50-788

Mupirocin Ointment, 2%



Clay-Park Labs, Inc.

Milton J. Sloan, Ph.D.
Division of Anti-Infective Drug Products (HFD-520)

Table of Contents

APPEARS THIS WAY
ON ORIGINAL

Chemistry Review Data Sheet

1. NDA 50-788

2. REVIEW #: 2

3. REVIEW DATE: December 03, 2002

4. REVIEWER: Milton J. Sloan, Ph. D.

5. PREVIOUS DOCUMENTS:

Previous Documents	Document Date
ORIGINAL	07-FEB-02
Amendment (BC)	01-APR-02
Amendment (BC)	18-JUL-02
Amendment (BC)	14-OCT-02

6. SUBMISSION (S) BEING REVIEWED:

Submission(s) Reviewed	Document Date
ORIGINAL	07-FEB-02
Faxed Amendment (hard copy to follow)	02-DEC-02

7. NAME & ADDRESS OF APPLICANT:

Name:	Clay Park Labs, Inc.
Address:	1700 Bathgate Ave., Bronx, NY 10457
Representative:	Candis Edwards, Director of Regulatory Affairs
Telephone:	718-960-9976

8. DRUG PRODUCT NAME/CODE/TYPE:

a) Proprietary Name: N/A
b) Non-Proprietary Name (USAN): Mupirocin Ointment, 2%
c) Code Name/# (ONDC only): N/A
d) Chem. Type/Submission Priority (ONDC only):
- Chem. Type: 3

- Submission Priority: S

9. LEGAL BASIS FOR SUBMISSION: Bactroban Ointment® (Mupirocin ointment, 2%), GlaxoSmithKline, NDA 50-591.

10. PHARMACOL. CATEGORY: Topical treatment of impetigo due to: Staphylococcus aureus and Streptococcus Pyogenes.

11. DOSAGE FORM: Ointment

12. STRENGTH/POTENCY: 2%

13. ROUTE OF ADMINISTRATION: Topical

14. Rx/OTC DISPENSED: __X_ R_x ___OTC

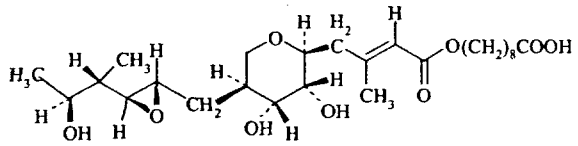
15. SPOTS (SPECIAL PRODUCTS ON-LINE TRACKING SYSTEM)[Note26]:

_____SPOTS product – Form Completed

___X___Not a SPOTS product

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

(*E*)-2*S*,3*R*,4*R*,5*S*)-5-[(2*S*,3*S*,4*S*,5*S*)-2,3-Epoxy-5-hydroxy-4-methylhexyl]-tetrahydro-3,4-dihydroxy β-methyl-2*H*-pyran-2-crotonic acid, ester with 9-hydroxynonanoic acid



CAS # 12650-69-0 M.F.=$C_{26}H_{44}O_9$ M.W.= 500.63

17. RELATED/SUPPORTING DOCUMENTS:

A. DMFs:
There are no changes from the previous Review #1.

B. Other Documents: N/A
There are no changes from the previous Review #1.

18. STATUS:
There are no changes from the previous Review #1.

The Chemistry Review for NDA 50-788

The Executive Summary

I. Recommendations

A. Recommendation and Conclusion on Approvability

The application is recommended for approval from the CMC viewpoint.

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

II. Summary of Chemistry Assessments

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

Drug Substance

Mupirocin is the active pharmaceutical ingredient (API) in Clay-Park Labs (CPL) Mupirocin Ointment, 2%. Mupirocin is the major metabolite produced from a strain of *Pseudomonas fluorescens* grown in a submerged culture. It is also known as pseudomonic acid A.

) is the proposed vendor of the Mupirocin, and has submitted . CPL has included a letter of authorization to in this application. The manufacturing facility is located in . Mupirocin is purchased through who serves as the The facility has an acceptable EER report recommendation based on the profile. The DMF has been reviewed and found adequate to support NDA 50-788. A description of the physical and chemical characteristics of Mupirocin is presented in the DMF. also provides the details of the fermentation procedure use to manufacture Mupirocin. has included stability data at both 25°C / 60% RH and under refrigeration conditions 2-8°C, on two batches. Specifications at the end of 24 months were met and the data included in the DMF.

CPL qualified as a vendor by evaluating 3 lots of drug substance according to specifications. Mupirocin is a compendial grade material and the tests and specifications in the USP 25 monograph (pages 1176-1177) include those of identification, crystallinity, pH, water and assay. In addition, the DMF holder performs tests for related substances and residual solvents. The analytical methodologies for related substances and residual solvents proposed by CPL are based on validated methods included in the DMF. CPL performed , and has included these study reports in their NDA.

Drug Product

The formulation consists of —— w/w Mupirocin, incorporated into a lipophilic vehicle which includes the following inactive ingredients: castor oil (——), oleyl alcohol (——) (Softisan 378 (hard fat) ——, and propylene glycol monostearate, pure ——). The formulation does not include any coloring or fragrance agents.

The drug product is to be manufactured at CPL's facility located in the Bronx, New York. CPL proposes to use a manufacturing procedure similar to that of other FDA-approved topical products manufactured by CPL. Their facility is registered with the FDA under Establishment Registration # 2450054 and has been given an acceptable recommendation (25-Mar-02) based on an acceptable District Office (DO) file review.

The drug product has a USP 25 monograph (pages 1176-1177) and the tests and specifications include identification, minimum fill and assay. Additional tests for —— are proposed for CPL's product specifications. CPL acknowledges the assay included in the USP monograph was developed for GSK' s hydrophilic-based drug product. CPL has modified the sample preparation in the USP monograph, in order to improve the extraction of Mupirocin from their lipophilic base formulation. CPL has validated the slightly modified USP assay for the drug substance. CPL has also developed and validated stability indicating methodology for the evaluation of the degradants in the related substance analysis. Their method validation reports are included in the NDA.

CPL's Mupirocin Ointment, 2% drug product is to be packaged into 15g, 22g and 30g lined aluminum, ——, blind end tubes with white, HDPE caps. The tubes are lined with —— which is a —— liner. The filled tubes are to be placed into outer folding cartons, which also contain the package insert. The marketed tubes and outer folding cartons will be pre-labeled with the approved labeling from this NDA. CPL has included a Packaging Comparability Protocol, in order to obtain approval of the 22 g packaging configuration.

CPL has updated long term stability data to include 24-months in order to support the 30 month expiry period. Three months of accelerated stability data has also been included in the NDA to support the 22 g tube configuration. Intermediate storage condition stability data has been also been included in the NDA. Statistical evaluation of the stability data on this packaging configuration indicates that the drug product is stable a minimum of 30 months.

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

CPL's Mupirocin Ointment, 2% drug product is a locally acting, ointment dosage form, intended for the topical route of administration. Mupirocin has been shown to be

effective in the treatment of impetigo. Impetigo is a superficial infection of the skin caused primarily by *Staphylococcus aureus,* Group A streptococci, and occasionally by other streptococci and is seen most often in young children, especially those living under conditions of poor hygiene, in semi-tropical and tropical climates. Minor trauma, such as a scratch or an insect bite, may serve to lodge bacteria into the skin and cause this infection. Impetigo is a highly contagious bacterial infection, which most commonly occurs on exposed areas of the body, such as the edge of the nose, the mouth, and on the arms and legs. A small amount of Mupirocin Ointment, 2% should be applied to the infected area three times daily.

Mupirocin, the major metabolite produced from a strain of *Pseudomonas fluorescens* is grown in a submerged culture. The unique mode of Mupirocin antimicrobial activity is due to the reversible inhibition of isoleucyl transfer RNA synthetase, which results in the inhibition of protein synthesis and RNA synthesis. Mupirocin competes for the bacterial isoleucine binding sites on the isoleucyl transfer RNA synthetase enzyme. The epoxide side chain terminus of the Mupirocin molecule occupies two hydrophobic sites. These two sites accommodate the methyl and ethyl groups of L-isoleucine on the isoleucine-binding site of the isoleucyl transfer RNA synthetase susceptible bacteria. The reversible inhibition of the formation of the enzyme complex prevents further isoleucine incorporation which deletes cellular concentration of isoleucine charged transfer RNA and leads to a cessation of protein and RNA synthesis in susceptible bacteria.

C. Basis for Approvability or Not-Approval Recommendation

Mupirocin Ointment, 2% was developed by Agis Industries, the parent company of CPL, as an equivalent product to Bactroban® Ointment, which is manufactured and marketed by GSK under NDA 50-591. Since GSK's product is protected under US Patent 4,524,075, CPL's goal was to develop a chemically and physically stable, non-infringing formulation. In order to improve the physical characteristics of Mupirocin Ointment, 2%, CPL changed the base of the ointment from the hydrophilic PEG base in GSK's Bactroban® Ointment to a lipophilic base. CPL's first meeting was held with the Office of Generic Drugs (OGD) to determine whether or not the Mupirocin Ointment, 2% application could be submitted as an abbreviated new drug application (ANDA) under Section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act). OGD informed CPL that the application could not be submitted as a 505(j) ANDA because the reference listed drug utilized a bland water miscible ointment base and OGD could not approve an ANDA that involved a change in the lipophilic properties of the vehicle or base. CPL has thus submitted this application as a 505(b) (2) NDA to the Office of New Drugs (OND).

The drug product has a USP 25 monograph (pages 1176-1177) and the tests and specifications include identification, minimum fill and assay. Additional tests for [redacted] are proposed for CPL using the slightly modified USP assay for the drug substance. CPL's finished drug product is to meet requirements of the compendial drug.

There were six draft review comments listed in Section VIII of Review #1. Only two of the draft comments were communicated to Clay-Park Labs by fax (11/27/02). Clay Park Labs has responded to these comments (12/02/02). Their responses to the comments have been reviewed and found acceptable. Two other comments were considered by DNDC III to be GMP in nature and thus more appropriate for the field investigator. The e-mail attachment at the end of this review raises the concerns to EES Questions. The final two comments that addressed a typographical error and a lack of clarity in the sampling plans were considered nice-to-know and were therefore not communicated.

III. Administrative

A. Reviewer's Signature

B. Endorsement Block

Milton J. Sloan, Ph. D. Date: December 03, 2002
Chemist Reviewer

Bonnie B. Dunn, Ph. D., *Chi-wan Chen for*
Acting Chemistry TeamLeader, Deputy Director DNDCIII Date: *12/03/02*

C. CC Block

HFD-520/DillonParker/PM
HFD-520/Bostwick/MO
HFD-520/Sloan/CHM

THIS SECTION WAS DETERMINED **NOT** TO BE RELEASABLE

4 pages

VI. APPENDIX

ATTACHMENT A

03-DEC-2002 FDA CDER EES Page 1 of 2
ESTABLISHMENT EVALUATION REQUEST
DETAIL REPORT

Application: NDA 50788/000
Stamp: 07-FEB-2002
Regulatory Due: 07-DEC-2002
Applicant: CLAY PARK LABS
1700 BETHGATE INDUSTRIES
BRONX, NY 10457
Priority: 3S
Org Code: 520

Action Goal:
District Goal: 08-OCT-2002
Brand Name: MUPIROCIN OINTMENT 2%
Estab. Name:
Generic Name: MUPIROCIN OINTMENT 2%
Dosage Form: (OINTMENT)
Strength: 2%

Application Comment:
FDA Contacts: M. DILLON PARKER (HFD-520) 301-827-2125 , Project Manager
M. SLOAN (HFD-520) 301-827-2174 , Review Chemist
ID = 107080 , Team Leader

Overall Recommendation: ACCEPTABLE on 25-MAR-2002 by J. D AMBROGIO (HFD-324) 301-827-0062

Establishment:

DMF No: AADA:
Responsibilities:
Profile: CFN OAI Status: NONE
Estab. Comment:

Milestone Name	Date	Req. Type	Insp. Date	Decision & Reason	Creator
SUBMITTED TO OC	15-MAR-2002				SLOANM
OC RECOMMENDATION	18-MAR-2002			ACCEPTABLE BASED ON PROFILE	DAMBROGIOJ

Establishment

DMF No: AADA:
Responsibilities:
Profile: CTL OAI Status: NONE
Estab. Comment:

Milestone Name	Date	Req. Type	Insp. Date	Decision & Reason	Creator
SUBMITTED TO OC	15-MAR-2002				SLOANM
OC RECOMMENDATION	15-MAR-2002			ACCEPTABLE BASED ON PROFILE	FERGUSONS

Establishment: 2450054
CLAY PARK LABORATORIES INC
1700 BATHGATE AVE
BRONX, NY 10457
DMF No: AADA:
Responsibilities: FINISHED DOSAGE MANUFACTURER
FINISHED DOSAGE PACKAGER
FINISHED DOSAGE RELEASE TESTER
FINISHED DOSAGE STABILITY TESTER
Profile: OIN OAI Status: NONE

ATTACHMENT A

Cont'd

Estab. Comment: THE FIRM REPORTS IN NDA TO PERFORM ALL MANUFACTURING, PACKAGING, RELEASE AND STABILITY TESTING OF DRUG PRODUCT WITH EXCEPTION OF ONE TEST ON DRUG SUBSTANCE. (on 15-MAR-2002 by M. SLOAN (HFD-520) 301-827-2174)

Milestone Name	Date	Req. Type	Insp. Date	Decision & Reason	Creator
SUBMITTED TO OC	15-MAR-2002				SLOANM
SUBMITTED TO DO	15-MAR-2002	10D			FERGUSONS
DO RECOMMENDATION	25-MAR-2002			ACCEPTABLE BASED ON FILE REVIEW	LFARINA
OC RECOMMENDATION	25-MAR-2002			ACCEPTABLE DISTRICT RECOMMENDATION	DAMBROGIOJ

APPEARS THIS WAY
ON ORIGINAL

THIS SECTION WAS DETERMINED **NOT** TO BE RELEASABLE

1 page

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

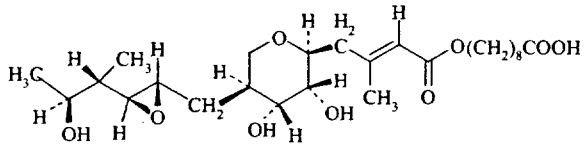
Milton Sloan
12/4/02 10:27:57 AM
CHEMIST

Chi Wan Chen
12/4/02 11:26:32 AM
CHEMIST

APPEARS THIS WAY
ON ORIGINAL

NDA 50-788

Mupirocin Ointment, 2%



Clay-Park Labs, Inc.

Milton J. Sloan, Ph.D.
Division of Anti-Infective Drug Products (HFD-520)

Table of Contents

Chemistry Review Data Sheet

1. NDA 50-788

2. REVIEW #: 1

3. REVIEW DATE: November 07, 2002

4. REVIEWER: Milton J. Sloan, Ph. D.

5. PREVIOUS DOCUMENTS:

Previous Documents	Document Date
ORIGINAL	07-FEB-02
Amendment (BC)	01-APR-02
Amendment (BC)	18-JUL-02
Amendment (BC)	14-OCT-02

6. SUBMISSION(S) BEING REVIEWED:

Submission(s) Reviewed	Document Date
ORIGINAL	07-FEB-02
Amendment (BC)	01-APR-02
Amendment (BC)	18-JUL-02
Amendment (BC)	14-OCT-02

7. NAME & ADDRESS OF APPLICANT:

Name:	Clay Park Labs, Inc.
Address:	1700 Bathgate Ave., Bronx, NY 10457
Representative:	Candis Edwards, Director of Regulatory Affairs
Telephone:	718-960-9976

8. DRUG PRODUCT NAME/CODE/TYPE:

a) Proprietary Name: N/A
b) Non-Proprietary Name (USAN): Mupirocin Ointment, 2%
c) Code Name/# (ONDC only): N/A
d) Chem. Type/Submission Priority (ONDC only):

- Chem. Type: 3
- Submission Priority: S

9. LEGAL BASIS FOR SUBMISSION: Bactroban Ointment® (Mupirocin ointment, 2%), GlaxoSmithKline, NDA 50-591.

10. PHARMACOL. CATEGORY: Topical treatment of impetigo due to: Staphylococcus aureus and Streptococcus Pyogenes.

11. DOSAGE FORM: Ointment

12. STRENGTH/POTENCY: 2%

13. ROUTE OF ADMINISTRATION: Topical

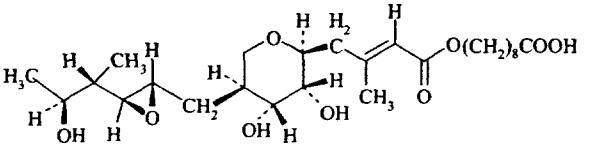
14. Rx/OTC DISPENSED: __X__ R_x ___OTC

15. SPOTS (SPECIAL PRODUCTS ON-LINE TRACKING SYSTEM)[Note26]:

_____SPOTS product – Form Completed

___X___Not a SPOTS product

16. CHEMICAL NAME, STRUCTURAL FORMULA, MOLECULAR FORMULA, MOLECULAR WEIGHT:
(*E*)-2*S*,3*R*,4*R*,5*S*)-5-[(2*S*,3*S*,4*S*,5*S*)-2,3-Epoxy-5-hydroxy-4-methylhexyl]-tetrahydro-3,4-dihydroxy β-methyl-2*H*-pyran-2-crotonic acid, ester with 9-hydroxynonanoic acid



CAS # 12650-69-0 M.F.=$C_{26}H_{44}O_9$ M.W.= 500.63

17. RELATED/SUPPORTING DOCUMENTS:

A. DMFs:

DMF #	TYPE	HOLDER	ITEM REFERENCED	CODE[1]	STATUS[2]	DATE REVIEW COMPLETED	COMMENTS
				1	Adequate	18-OCT-2002	Responses to deficiencies have been adequately addressed. IR letter sent for updated list of Companies
				7	Adequate	11-AUG-2000	The DMF has been previously reviewed and found adequate. There have been two annual updates since time of review. No CMC changes.
				7	Current	N/A	No review was done because sufficient information is contained in the application.

[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: N/A

18. STATUS:

CONSULTS/ CMC RELATED REVIEWS	RECOMMENDATION	DATE	REVIEWER
Biometrics	N/A		
Establishment Evaluation Request (EER)	Acceptable	25-MAR-02	J. D. Ambrogio
Pharm/Tox	N/A		
Biopharm	N/A		
Labeling and Nomenclature Committee/ OPDRA	N/A		
Methods Validation	N/A		
Environmental Assessment	Categorical Exclusion Requested	N/A	N/A
Microbiology	N/A		

APPEARS THIS WAY
ON ORIGINAL

The Chemistry Review for NDA 50-788

The Executive Summary

I. Recommendations

A. Recommendation and Conclusion on Approvability

There are some pending CMC issues that remain to be resolved. However, there are no outstanding approvability issues. The application is recommended for approval from the CMC viewpoint.

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

II. Summary of Chemistry Assessments

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

Drug Substance
Mupirocin is the active pharmaceutical ingredient (API) in Clay-Park Labs (CPL) Mupirocin Ointment, 2%. Mupirocin is the major metabolite produced from a strain of *Pseudomonas fluorescens* grown in a submerged culture. It is also known as pseudomonic acid A.

[redacted] is the proposed vendor of the Mupirocin, and has submitted [redacted] CPL has included a letter of authorization to [redacted] in this application. The manufacturing facility is located in [redacted]. Mupirocin is purchased through [redacted], who serves as the U.S. agent. The facility has an acceptable EER report recommendation based on the profile. The DMF has been reviewed and found adequate to support NDA 50-788. A description of the physical and chemical characteristics of Mupirocin is presented in the DMF. [redacted] also provides the details of the fermentation procedure use to manufacture Mupirocin. [redacted] has included stability data at both 25°C / 60% RH and under refrigeration conditions 2-8°C, on two batches. Specifications at the end of 24 months were met and the data included in the DMF.

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The formulation consists of , w/w Mupirocin, incorporated into a lipophilic vehicle which includes the following inactive ingredients: castor oil , oleyl alcohol , (Softisan 378 (hard fat) , and propylene glycol monostearate, pure). The formulation does not include any coloring or fragrance agents.

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CPL has updated long term stability data to include 24-months in order to support the 30 month expiry period. Three months of accelerated stability data has also been included in the NDA to support the 22 g tube configuration. Intermediate storage condition stability data has been also been included in the NDA. Statistical evaluation of the stability data on this packaging configuration indicates that the drug product is stable a minimum of 30 months.

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

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C. Basis for Approvability or Not-Approval Recommendation

Mupirocin Ointment, 2% was developed by Agis Industries, the parent company of CPL, as an equivalent product to Bactroban® Ointment, which is manufactured and marketed by GSK under NDA 50-591. Since GSK's product is protected under US Patent 4,524,075, CPL's goal was to develop a chemically and physically stable, non-infringing formulation. In order to improve the physical characteristics of Mupirocin Ointment, 2%, CPL changed the base of the ointment from the hydrophilic PEG base in GSK's Bactroban ® Ointment, to a lipophilic base. CPL's first meeting was held with the Office of Generic Drugs (OGD) to determine whether or not the Mupirocin Ointment, 2% application could be submitted as an abbreviated new drug application (ANDA) under Section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act). OGD informed CPL that the application could not be submitted as a 505(j) ANDA because the reference listed drug utilized a bland water miscible ointment base and OGD could not approve an ANDA that involved a change in the lipophilic properties of the vehicle or base. CPL has thus submitted this application as a 505(b) (2) NDA to the Office of New Drugs (OND). The drug product has a USP 25 monograph (pages 1176-1177) and the tests and specifications include identification, minimum fill and assay. Additional tests for organoleptic attributes, related substances and microbiological

evaluations are proposed for CPL using the slightly modified USP assay for the drug substance. CPL finished drug product is to meet requirements of the compendial drug.

III. Administrative

A. Reviewer's Signature

B. Endorsement Block

Milton J. Sloan, Ph. D. Date: November 19, 2002
Chemist Reviewer

Bonnie B. Dunn, Ph. D.,
Acting Chemistry TeamLeader, Deputy Director DNDCIII Date:

C. CC Block

HFD-520/DillonParker/PM
HFD-520/Bostwick/MO
HFD-520/Sloan/CHM

APPEARS THIS WAY
ON ORIGINAL

THIS SECTION WAS DETERMINED **NOT** TO BE RELEASABLE

40 Pages

VI. APPENDIX

ATTACHMENT A

14-NOV-2002 FDA CDER EES Page 1 of 2
ESTABLISHMENT EVALUATION REQUEST
DETAIL REPORT

Application: NDA 50788/000 Action Goal:
Stamp: 07-FEB-2002 District Goal: 08-OCT-2002
Regulatory Due: 07-DEC-2002 Brand Name: MUPIROCIN OINTMENT 2%
Applicant: CLAY PARK LABS Estab. Name:
1700 BETHGATE INDUSTRIES Generic Name: MUPIROCIN OINTMENT 2%
BRONX, NY 10457
Priority: 3S Dosage Form: (OINTMENT)
Org Code: 520 Strength: 2%
Application Comment:
FDA Contacts: M. DILLON PARKER (HFD-520) 301-827-2125 , Project Manager
M. SLOAN (HFD-520) 301-827-2174 , Review Chemist
ID = 107080 , Team Leader

Overall Recommendation: ACCEPTABLE on 25-MAR-2002 by J. D AMBROGIO (HFD-324) 301-827-0062

Establishment: [redacted]

DMF No: [redacted] AADA:
Responsibilities: [redacted]
Profile: CFN OAI Status: NONE
Estab. Comment: [redacted]

Milestone Name	Date	Req. Type	Insp. Date	Decision & Reason	Creator
SUBMITTED TO OC	15-MAR-2002				SLOANM
OC RECOMMENDATION	18-MAR-2002			ACCEPTABLE BASED ON PROFILE	DAMBROGIOJ

Establishment: [redacted]

DMF No: AADA:
Responsibilities: [redacted]
Profile: CTL OAI Status: NONE
Estab. Comment: [redacted]

Milestone Name	Date	Req. Type	Insp. Date	Decision & Reason	Creator
SUBMITTED TO OC	15-MAR-2002				SLOANM
OC RECOMMENDATION	15-MAR-2002			ACCEPTABLE BASED ON PROFILE	FERGUSONS

Establishment: 2450054
CLAY PARK LABORATORIES INC
1700 BATHGATE AVE
BRONX, NY 10457
DMF No: AADA:
Responsibilities: FINISHED DOSAGE MANUFACTURER
FINISHED DOSAGE PACKAGER
FINISHED DOSAGE RELEASE TESTER
FINISHED DOSAGE STABILITY TESTER
Profile: OIN OAI Status: NONE

ATTACHMENT A
Cont'd

14-NOV-2002 FDA CDER EES Page 2 of 2
ESTABLISHMENT EVALUATION REQUEST
DETAIL REPORT

Estab. Comment: THE FIRM REPORTS IN NDA TO PERFORM ALL MANUFACTURING, PACKAGING, RELEASE AND STABILITY TESTING OF DRUG PRODUCT WITH EXCEPTION OF ONE TEST ON DRUG SUBSTANCE. (on 15-MAR-2002 by M. SLOAN (HFD-520) 301-827-2174)

Milestone Name	Date	Req. Type	Insp. Date	Decision & Reason	Creator
SUBMITTED TO OC	15-MAR-2002				SLOANM
SUBMITTED TO DO	15-MAR-2002	10D			FERGUSONS
DO RECOMMENDATION	25-MAR-2002			ACCEPTABLE BASED ON FILE REVIEW	LFARINA
OC RECOMMENDATION	25-MAR-2002			ACCEPTABLE DISTRICT RECOMMENDATION	DAMBROGIOJ

APPEARS THIS WAY
ON ORIGINAL

THIS SECTION WAS DETERMINED **NOT** TO BE RELEASABLE

1 page

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Milton Sloan
11/27/02 05:35:05 PM
CHEMIST

Bonnie Dunn
11/27/02 05:51:17 PM
CHEMIST

APPEARS THIS WAY
ON ORIGINAL

SEE CHEMISTRY REVIEW

VI. APPENDIX

ATTACHMENT A

14-NOV-2002 FDA CDER EES Page 1 of 2
ESTABLISHMENT EVALUATION REQUEST
DETAIL REPORT

Application: NDA 50788/000
Stamp: 07-FEB-2002
Regulatory Due: 07-DEC-2002
Applicant: CLAY PARK LABS
1700 BETHGATE INDUSTRIES
BRONX, NY 10457
Priority: 3S
Org Code: 520

Action Goal:
District Goal: 08-OCT-2002
Brand Name: MUPIROCIN OINTMENT 2%
Estab. Name:
Generic Name: MUPIROCIN OINTMENT 2%
Dosage Form: (OINTMENT)
Strength: 2%

Application Comment:
FDA Contacts: M. DILLON PARKER (HFD-520) 301-827-2125 , Project Manager
M. SLOAN (HFD-520) 301-827-2174 , Review Chemist
ID = 107080 , Team Leader

Overall Recommendation: ACCEPTABLE on 25-MAR-2002 by J. D AMBROGIO (HFD-324) 301-827-0062

Establishment: [redacted]

DMF No: [redacted]
Responsibilities: [redacted]
Profile: CFN
Estab. Comment: [redacted]

AADA:
OAI Status: NONE

Milestone Name	Date	Req. Type	Insp. Date	Decision & Reason	Creator
SUBMITTED TO OC	15-MAR-2002				SLOANM
OC RECOMMENDATION	18-MAR-2002			ACCEPTABLE BASED ON PROFILE	DAMBROGIOJ

Establishment: [redacted]

DMF No:
Responsibilities: [redacted]
Profile: CTL
Estab. Comment:

AADA:
OAI Status: NONE

Milestone Name	Date	Req. Type	Insp. Date	Decision & Reason	Creator
SUBMITTED TO OC	15-MAR-2002				SLOANM
OC RECOMMENDATION	15-MAR-2002			ACCEPTABLE BASED ON PROFILE	FERGUSONS

Establishment: 2450054
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Responsibilities: FINISHED DOSAGE MANUFACTURER
FINISHED DOSAGE PACKAGER
FINISHED DOSAGE RELEASE TESTER
FINISHED DOSAGE STABILITY TESTER
Profile: OIN

AADA:
OAI Status: NONE

ATTACHMENT A
Cont'd

14-NOV-2002 FDA CDER EES Page 2 of 2
ESTABLISHMENT EVALUATION REQUEST
DETAIL REPORT

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OC RECOMMENDATION	25-MAR-2002			ACCEPTABLE DISTRICT RECOMMENDATION	DAMBROGIOJ

APPEARS THIS WAY
ON ORIGINAL