

CENTER FOR DRUG EVALUATION AND RESEARCH

APPROVAL PACKAGE FOR:

APPLICATION NUMBER

NDA 21-882

Chemistry Review(s)



NDA 21-882

Exjade[®] (deferasirox) Tablets for Oral Suspension

Novartis Pharmaceuticals Corp.

Raymond P. Frankewich, Ph.D.

Division of GI and Coagulation Drug Products (HFD-180)



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I. Review Of Common Technical Document-Quality (Ctd-Q) Module 3.2: Body Of Data.....	NA
S DRUG SUBSTANCE [deferasirox, Novartis Pharmaceuticals Corp.]	NA
P DRUG PRODUCT [Exjade [®] Tablets for Oral Suspension, 125, 250, and 500 mg]	NA
A APPENDICES	NA
R REGIONAL INFORMATION	NA
II. Review Of Common Technical Document-Quality (Ctd-Q) Module 1	NA
A. Labeling & Package Insert	NA
B. Environmental Assessment Or Claim Of Categorical Exclusion	NA
III. List Of Deficiencies To Be Communicated.....	NA



Chemistry Review Data Sheet

1. NDA or ANDA 21-882
2. REVIEW #: 2
3. REVIEW DATE: October 10, 2005
4. REVIEWER: Raymond P. Frankewich, Ph.D.
5. PREVIOUS DOCUMENTS:

Previous Documents

CMC Review #1

Document Date

July 6, 2005

6. SUBMISSION(S) BEING REVIEWED:

Submission(s) Reviewed

CMC Reviewable Unit (RUC)

NDA

CMC Amendment (BC)

CMC Amendment (BC)

CMC Amendment (BC)

Amendment

Document Date

January 10, 2005

April 29, 2005

May 10, 2005

May 27, 2005

July 28, 2005

September 16, 2005

7. NAME & ADDRESS OF APPLICANT:

Name: Novartis Pharmaceuticals Corporation

Address: One Health Plaza
East Hanover, NJ 07936-1080Representative: Susan P. Nemeth, Ph.D., Associate Director, Drug
Regulatory Affairs

Telephone: (862) 778-2003



Chemistry Review Data Sheet

8. DRUG PRODUCT NAME/CODE/TYPE:

- a) Proprietary Name: None[®]
b) Non-Proprietary Name (USAN): deferasirox
c) Code Name/# (ONDC only): ICL670 / 201530-41-8 (CAS Registry Number)
d) Chem. Type/Submission Priority (ONDC only):
 - Chem. Type: 1
 - Submission Priority: P

9. LEGAL BASIS FOR SUBMISSION: NA for 505(b)(1).

10. PHARMACOL. CATEGORY: Metal chelator (code: 8016400)

11. DOSAGE FORM: Tablet (Tentative: Tab Soluble, code 507; see Executive Summary)

12. STRENGTH/POTENCY: 125, 250, and 500 mg

13. ROUTE OF ADMINISTRATION: (Oral, code 001)

14. Rx/OTC DISPENSED: Rx OTC15. SPOTS (SPECIAL PRODUCTS ON-LINE TRACKING SYSTEM): SPOTS product – Form Completed Not a SPOTS product

16. CHEMICAL NAME, STRUCTURAL FORMULA, MOLECULAR FORMULA, MOLECULAR WEIGHT: See Section S.1 below.



Chemistry Review Data Sheet

17. RELATED/SUPPORTING DOCUMENTS:

A. DMFs:

DMF #	TYPE	HOLDER	ITEM REFERENCED	CODE ¹	STATUS ²	DATE REVIEW COMPLETED	COMMENTS
7	III	[]	[]	3	Adequate	9/26/01 DMF Review Strike Force.	
	III		[]	1	Adequate	3 / 05	
	III		[]	3	Adequate	4 / 22 / 02	
	III		[]	1	Adequate	7 / 05	
	III		[]	1	Adequate	7 / 05	

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

18. STATUS: NOTE: The CMC section of this NDA was submitted as a Reviewable Unit on January 10, 2005. The rest of the NDA was submitted on



CHEMISTRY REVIEW



Chemistry Review Data Sheet

April 29, 2005. As a result, many of the consult reviews below will be listed as pending.

ONDC:

CONSULTS/ CMC RELATED REVIEWS	RECOMMENDATION	DATE	REVIEWER
Biometrics	Non-inferiority of Exjade to deferoxamine mesylate not demonstrated	Not provided	Sonia Castillo, Ph.D.
EES	Acceptable	8-2-05	Frankewich / Shawnte Adams (Pre-approval Manager)
Pharm/Tox	Approve	9-28-05	Tamal K. Chakraborti, Ph.D.
Biopharm	Acceptable, conditional on acceptable Phase 4 commitments and labeling changes	10-11-05	Suliman Al-Fayoumi
DDMAC	Labeling changes recommended	9-29-05	Debi Tran, PharmD
DMETS	Proprietary name acceptable, labeling changes recommended	8-4-05	Felicia Duffy, RN, BSN
Methods Validation	To be requested after resolution of concerns with analytical procedures	7-6-05	Frankewich
EA	Acceptable	10-11-05	Frankewich
Microbiology	NA	-	-

OGD:

CONSULTS/ CMC RELATED REVIEWS	RECOMMENDATION	DATE	REVIEWER
Microbiology			
EES			
Methods Validation			
Labeling			
Bioequivalence			
EA			
Radiopharmaceutical			

19. ORDER OF REVIEW (OGD Only)

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



The Chemistry Review for NDA 21-882

The Executive Summary

I. Recommendations

A. Recommendation and Conclusion on Approvability

From CMC perspective, approval is recommended for this application.

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

None.

II. Summary of Chemistry Assessments

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

Drug substance is known as deferasirox, which is the non-proprietary name designated by USAN. The deferasirox molecule consists of three substituted phenyl groups, all covalently bonded (radiating from) a triazole structure. In this NDA deferasirox is proposed as an iron chelator.

At room temperature and atmospheric pressure, deferasirox appears as a white to slightly yellow powder. ☐

☐ Deferasirox has no chiral centers, and is not optically active.

Deferasirox is highly water-insoluble. It is highly lipid-soluble, and is observed to possess good permeability.

The drug product is a tablet in three proposed strengths: 125 mg, 250 mg, and 500 mg. The tablet(s) should be placed in an appropriate amount of liquid (described in package insert) and stirred until a suspension is obtained. The patient is to drink the resulting suspension. According to the package insert, doses should be calculated so that whole tablets will be used (calculated to the nearest whole tablet). When the suspension is prepared in water, the suspension appears white and opaque. During development of the drug, tests results were obtained that indicated several liquids could be used (see section P.2.6, Pharmaceutical Development/Compatibility).

The proposed name of the drug product is Exjade[®] (deferasirox) Tablets for Oral Suspension. At this time, the dosage form name "Tablet for Oral Suspension" does not exist in CDER Data Standards Manual C-DRG-00201, revision no. 2 (latest revision is

Executive Summary Section

dated 2000; this manual establishes dosage form names). However, in 2003, discussions were initiated with Capt. William A. Hess, Lexicographer/Center Consultant, the person responsible for maintaining Manual C-DRG-00201. Capt. Hess indicated it was possible to revise Manual C-DRG-00201 so that this and perhaps other appropriate dosage form names could be provided for. At this time, it is the understanding of the review division that this will be accomplished at an appropriate time.

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

The administration of the drug product is described above. The proposed indication is treatment of chronic iron overload due to blood transfusions (transfusional hemosiderosis). It is to be used for both adult patients and for pediatric patients aged 2 years and over.

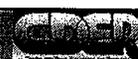
Package insert (Dosage and Administration section) indicates that after swallowing the suspension, any residue should be resuspended in liquid and swallowed. It is also indicated that tablets should not be swallowed whole.

It was determined that [redacted] for this drug substance, [redacted].
[redacted] The applicant indicates that [redacted] of the drug substance; it is indicated that [redacted] was necessary because [redacted].

C. Basis for Approvability or Not-Approval Recommendation

The reasons for the recommendation of approval are as follows:

- Inspections of all facilities are complete. Overall Compliance recommendation (dated August 2, 2005) is Acceptable;
- It has been indicated that the Proposed Dosage Form name (Tablet for Oral Suspension) will be added to CDER Data Standards Manual C-DRG-00201 (see section IIA above);
- Satisfactory responses by the firm to 19 information requests, sent to the applicant in a letter dated July 7, 2005. Responses to those requests, and evaluation of those responses, are provided in this review.



III. Administrative

A. Reviewer's Signature

B. Endorsement Block

ChemistName/Date: Same date as draft review

ChemistryTeamLeaderName/Date

ProjectManagerName/Date

C. CC Block

17 Page(s) Withheld



 § 552(b)(4) Trade Secret / Confidential

 § 552(b)(5) Deliberative Process

 § 552(b)(5) Draft Labeling

**This is a representation of an electronic record that was signed electronically and
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/s/

Ray Frankewich
10/12/2005 12:41:16 PM
CHEMIST

Liang Zhou
10/12/2005 12:47:39 PM
CHEMIST

NDA 21-882

Exjade[®] (deferasirox) Tablets for Oral Suspension

Novartis Pharmaceuticals Corp.

Raymond P. Frankewich, Ph.D.

Division of GI and Coagulation Drug Products (HFD-180)

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A. Reviewer's Signature	10
B. Endorsement Block	10
C. CC Block	10
Chemistry Assessment	11
I. Review Of Common Technical Document-Quality (Ctd-Q) Module 3.2: Body Of Data	11
S DRUG SUBSTANCE [deferasirox, Novartis Pharmaceuticals Corp.]	11
P DRUG PRODUCT [Exjade [®] Tablets for Oral Suspension, 125, 250, and 500 mg]	64
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II. Review Of Common Technical Document-Quality (Ctd-Q) Module 1	109
A. Labeling & Package Insert	109
B. Environmental Assessment Or Claim Of Categorical Exclusion	113
III. List Of Deficiencies To Be Communicated	113

Chemistry Review Data Sheet

- 1: NDA or ANDA 21-882
2. REVIEW #: 1
3. REVIEW DATE: July 6, 2005
4. REVIEWER: Raymond P. Frankewich, Ph.D.

5. PREVIOUS DOCUMENTS:

Previous Documents

Document Date

None

6. SUBMISSION(S) BEING REVIEWED:

Submission(s) Reviewed

Document Date

CMC Reviewable Unit

January 10, 2005

NDA

April 29, 2005

Amendment

May 10, 2005

Amendment

May 27, 2005

Amendment

June 29, 2005

7. NAME & ADDRESS OF APPLICANT:

Name: Novartis Pharmaceuticals Corporation

Address: One Health Plaza
East Hanover, NJ 07936-1080

Representative: Susan P. Nemeth, Ph.D., Associate Director, Drug
Regulatory Affairs

Telephone: (862) 778-2003

CHEMISTRY REVIEW

Chemistry Review Data Sheet

8. DRUG PRODUCT NAME/CODE/TYPE:

- a) Proprietary Name: None[®]
b) Non-Proprietary Name (USAN): deferasirox
c) Code Name/# (ONDC only): ICL670 / 201530-41-8 (CAS Registry Number)
d) Chem. Type/Submission Priority (ONDC only):
 • Chem. Type: 1
 • Submission Priority: S

9. LEGAL BASIS FOR SUBMISSION: NA for 505(b)(1).

10. PHARMACOL. CATEGORY: Metal chelator (code: 8016400)

11. DOSAGE FORM: Tablet (Tentative: Tab Soluble, code 507; see Executive Summary)

12. STRENGTH/POTENCY: 125, 250, and 500 mg

13. ROUTE OF ADMINISTRATION: (Oral, code 001)

14. Rx/OTC DISPENSED: Rx OTC

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

SPOTS product – Form Completed

Not a SPOTS product

16. CHEMICAL NAME, STRUCTURAL FORMULA, MOLECULAR FORMULA, MOLECULAR WEIGHT: See Section S.1 below.

17. RELATED/SUPPORTING DOCUMENTS:



CHEMISTRY REVIEW



Chemistry Review Data Sheet

A. DMFs:

DMF #	TYPE	HOLDER	ITEM REFERENCED	CODE ¹	STATUS ²	DATE REVIEW COMPLETED	COMMENTS
☐	III	☐	☐	3	Adequate	9/26/01 DMF Review Strike Force.	
	III			1	Adequate	3 / 05	
	III			3	Adequate	4 / 22 / 02	
	III			1	Adequate	7 / 05	
☐	III	☐	☐	1	Adequate	7 / 05	

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

CHEMISTRY REVIEW

Chemistry Review Data Sheet

18. STATUS: NOTE: The CMC section of this NDA was submitted as a Reviewable Unit on January 10, 2005. The rest of the NDA was submitted on April 29, 2005. As a result, many of the consult reviews below will be listed as pending.

ONDC:

CONSULTS/ CMC RELATED REVIEWS	RECOMMENDATION	DATE	REVIEWER
Biometrics	Pending	7-6-05	None noted in DSS
EES	3 facilities Pending, rest AC	7-6-05	Frankewich / Shawnte Adams (Pre-approval Manager)
Pharm/Tox	Pending	7-6-05	Tamal K. Chakraborti, Ph.D.
Biopharm	Pending	7-6-05	None noted in DSS
DDMAC	Pending	4-29-05	Consult sent to Elaine Hu, Shannon Benedetto
DMETS	Pending (consult for proposed tradename, labels)	4-29-05	No name on consult request
Methods Validation	To be requested after resolution of concerns with analytical procedures	7-6-05	Frankewich
EA	None (see comment in Appendix III)	7-6-05	Frankewich
CDRH (HFZ-450)	Pending (evaluation of SQUID)	7-6-05	Elias Mallis/Charles Ho
Microbiology	NA	-	-

OGD:

CONSULTS/ CMC RELATED REVIEWS	RECOMMENDATION	DATE	REVIEWER
Microbiology			
EES			
Methods Validation			
Labeling			
Bioequivalence			
EA			
Radiopharmaceutical			



CHEMISTRY REVIEW



Chemistry Review Data Sheet

19. ORDER OF REVIEW (OGD Only)

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

Appears This Way
On Original

The Chemistry Review for NDA 21-882

The Executive Summary

I. Recommendations

A. Recommendation and Conclusion on Approvability

Approvable for CMC. Pending issues are EER, and responses to information requests in DR letter.

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

None at this time.

II. Summary of Chemistry Assessments

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

Drug substance is known as deferasirox, which is the non-proprietary name designated by USAN. The deferasirox molecule consists of three substituted phenyl groups, all covalently bonded (radiating from) a triazole structure. In this NDA deferasirox is proposed as an iron chelator.

At room temperature and atmospheric pressure, deferasirox appears as a white to slightly yellow powder. □

Deferasirox has no chiral centers, and is not optically active.

Deferasirox is highly water-insoluble. It is highly lipid-soluble, and is observed to possess good permeability.

The drug product is a tablet in three proposed strengths: 125 mg, 250 mg, and 500 mg. The tablet(s) should be placed in an appropriate amount of liquid (described in package insert) and stirred until a suspension is obtained. The patient is to drink the resulting suspension. According to the package insert, doses should be calculated so that whole tablets will be used (calculated to the nearest whole tablet). When the suspension is prepared in water, the suspension appears white and opaque. During development of the drug, tests results were obtained that indicated several liquids could be used (see section P.2.6, Pharmaceutical Development/Compatibility).

The proposed name of the drug product is Exjade[®] (deferasirox) Tablets for Oral Suspension. At this time, the dosage form name "Tablet for Oral Suspension" does not

Executive Summary Section

exist in CDER Data Standards Manual C-DRG-00201, revision no. 2 (latest revision is dated 2000; this manual establishes dosage form names). However, in 2003, discussions were initiated with Capt. William A. Hess, Lexicographer/Center Consultant, the person responsible for maintaining Manual C-DRG-00201. Capt. Hess indicated it was possible to expand Manual C-DRG-00201 so that appropriate dosage form names could be provided for. This issue will be considered further, and any decisions or results will be reported in future CMC reviews.

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

The administration of the drug product is described above. The proposed indication is treatment of chronic iron overload due to blood transfusions (transfusional hemosiderosis). It is to be used for both adult patients and for pediatric patients aged 2 years and over.

Package insert (Dosage and Administration section) indicates that after swallowing the suspension, any residue should be resuspended in liquid and swallowed. It is also indicated that tablets should not be swallowed whole.

It was determined that [redacted] for this drug substance, [redacted] of the drug substance. The applicant indicates that [redacted] of the drug substance; it is indicated that [redacted] was necessary because [redacted]

C. Basis for Approvability or Not-Approval Recommendation

The primary reason for the Approvable recommendation is because of the outstanding inspections (see section P.3.1, Drug Product Manufacturers). Inspection was scheduled for the Novartis Basel facility (CFN# 9692042, drug substance manufacturer) for May 30 – June 1, 2005 (for CSN profile). Inspections were scheduled for the Novartis Stein facility (CFN# 9692043, drug product manufacturer, drug substance [redacted] for June 6 – 9, 2005 (for the CRU and TCM profiles). The inspection of [redacted] which performs [redacted] the drug product, was scheduled for June 3, 2005.

Another outstanding issue is the name of the dosage form, discussed above.

There are a total of 19 information requests (that do not involve labeling) are listed in the section of this review entitled List Of Comments To Be Communicated in Action Letter. These requests will be sent to the applicant. It is expected that these issues will be addressed in this review cycle. The most important issues appearing in the List of Comments are these:

- Clarification and justification of some of the parameters and acceptance criteria for the tests [redacted] For a dosage form of this kind, in which a tablet is to be dispersed in liquid, these tests are important indicators of bioavailability of the drug substance;

Executive Summary Section

- Whether or not the tests ζ will be performed for stability evaluation of annual batches of drug product, and for stability evaluation for post-approval changes (comment no. 18);
- It does not appear that any stability data has been submitted for drug substance manufactured at one of the proposed sites for drug substance manufacturing (located at Pratteln, Switzerland). It also does not appear that any stability data for drug product manufactured with drug substance produced at the Pratteln, Switzerland site has been submitted.

III. Administrative**A. Reviewer's Signature****B. Endorsement Block**

ChemistName/Date: Same date as draft review
ChemistryTeamLeaderName/Date
ProjectManagerName/Date

C. CC Block

106 Page(s) Withheld

✓ § 552(b)(4) Trade Secret / Confidential

 § 552(b)(5) Deliberative Process

 § 552(b)(5) Draft Labeling

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/s/

Ray Frankewich
7/6/05 03:00:41 PM
CHEMIST

Liang Zhou
7/6/05 03:47:36 PM
CHEMIST

NDA 21-882

Exjade (deferatorix) Tablets for Oral Suspension

Environmental Assessment-See October 12, 2005 cmc review for the request for categorical exclusion form conducting an Environmental Assessment.

Alice Kacuba 10-16-05

Alice Kacuba

Regulatory Health Project Manager

NDA 21-882

Exjade (deferasorix) Tablets for Oral Suspension

Methods Validation-This section is Not Applicable for this application.

Alice Kacuba 10-17-05

Alice Kacuba

Regulatory Health Project Manager

NDA 21-882

Exjade (deferasorix) Tablets for Oral Suspension

Statistical Review-stability-This section is not applicable for this application.

Alice Kacuba 7/1/05

Alice Kacuba

Regulatory Health Project Manager

NDA 21-882

Exjade (deferasorix) Tablets for Oral Suspension

Microbiology Review-sterilization-This section is not applicable for this application.

Alice Kacuba 7-11-05

Alice Kacuba

Regulatory Health Project Manager

Establishment : CFN : 9611204 FEI : 3002807772

NOVARTIS PHARMA INC
LICHSTRASSE 35, ST. JOHANN SITE
BASEL, , CH

DMF No: AADA:

Responsibilities: DRUG SUBSTANCE MANUFACTURER

Profile : CSN OAI Status: NONE

Last Milestone: OC RECOMMENDATION

Milestone Date: 29-MAR-05

Decision : ACCEPTABLE

Reason : DISTRICT RECOMMENDATION

Establishment : CFN : 9612715 FEI : 3002807776

NOVARTIS PHARMA INC
CORK
RINGASKIDDY, CORK, , EI

DMF No: AADA:

Responsibilities: DRUG SUBSTANCE RELEASE TESTER
DRUG SUBSTANCE STABILITY TESTER

ESTABLISHMENT EVALUATION REQUEST

SUMMARY REPORT

Profile : CTL OAI Status: NONE
 Last Milestone: OC RECOMMENDATION
 Milestone Date: 29-MAY-05
 Decision : ACCEPTABLE
 Reason : DISTRICT RECOMMENDATION

Establishment : CFN : 9692042 FEI : 3002865753
 NOVARTIS PHARMA STEIN AG
 SCHWEIZERHALLE, BASEL, SZ

DMF No: AADA:

Responsibilities: DRUG SUBSTANCE MANUFACTURER

Profile : CSN OAI Status: NONE
 Last Milestone: OC RECOMMENDATION
 Milestone Date: 20-JUL-05
 Decision : ACCEPTABLE
 Reason : DISTRICT RECOMMENDATION

Establishment : CFN : 9692043 FEI : 3002653483
 NOVARTIS PHARMA STEIN AG
 SCHAFFHAUSERSTRASSE
 STEIN, , SZ

DMF No: AADA:

Responsibilities: DRUG SUBSTANCE
 FINISHED DOSAGE MANUFACTURER

Profile : CRU OAI Status: NONE
 Last Milestone: OC RECOMMENDATION
 Milestone Date: 02-AUG-05

Decision : ACCEPTABLE
Reason : DISTRICT RECOMMENDATION
Profile : TCM OAI Status: NONE
Last Milestone: OC RECOMMENDATION
Milestone Date: 02-~~24~~5-05
Decision : ACCEPTABLE
Reason : DISTRICT RECOMMENDATION

Establishment : CFN : 2416082 FEI : 2416082

NOVARTIS PHARMACEUTICALS CORP

OLD MILL RD

SUFFERN, NY 10901

DMF No: AADA:

Responsibilities: FINISHED DOSAGE PACKAGER
FINISHED DOSAGE RELEASE TESTER
FINISHED DOSAGE STABILITY TESTER

Profile : CTL OAI Status: NONE
Last Milestone: OC RECOMMENDATION
Milestone Date: 22-MAR-05
Decision : ACCEPTABLE
Reason : BASED ON PROFILE

ESTABLISHMENT EVALUATION REQUEST

SUMMARY REPORT

Profile : TCM OAI Status: NONE
 Last Milestone: OC RECOMMENDATION
 Milestone Date: 22-MAR-05
 Decision : ACCEPTABLE
 Reason : BASED ON PROFILE

Establishment : CFN : [] FEI : []

DMF No: AADA:

Responsibilities: []

Profile : CTL OAI Status: NONE
 Last Milestone: OC RECOMMENDATION
 Milestone Date: 02-AUG-05
 Decision : ACCEPTABLE
 Reason : DISTRICT RECOMMENDATION