CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-730

CHEMISTRY REVIEW(S)

CMC TEAM LEADER'S MEMORANDUM

Date: March 11, 2005

To: NDA 21-730

From: Rik Lostritto, Ph.D
Team Leader, DNDC-II, ONDC and
Division of Pulmonary and Allergy Drug Products HFD-570

Product: XOPENEX HFA (levalbuterol tartrate) Inhalation Aerosol

Applicant: Sepracor, Inc.

Administrative and Introduction

XOPENEX HFA inhalation aerosol was submitted by Sepracor as NDA 21-730 on 5/12/04, under Section 505(b)(2). The PDUFA due date for this standard NDA application is 3/12/05. The proposed indication is for the treatment of bronchospasm in adults, adolescents, and children 4 years of age and older with asthma.

The drug product is a pressurized metered dose inhaler (MDI) containing micronized $(levalbuterol)_2$ tartrate in a suspension formulation with HFA-134a (propellant), Dehydrated Alcohol USP and Oleic Acid, NF. Levalbuterol is the (R)-enantiomer of the $beta_2$-adrenergic receptor agonist albuterol. Levalbuterol hydrochloride is used in another approved drug product (Sepracor's Xopenex Inhalation Solution, N20-837, approved 5/25/99).

This MDI drug product emits a dose of 45mcg levalbuterol base per actuation (equivalent to 59mcg levalbuterol tartrate). The proposed dose is 2 actuations every 4 to 6 hours.

Chemistry Review #1 was completed by the primary CMC Reviewing Chemist on 12/30/04 and an Information Request letter was went to the applicant communicating all deficiencies. The applicant provided a complete response to all deficiencies (except labeling) on 2/04/05. Further labeling discussions followed and the chemistry Review #2 was completed 3/09/05 with a recommendation for APPROVAL.

Chemistry, Manufacturing, and Controls Evaluation

Consults for EER, Microbiology, and PharmTox (leachables assessment) were initiated early in the review cycle.

The drug substance levalbuterol tartrate (USAN) is manufactured by Sepracor in Nova Scotia, Canada and it is the same site as used for the currently approved levalbuterol hydrochloride which is used in the applicant's inhalation solution drug product. The drug

substance for this NDA is micronized by [redacted] There were no deficiency issues with the micronized drug substance.

The MDI drug product is manufactured for Sepracor by 3M in Northridge, CA. There is only one package presentation (15 gram target fill for 200 actuations) with the following formulation:

Component	Function	Amount per actuation	Amount per canister
Levalbuterol tartrate	Active	[redacted]	[redacted]
Oleic Acid, NF	[redacted]	[redacted]	[redacted]
Dehydrated Alcohol, USP	[redacted]	[redacted]	[redacted]
HFA-134a	Propellant	[redacted]	[redacted]
TOTAL	---	60.00 mg	15.00 g

*equivalent to [redacted] ug of levalbuterol base ex-VALVE which corresponds to [redacted] g of levalbuterol base ex-ACTUATOR.

The MDIs are manufactured using [redacted]

The actuator is a single piece of [redacted] manufactured by [redacted] This simple but important component provides for final mechanical break up of the emitted formulation and spray pattern formation for oral inhalation.

The NDA was filed with [redacted] of stability data at 25C/60%RH, [redacted] at 30C/60%RH and [redacted] at 40C/75%RH. On 12/24/04, the applicant updated the stability data base to [redacted] at 25C/60%RH.

It is noteworthy that the applicant followed Agency DRAFT guidance recommendations for MDI drug products with respect to setting specifications for Dose Content Uniformity (DCU) and APSD Mass Balance. This further facilitated the primary review.

A complete list of sixteen CMC deficiencies were communicated to the applicant in an IR letter dated 12/30/04 and may be summarized in the following categories:

- improve excipient controls
- clarify and improve in process manufacturing controls
- provide data to substantiate the —
- regroup APSD cascade impactor stage groupings and adjust acceptance criteria
- provide missing test method descriptions
- revise — specification better reflect the data provided
- provide plans for a dose counting mechanism
- labeling issues

On 2/04/05, the applicant provided a complete response to all deficiencies except for labeling issues.

Also, all consults (EER, Microbiology, and PharmTox) came back affirming an approval CMC recommendation. The PharmTox consult required the applicant to revise leachable limits to lower levels. These limits were accepted by the applicant.

The applicant requested a 24 month shelf life and it was granted.

The CMC labeling issues were resolved on 3/03/05 and the second primary review was promptly completed on 3/09/05. The following labeling comments are noted:

XOPENEX HFA (levalbuterol tartrate) Inhalation Aerosol is supplied as a pressurized aluminum canister in a box (NDC 63402-510-01). The canister is labeled with a net weight of 15 g and contains 200 metered actuations (or inhalations). Each canister is supplied with a blue plastic actuator (or mouthpiece), a red mouthpiece cap, and patient's instructions.

SHAKE WELL BEFORE USING. Store between 20° and 25°C (68° and 77°F; see USP controlled room temperature). Protect from freezing temperatures and direct sunlight. Store inhaler with the actuator (or mouthpiece) down. Avoid spraying in eyes. Contents under pressure. Do not puncture or incinerate. Exposure to temperatures above 120°F may cause bursting. Keep out of reach of children.
The blue actuator supplied with XOPENEX HFA should not be used with any other product canisters. Actuators from other products should not be used with a XOPENEX HFA canister. The correct amount of medication in each actuation cannot be assured after 200 actuations, even though the canister is not completely empty. The canister should be discarded when 200 actuations have been used.

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

/s/

Richard Lostritto
3/11/05 10:55:05 AM
CHEMIST

Richard Lostritto
3/11/05 10:57:50 AM
CHEMIST

NDA 21-730

Xopenex HFA
(levalbuterol tartrate)
Inhalation Aerosol

Sepracor, Inc.

Reviewer: Suong Tran, PhD

Division of Pulmonary Drug Products

Table of Contents

Chemistry Review Data Sheet

1. NDA 21-730

2. REVIEW #: 2

3. REVIEW DATE: 9-MAR-2005

4. REVIEWER: Suong Tran, PhD

5. PREVIOUS DOCUMENTS:
   Chemistry Review #1
   Chemistry Information Request Letter dated 5-JAN-2005
   Chemistry Information Request Letter dated 22-FEB-2005

6. SUBMISSION(S) BEING REVIEWED:

Submission(s) Reviewed	Document Date
Amendment	4-FEB-2005
Amendment	3-MAR-2005

7. NAME & ADDRESS OF APPLICANT:

   Sepracor, Inc.
   84 Waterford Drive
   Marlborough MA 01752-7010

8. DRUG PRODUCT NAME/CODE/TYPE:

   Full Name: Xopenex™ HFA (levalbuterol tartrate) Inhalation Aerosol
   Non-Proprietary Name (USAN): levalbuterol tartrate
   Code Name/# (OGD only): Not Applicable
   Chem. Type(ONDC only): 2
   Submission Priority(ONDC only): S

9. LEGAL BASIS FOR SUBMISSION: Not Applicable

10. INDICATION: Treatment or prevention of bronchospasm in adults, adolescents, and children 4 years of age and older, with reversible obstructive airway disease.

11. DOSAGE FORM: inhalation aerosol

12. STRENGTH/POTENCY: 45 µg levalbuterol per actuation

13. ROUTE OF ADMINISTRATION: oral inhalation

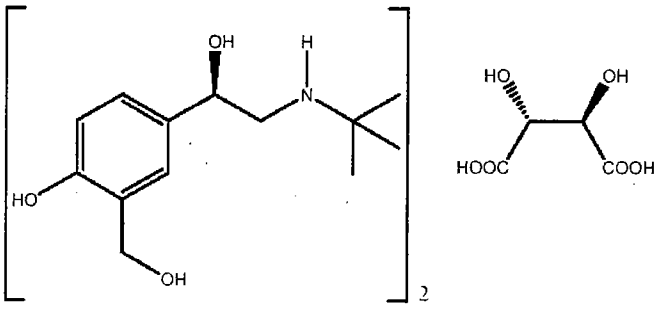
14. Rx/OTC DISPENSED: _x_ Rx ___OTC

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

____SPOTS product – Form Completed

__x__Not a SPOTS product

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



Molecular Formula: $(C_{13}H_{21}NO_3)_2 \cdot C_4H_6O_6$

Formula Weight: 628.71

CAS 661464-94-4

Chemical Name: (R)-α^1-[[(1,1-Dimethylethyl)amino]methyl]-4-hydroxy-1,3-benzenedimethanol hemi-L-tartrate salt

(R)- α^1-[[(1,1-Dimethylethyl)amino]methyl]-4-hydroxy-1,3-benzenedimethanol L-tartrate (2 :1 salt)

USAN: Levalbuterol tartrate

17. RELATED/SUPPORTING DOCUMENTS:

A. DMFs:

DMF	TYPE	HOLDER	ITEM REFERENCED	CODE[1]	STATUS[2]	REVIEW COMPLETED	COMMENT
✓	IV			3	Adequate	27-APR-2004	
✓	III			4	N/A	N/A	Refer to DMF ✓
✓	III			3	Adequate	20-DEC-2002	
✓	III			4	N/A	N/A	Refer to DMF ✓

DMF	TYPE	HOLDER	ITEM REFERENCED	CODE[1]	STATUS[2]	REVIEW COMPLETED	COMMENT
	III			3	Adequate	27-OCT-2004	
	III			3	Adequate	12-OCT-2004	
	III			3	Adequate	28-AUG-2003	

[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: none

18. STATUS:

ONDC:

CONSULTS/ CMC RELATED REVIEWS	RECOMMENDATION	DATE	REVIEWER
Biometrics	*Not Applicable*		
EES	Acceptable	25-AUG-2004	J. D'Ambrogio
Pharm/Tox	Acceptable (with recommended limits on specific extractables/leachables, which were accepted by the applicant in the final drug product specification dated 3-MAR-2005)	17-FEB-2005	V. Whitehurst
ClinPharm	*Not Applicable*		
LNC	*Not Applicable*		
Methods Validation	Package will be submitted to FDA labs after test methods are finalized.		
EA	*Not Applicable*		
Microbiology	Acceptable (acceptance criteria for Microbial Limits and adequacy of Microbial Challenge study)	4-MAR-2005	S. Languille
CDRH	*Not Applicable*		

19. ORDER OF REVIEW (OGD Only) Not Applicable

The Executive Summary

Recommendations

A. Recommendation and Conclusion on Approvability

The final recommendation from Chemistry is "Approval".

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

Post-marketing agreement - As requested by FDA in the 5-JAN-2005 Chemistry Information Request letter, the applicant agrees to integrate a dose counting mechanism as follows:

4-FEB-2005 amendment:
"Sepracor agrees to a post-approval commitment for the integration of a dose counting mechanism for our Xopenex MDI product.

Summary of Chemistry Assessments

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

Drug product –

- Name: Xopenex HFA (levalbuterol tartrate) Inhalation Aerosol
- Strength: 45 µg (free base) per actuation
- Dosage form: suspension for inhalation (with metered dose inhaler)
- Formulation: micronized levalbuterol tartrate, dehydrated alcohol USP, oleic acid NF, and HFA-134a.
- Primary packaging: µL metered valve, canister, and .nm-orifice actuator with dust cap.
- Stability data: Primary stability data are for batches used in 2 of the 3 pivotal studies). All batches were manufactured at the commercial site, and packaged in the commercial primary container/closure system (no protective secondary packaging). Data are provided for at 25 °C/60% RH, at 30 °C/60% RH, and , at 40 °C/75% RH.

Drug substance –

- USAN: levalbuterol tartrate

- The drug substance is micronized levalbuterol tartrate. The currently approved NDA 20-837 (levalbuterol HCl) is referenced for the synthesis of the
- The drug substance is

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

- Dosage administration: 2 actuations by oral inhalation per dose
- Daily dose: For treatment of acute episodes of bronchospasm or prevention of asthmatic symptoms, the usual dosage for adults and children 4 years of age and older is 2 oral inhalations (90 mcg) repeated every 4 to 6 hours.
- Expiry: 24 months at controlled room temperature based on stability data provided in the NDA.

C. Basis for Approvability or Not-Approval Recommendation

- An "Acceptable" recommendation on the safety of proposed acceptance criteria for Extractables, Leachables, and Particulate Matter was obtained from the Pharm. Tox. reviewer (V. Whitehurst) on 17-FEB-2005 with recommended limits on the leachables/extractables , (NMT), NMT , and (NMT . These limits were accepted by the applicant in the revised drug product specification included in the 3-MAR-2005 amendment.
- A recommendation for "approval" was obtained from the Microbiology Team on 4-MAR-2005.
- The "Acceptable" recommendation on the GMP status of facilities was issued on 25-AUG-2004 by the Office of Compliance.

Administrative

A. Reviewer's Signature

Electronically captured in DFS

B. Endorsement Block

Electronically captured in DFS

C. CC Block

Electronically captured in DFS

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_ § 552(b)(5) Deliberative Process

_ § 552(b)(4) Draft Labeling

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/s/

Suong Tran
3/9/05 10:02:45 AM
CHEMIST

revised per your instructions

Richard Lostritto
3/9/05 02:35:51 PM
CHEMIST

NDA 21-730

Xopenex HFA
(levalbuterol tartrate)
Inhalation Aerosol

Sepracor, Inc.

Reviewer: Suong Tran, PhD

Division of Pulmonary Drug Products

Table of Contents

Chemistry Review Data Sheet

1. NDA 21-730

2. REVIEW #: 1

3. REVIEW DATE: 30-DEC-2004

4. REVIEWER: Suong Tran, PhD

5. PREVIOUS DOCUMENTS: none

6. SUBMISSION(S) BEING REVIEWED:

Submission(s) Reviewed	Document/DFS Date
Original	11-MAY-2004
Amendment	6-JUL-2004
Amendment	24-DEC-2004

7. NAME & ADDRESS OF APPLICANT:

   Sepracor, Inc.
   84 Waterford Drive
   Marlborough MA 01752-7010

8. DRUG PRODUCT NAME/CODE/TYPE:

   Full Name: Xopenex™ HFA (levalbuterol tartrate) Inhalation Aerosol
   Non-Proprietary Name (USAN): levalbuterol tartrate
   Code Name/# (OGD only): Not Applicable
   Chem. Type(ONDC only): 2
   Submission Priority(ONDC only): S

9. LEGAL BASIS FOR SUBMISSION: Not Applicable

10. INDICATION: Treatment or prevention of bronchospasm in adults, adolescents, and children 4 years of age and older, with reversible obstructive airway disease.

11. DOSAGE FORM: inhalation aerosol

12. STRENGTH/POTENCY: 45 µg levalbuterol per actuation

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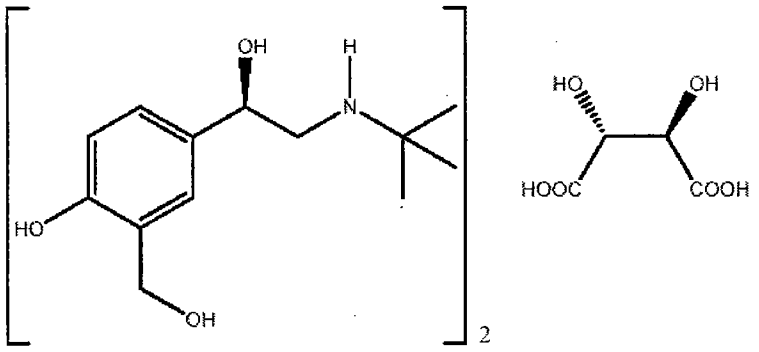

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CAS 661464-94-4

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	III			4	N/A	N/A	Refer to DMF
	III			3	Adequate	20-DEC-2002	

DMF	TYPE	HOLDER	ITEM REFERENCED	CODE[1]	STATUS[2]	REVIEW COMPLETED	COMMENT
	III			4	N/A	N/A	Refer to DMF [redacted]
	III			3	Adequate	27-OCT-2004	
	III			3	Adequate	12-OCT-2004	
	III			3	Adequate	28-AUG-2003	

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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: none

18. STATUS:

ONDC:

CONSULTS/ CMC RELATED REVIEWS	RECOMMENDATION	DATE	REVIEWER
Biometrics	*Not Applicable*		
EES	**Acceptable**	25-AUG-2004	J. D'Ambrogio
Pharm/Tox	**Ongoing review by Pharm.Tox.** Review of acceptance criteria for Extractables and Leachables.		
ClinPharm	*Not Applicable*		
LNC	*Not Applicable*		
Methods Validation	Package will be submitted to FDA labs after test methods are finalized.		
EA	*Not Applicable*		
Microbiology	**Ongoing review by Microbiology** Review of acceptance criteria for Microbial Limits and adequacy of Microbial Challenge study.		
CDRH	*Not Applicable*		

19. ORDER OF REVIEW (OGD Only) Not Applicable

APPEARS THIS WAY
ON ORIGINAL

APPEARS THIS WAY
ON ORIGINAL

APPEARS THIS WAY
ON ORIGINAL

The Executive Summary

Recommendations

A. Recommendation and Conclusion on Approvability

The final recommendation from Chemistry is approvable pending a satisfactory response to the chemistry issues delineated in the attached draft letter and satisfactory recommendations from Microbiology and Pharm. Tox. reviewers.

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

A post-approval commitment is requested (see Draft Information Request at the end of this review) for the integration of a dose counting mechanism in the MDI.

Summary of Chemistry Assessments

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

Drug product –

- Name: Xopenex HFA (levalbuterol tartrate) Inhalation Aerosol
- Strength: 45 µg (free base) per actuation
- Dosage form: suspension for inhalation (with metered dose inhaler)
- Formulation: micronized levalbuterol tartrate, dehydrated alcohol USP, oleic acid NF, and HFA-134a.
- Primary packaging: — , metered valve, — , canister, and —mm-orifice actuator with dust cap.
- Stability data: Primary stability data are for batches — (also a clinical batch used in 2 of the 3 pivotal studies) — All batches were manufactured at the commercial site, and packaged in the commercial primary container/closure system (no protective secondary packaging). Data are provided for — at 25 °C/60% RH, — at 30 °C/60% RH, and — months at 40 °C/75% RH.

Drug substance –

- USAN: levalbuterol tartrate
- The drug substance is micronized levalbuterol tartrate (2:1). The currently approved NDA 20-837 (levalbuterol HCl) is referenced for the synthesis of —
- The drug substance is —

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

- Dosage administration: 2 actuations per dose
- Daily dose: For treatment of acute episodes of bronchospasm or prevention of asthmatic symptoms, the usual dosage for adults and children 4 years of age and older is 2 inhalations (90 mcg) repeated every 4 to 6 hours.
- Expiry: 24 months at controlled room temperature based on stability data provided in the NDA.

C. Basis for Approvability or Not-Approval Recommendation

- A recommendation on the safety of proposed acceptance criteria for Extractables, Leachables, and Particulate Matter is pending from the Pharm. Tox. reviewer.
- A recommendation on the safety of proposed acceptance criteria for Microbial Limits and adequacy of the Microbial Challenge study is pending from the Microbiology Team.
- The "Acceptable" recommendation on the GMP status of facilities was issued on 25-AUG-2004 by the Office of Compliance.
- The chemistry recommendation is approvable pending satisfactory recommendations from the consults listed above and a satisfactory response to issues delineated in the draft letter.

Administrative

A. Reviewer's Signature

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B. Endorsement Block

Electronically captured in DFS

C. CC Block

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/s/

Suong Tran
12/30/04 02:44:57 PM
CHEMIST

revised per your instructions

Richard Lostritto
1/3/05 11:09:19 AM
CHEMIST

CHEMISTRY NDA FILEABILITY CHECKLIST

NDA: 21-730
Applicant: Sepracor Inc.
Letter Date: 11-MAY-2004

Proposed Drug Name: Xopenex HFA (levalbuterol tartrate) Inhalation Aerosol

IS THE CMC SECTION OF APPLICATION FILEABLE? Yes

The following parameters are necessary in order to initiate a full review, i.e., complete enough to review but may have deficiencies.

	Parameter	Yes	No	Comment
1	On its face, is the section organized adequately?	X		
2	Is the section indexed and paginated adequately?	X		
3	On its face, is the section legible?	X		
4	Are ALL of the facilities (including contract facilities and test laboratories) identified with full street addresses and CFNs?	X		
5	Is a statement provided that all facilities are ready for GMP inspection?	X		All facilities are listed.
6	Has an environmental assessment report or categorical exclusion been provided?	X		
7	Does the section contain controls for the drug substance?	X		
8	Does the section contain controls for the drug product?	X		
9	Have stability data and analysis been provided to support the requested expiration date?	X		
10	Has all information requested during the IND phase, and at the pre-NDA meetings been included?	X		
11	Have draft container labels been provided?	X		
12	Has the draft package insert been provided?	X		
13	Has an investigational formulations section been provided?	X		
14	Is there a Methods Validation package?	X		
15	Is a separate microbiological section included?	Not applicable		Product is not sterile. A Microbiology consult may be requested for the review of Microbial Limits, test method, and microbial challenge test.

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_ § 552(b)(5) Deliberative Process

_ § 552(b)(4) Draft Labeling

Conclusion: **NDA is ACCEPTABLE FOR FILING.**

- **Samples of the drug product as well as a disassembled container/closure system should be provided.**

Comments:

- See the attached Chemist's Review Notes for additional information.

Review Chemist: *electronic signature in DFS*

Team Leader: *electronic signature in DFS*

cc: *on file in DFS*

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/s/

Suong Tran
3/8/2006 10:51:51 AM
CHEMIST

Suong Tran
3/8/2006 10:54:10 AM
CHEMIST

ESTABLISHMENT EVALUATION REQUEST

SUMMARY REPORT

Application : NDA 21730/000
Org Code : 570
Priority : 3S

Sponsor: SEPRACOR
84 WATERFORD DR
MARLBOROUGH, MA 01752

Stamp Date : 12-MAY-2004
PDUFA Date : 12-MAR-2005
Action Goal :
District Goal: 11-JAN-2005

Brand Name : XOPENEX HFA (LEVALBUTEROL TARTRATE)INHAL
Estab. Name:
Generic Name: LEVALBUTEROL TARTRATE HFA INHALATION AER
Dosage Form: (AEROSOL)
Strength : 45 MCG/ACT.(EX-ACT.)

FDA Contacts:	A. GREEN	Project Manager	(HFD-570) 301-827-5585
	S. TRAN	Review Chemist	(HFD-580) 301-827-4260
	R. LOSTRITTO	Team Leader	(HFD-570) 301-827-1053

Overall Recommendation: ACCEPTABLE on 25-AUG-2004by J. D AMBROGIO(HFD-322) 301-827-9049

Establishment : CFN : 2010441 FEI : 2010441
3M PHARMACEUTICALS INC
19901 NORDHOFF ST

NORTHRIDGE, CA 91328

DMF No: AADA:

Responsibilities: FINISHED DOSAGE MANUFACTURER

Profile : ADM OAI Status: NONE
Last Milestone: OC RECOMMENDATION
Milestone Date: 14-JUL-04
Decision : ACCEPTABLE
Reason : DISTRICT RECOMMENDATION

Establishment : CFN : — FEI : —

DMF No: AADA:

Responsibilities: —

Profile : CTL OAI Status: NONE
Last Milestone: OC RECOMMENDATION
Milestone Date: 28-JUN-04
Decision : ACCEPTABLE
Reason : DISTRICT RECOMMENDATION

Establishment : CFN : — FEI : —

DMF No: AADA:

FDA CDER EES

ESTABLISHMENT EVALUATION REQUEST

SUMMARY REPORT

Responsibilities:

Profile : CTL OAI Status: NONE
Last Milestone: OC RECOMMENDATION
Milestone Date: 22-JUN-04
Decision : ACCEPTABLE
Reason : BASED ON PROFILE

Establishment : CFN : FEI :

DMF No: AADA:

Responsibilities:

Profile : CTL OAI Status: NONE
Last Milestone: OC RECOMMENDATION
Milestone Date: 22-JUN-04
Decision : ACCEPTABLE
Reason : BASED ON PROFILE

Establishment : CFN : FEI :

DMF No: AADA:

Responsibilities:

Profile : CRU OAI Status: NONE
Last Milestone: OC RECOMMENDATION
Milestone Date: 23-JUN-04
Decision : ACCEPTABLE
Reason : DISTRICT RECOMMENDATION

Establishment : CFN : FEI :

DMF No: AADA:

Responsibilities:

Profile : CTL OAI Status: NONE
Last Milestone: OC RECOMMENDATION
Milestone Date: 22-JUN-04

Decision : ACCEPTABLE

Reason : BASED ON PROFILE

Establishment : CFN : FEI :

ESTABLISHMENT EVALUATION REQUEST

SUMMARY REPORT

DMF No: AADA:

Responsibilities:

Profile : CSN OAI Status: NONE

Last Milestone: OC RECOMMENDATION

Milestone Date: 24-JUN-04

Decision : ACCEPTABLE

Reason : DISTRICT RECOMMENDATION

Establishment : CFN : 9615342 FEI : 3002808239

SEPRACOR INC

24 IVEY LANE

WINDSOR, NOVA SCOTIA, CA

DMF No: AADA:

Responsibilities: DRUG SUBSTANCE MANUFACTURER

Profile : CSN OAI Status: NONE
Last Milestone: OC RECOMMENDATION
Milestone Date: 24-JUN-04
Decision : ACCEPTABLE
Reason : DISTRICT RECOMMENDATION

Establishment : CFN : — FEI :

DMF No: AADA:

Responsibilities: —

Profile : CTL OAI Status: NONE
Last Milestone: OC RECOMMENDATION
Milestone Date: 22-JUN-04
Decision : ACCEPTABLE
Reason : BASED ON PROFILE
