CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

ANDA 76-458

CHEMISTRY REVIEW(S)

ANDA 76-458

Fluoxetine Oral Solution, USP

Par Pharmaceutical, Inc.

Lucia C. Tang
Chemistry Divison II

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II. Summary of Chemistry Assessments 7

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B. Description of How the Drug Product is Intended to be Used 7

C. Basis for Approvability or Not-Approval Recommendation 8

III. Administrative 8

A. Reviewer's Signature 8

B. Endorsement Block 8

C. CC Block 8

Chemistry Assessment 9

I. Review Of Common Technical Document-Quality (Ctd-Q) Module 3.2: Body Of Data .....

S DRUG SUBSTANCE [Name, Manufacturer] .....

P DRUG PRODUCT [Name, Dosage form] .....

A APPENDICES .....

R REGIONAL INFORMATION .....

II. Review Of Common Technical Document-Quality (Ctd-Q) Module 1 .....

A. Labeling & Package Insert .....

B. Environmental Assessment Or Claim Of Categorical Exclusion .....

III. List Of Deficiencies To Be Communicated .....

Chemistry Review Data Sheet

1. ANDA #76-458

2. REVIEW #:1

3. REVIEW DATE: November 6, 2002

4. REVIEWER: Lucia C. Tang

5. PREVIOUS DOCUMENTS:

Previous Documents	Document Date
N/A	

6. SUBMISSION(S) BEING REVIEWED:

Submission(s) Reviewed	Document Date
Original submission	7-15-2002

7. NAME & ADDRESS OF APPLICANT:

Name: Par Pharmaceutical, Inc.

Address: One Ram Ridge Road, Spring Valley, NY 10977

Representative: Michelle Bonomi-Huvala

Telephone: 845-425-7100

Chemistry Review Data Sheet

8. DRUG PRODUCT NAME/CODE/TYPE:

a) Proprietary Name: N/A
b) Non-Proprietary Name (USAN): Fluoxetine Hydrochloride Oral Solution

9. LEGAL BASIS FOR SUBMISSION:

Innovator Product: Prozac□Liquid, 20 mg/5mL
Innovator Company: Eli Lilly & Co.
US Patent 4,314,081 Expiration Date: 2/02/01
US Patent 4,626,549 Expiration Date: 12/02/03
US Patent 4,626549*PED Expiration Date: 6/02/04

There exist no listed exclusivities for the referenced drug product, Prozac, for NDA #20-101

10. PHARMACOL. CATEGORY:

Antidepressant

11. DOSAGE FORM:

Oral Solution

12. STRENGTH/POTENCY:

20 mg /5 mL

13. ROUTE OF ADMINISTRATION:

Oral

14. Rx/OTC DISPENSED: _x__Rx ___OTC

15. SPOTS (SPECIAL PRODUCTS ON-LINE TRACKING SYSTEM)[Note24]:

_____SPOTS product – Form Completed

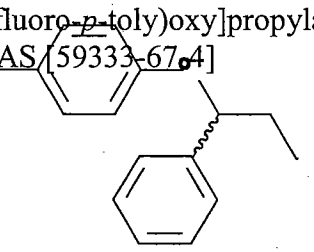
____x_Not a SPOTS product

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

Fluoxetine Hydrochloride

Formula: $C_{17}H_{18}F_3NO.HCl$; Molecular weight: 345.79

( )-*N*-Methyl-3-phenyl-3-[(α,α,α-trifluoro-*p*-toly)oxy]propylamine monohydrochloride, CAS [59333-67-4]



17. RELATED/SUPPORTING DOCUMENTS:

A. DMFs:

DMF #	TYPE	HOLDER	ITEM REFERENCED	CODE[1]	STATUS[2]	DATE REVIEW COMPLETED	COMMENTS
	II			1	SAT	6-21-02	D. Klein (HFD-120)
	III			4			
	III			4			
	III			4			
	III			4			
	III			4			
	III			4			
	IV			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:

Chemistry Review Data Sheet

DOCUMENT	APPLICATION NUMBER	DESCRIPTION

18. STATUS:

CONSULTS/ CMC RELATED REVIEWS	RECOMMENDATION	DATE	REVIEWER
Microbiology	N/A		
EES	Acceptable	9-19-02	S.Ferguson
Methods Validation	N/A, USP items		
Labeling	Pending		
Bioequivalence	Waiver pending		
EA			
Radiopharmaceutical			

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

Redacted 16 page(s)

of trade secret and/or

confidential commercial

information from

CHEMISTRY REVIEW #1

CHEMISTRY REVIEW TEMPLATE

Chemistry Assessment Section

cc: ANDA 76-458
ANDA DUP
DIV FILE
Field Copy

Endorsements:

HFD-647/LTang/11-26-2002, revised 12-3-02 12-9-02

HFD-647/UVenkataram/11-26-02;12/04/02 U. V. Venkataram 12/9/02

HFD-647/SShepperson/12-6-02 S Shepperson 12/10/02

F/T by ew/12-6-2002

76458N01.RLT/disk LCT D#1

V:\FIRMSNZ\Par\LTRS&REV\76458N01.RLT.DOC

CHEMISTRY REVIEW - NOT APPROVABLE - Minor

ANDA 76-458

Fluoxetine Oral Solution, USP

Par Pharmaceutical, Inc.

Lucia C. Tang
Chemistry Divison II

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Chemistry Assessment 9

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P DRUG PRODUCT [Name, Dosage form] .....

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R REGIONAL INFORMATION .....

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A. Labeling & Package Insert .....

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III. List Of Deficiencies To Be Communicated .....

Chemistry Review Data Sheet

1. ANDA #76-458

2. REVIEW #: 2

3. REVIEW DATE: February 4, 2003

4. REVIEWER: Lucia C. Tang

5. PREVIOUS DOCUMENTS:

Previous Documents	Document Date
Original submission	7-15-2002

6. SUBMISSION(S) BEING REVIEWED:

Submission(s) Reviewed	Document Date
Minor amendment	1-13-2003

7. NAME & ADDRESS OF APPLICANT:

Name: Par Pharmaceutical, Inc.

Address: One Ram Ridge Road, Spring Valley, NY 10977

Representative: Michelle Bonomi-Huvala

Telephone: 845-425-7100

Chemistry Review Data Sheet

8. DRUG PRODUCT NAME/CODE/TYPE:

a) Proprietary Name: N/A
b) Non-Proprietary Name (USAN): Fluoxetine Hydrochloride Oral Solution

9. LEGAL BASIS FOR SUBMISSION:

Innovator Product: Prozac® Liquid, 20 mg/5mL
Innovator Company: Eli Lilly & Co.
US Patent 4,314,081 Expiration Date: 2/02/01
US Patent 4,626,549 Expiration Date: 12/02/03
US Patent 4,626549*PED Expiration Date: 6/02/04

There exist no listed exclusivities for the referenced drug product, Prozac, for NDA #20-101

10. PHARMACOL. CATEGORY:

Antidepressant

11. DOSAGE FORM:

Oral Solution

12. STRENGTH/POTENCY:

20 mg /5 mL

13. ROUTE OF ADMINISTRATION:

Oral

14. Rx/OTC DISPENSED: _x__Rx ___OTC

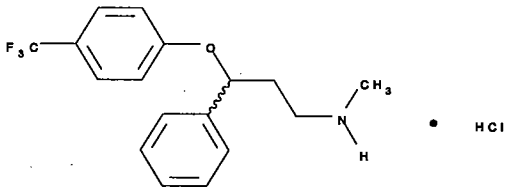
15. SPOTS (SPECIAL PRODUCTS ON-LINE TRACKING SYSTEM):
_____SPOTS product – Form Completed

____x_Not a SPOTS product

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

Chemistry Review Data Sheet

Fluoxetine Hydrochloride
Formula: $C_{17}H_{18}F_3NO.HCl$; Molecular weight: 345.79



(±)-*N*-Methyl-3-phenyl-3-[(α,α,α-trifluoro-*p*-tolyl)oxy]propylamine monohydrochloride. CAS [59333-67-4]

17. RELATED/SUPPORTING DOCUMENTS:

A. DMFs:

DMF #	TYPE	HOLDER	ITEM REFERENCED	CODE[1]	STATUS[2]	DATE REVIEW COMPLETED	COMMENTS
	II			1	SAT	6-21-02	D. Klein (HFD-120)
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	III			4			
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	III			4			
	III			4			
	III			4			
	IV			4			

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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

18. STATUS:

CONSULTS/ CMC RELATED REVIEWS	RECOMMENDATION	DATE	REVIEWER
Microbiology	N/A		
EES	Acceptable	9-19-02	S.Ferguson
Methods Validation	N/A, USP items		
Labeling	Pending		
Bioequivalence	Waiver pending		
EA			
Radiopharmaceutical			

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

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of trade secret and/or

confidential commercial

information from

CHEMISTRY REVIEW #2

Both the drug substance and the finished product are USP items. Method validation will not be requested.

32. LABELING

Pending for labeling

33. ESTABLISHMENT INSPECTION

Satisfactory

EER was requested for ———————————————— and Par pharmaceutical, Inc. by S. Shepperson on July 17 , 2002 and found acceptable on September 19, 2002.

34. BIOEQUIVALENCY/MICROBIOLOGY STATUS

Bio –Waiver is found pending

35. ENVIRONMENTAL IMPACT CONSIDERATIONS/CATEGORICAL EXCLUSION:

Categorical exemption requested per 21 CFR 25.31 (a).

APPEARS THIS WAY
ON ORIGINAL

36. Chemistry Comments to be Provided to the Applicant

ANDA: 76-458 APPLICANT: Par Pharmaceutical, Inc.

DRUG PRODUCT: Fluoxetine Oral Solution USP, 20 mg base/5 mL

The deficiencies presented below represent MINOR deficiencies:

The Division of chemistry has no further comments regarding the Chemistry, Manufacturing and Controls (CMC) issues. However, review of Labeling and Bio-waiver request are pending. We may request additional data if necessary.

Sincerely yours,

Florence S. Fang
Director
Division of Chemistry II
Office of Generic Drugs
Center for Drug Evaluation and Research

APPEARS THIS WAY
ON ORIGINAL

cc: ANDA 76-458
ANDA DUP
DIV FILE
Field Copy

Endorsements:

HFD-647/LTang/2-5-2003

HFD-647/UVenkataram/2-6-03

HFD-647/SShepperson/2-x-03

F/T by rad//2-x-2003

76458N02.RLT/disk LCT D#1

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CHEMISTRY REVIEW - NOT APPROVABLE - Minor

APPEARS THIS WAY
ON ORIGINAL

#3

ANDA 76-458

Fluoxetine Oral Solution USP, 20 mg/5 mL

Par Pharmaceutical, Inc.

Lucia C. Tang
Chemistry Divison II

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III. Administrative 9

A. Reviewer's Signature 9

B. Endorsement Block 9

C. CC Block 9

Chemistry Assessment 10

I. Review Of Common Technical Document-Quality (Ctd-Q) Module 3.2: Body Of Data .....

S DRUG SUBSTANCE [Name, Manufacturer] .....

P DRUG PRODUCT [Name, Dosage form] .....

A APPENDICES .....

R REGIONAL INFORMATION .....

II. Review Of Common Technical Document-Quality (Ctd-Q) Module 1 .....

A. Labeling & Package Insert .....

B. Environmental Assessment Or Claim Of Categorical Exclusion .....

III. List Of Deficiencies To Be Communicated .....

Chemistry Review Data Sheet

1. ANDA #76-458

2. REVIEW #:3

3. REVIEW DATE: June 2, 2003

4. REVIEWER: Lucia C. Tang

5. PREVIOUS DOCUMENTS:

Previous Documents	Document Date
Original submission	7-15-2002

6. SUBMISSION(S) BEING REVIEWED:

Submission(s) Reviewed	Document Date
Minor amendment	1-13-2003
Addendum to minor amendment	2-10-2003

7. NAME & ADDRESS OF APPLICANT:

Name: Par Pharmaceutical, Inc.

Address: One Ram Ridge Road, Spring Valley, NY 10977

Representative: Michelle Bonomi-Huvala

Telephone: 845-425-7100

8. DRUG PRODUCT NAME/CODE/TYPE:

a) Proprietary Name: N/A
b) Non-Proprietary Name (USAN): Fluoxetine Hydrochloride Oral Solution

9. LEGAL BASIS FOR SUBMISSION:

Chemistry Review Data Sheet

Innovator Product: Prozac® Liquid, 20 mg/5mL
Innovator Company: Eli Lilly & Co.
US Patent 4,314,081 Expiration Date: 2/02/01
US Patent 4,626,549 Expiration Date: 12/02/03
US Patent 4,626549*PED Expiration Date: 6/02/04

There exist no listed exclusivities for the referenced drug product, Prozac, for NDA #20-101

10. PHARMACOL. CATEGORY:

Antidepressant

11. DOSAGE FORM:

Oral Solution

12. STRENGTH/POTENCY:

20 mg /5 mL

13. ROUTE OF ADMINISTRATION:

Oral

14. Rx/OTC DISPENSED: _x__Rx ___OTC

15. SPOTS (SPECIAL PRODUCTS ON-LINE TRACKING SYSTEM)[Note24]:

_____SPOTS product – Form Completed

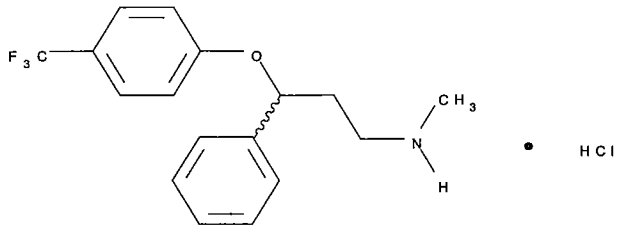
_____x_Not a SPOTS product

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

Fluoxetine Hydrochloride

Formula: $C_{17}H_{18}F_3NO.HCl$; Molecular weight: 345.79

Chemistry Review Data Sheet



(∀)-*N*-Methyl-3-phenyl-3-[(α,α,α-trifluoro-*p*-tolyl)oxy]propylamine monohydrochloride. CAS [59333-67-4]

17. RELATED/SUPPORTING DOCUMENTS:

A. DMFs:

DMF #	TYPE	HOLDER	ITEM REFERENCED	CODE[1]	STATUS[2]	DATE REVIEW COMPLETED	COMMENTS
	II			1	SAT	6-21-02	D. Klein (HFD 120)
	III			4			
	III			4			
	III			4			
	III			4			
	III			4			
	III			4			
	IV			4			

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2 –Type 1 DMF
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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

18. STATUS:

CONSULTS/ CMC RELATED REVIEWS	RECOMMENDATION	DATE	REVIEWER
Microbiology	N/A		
EES	Acceptable	9-19-02	S.Ferguson
Methods Validation	N/A, USP items		
Labeling	Not Satisfactory	12-18-03	A.Vezza
Bioequivalence	Waiver granted	3-31-03	G. Singh
EA	Catagorical Exclusion		Per 21 CFR
Radiopharmaceutical			

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

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of trade secret and/or

confidential commercial

information from

CHEMISTRY REVIEW #3

36. Chemistry Comments to be Provided to the Applicant

ANDA: 76-458 APPLICANT: Par Pharmaceutical, Inc.

DRUG PRODUCT: Fluoxetine Oral Solution USP, 20 mg(base)/5 mL

The deficiency presented below represents a MINOR deficiency:

The Division of Chemistry has no further comments regarding the Chemistry, Manufacturing and Controls (CMC) issues. However, Labeling is deficient and the deficiencies were communicated to you on December 18, 2003. It is necessary that all the Labeling deficiencies be corrected before the approval of this application. We may request additional data, if necessary.

Sincerely yours,

for 12/22/03

Florence S. Fang
Director
Division of Chemistry II
Office of Generic Drugs
Center for Drug Evaluation and Research

APPEARS THIS WAY
ON ORIGINAL

CHEMISTRY REVIEW TEMPLATE

Chemistry Assessment Section

cc: ANDA 76-458
ANDA DUP
DIV FILE
Field Copy

Endorsements:

HFD-647/LTang/12-18-2003 12-19-03

HFD-647/UVenkataram/12-19-03 U.V. Venkataram 12-22-2003

HFD-647/SShepperson/12-19-03 S Shepperson 12/22/03

F/T by: EW 12/19/03

76458N03.RLT/disk LCT D#2

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CHEMISTRY REVIEW - NOT APPROVABLE - Minor

Chemistry Review Data Sheet

ANDA 76-458

Fluoxetine Oral Solution USP, 20 mg(base)/5 mL

Par Pharmaceutical, Inc.

Lucia C. Tang
Chemistry Divison II

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C. Basis for Approvability or Not-Approval Recommendation 8

III. Administrative 8

A. Reviewer's Signature 8

B. Endorsement Block 8

C. CC Block 8

Chemistry Assessment 9

I. Review Of Common Technical Document-Quality (Ctd-Q) Module 3.2: Body Of Data .....

S DRUG SUBSTANCE [Name, Manufacturer] .....

P DRUG PRODUCT [Name, Dosage form] .....

A APPENDICES .....

R REGIONAL INFORMATION .....

II. Review Of Common Technical Document-Quality (Ctd-Q) Module 1 .....

A. Labeling & Package Insert .....

B. Environmental Assessment Or Claim Of Categorical Exclusion .....

III. List Of Deficiencies To Be Communicated .....

Chemistry Review Data Sheet

1. ANDA #76-458

2. REVIEW #:4

3. REVIEW DATE: April 1, 2004

4. REVIEWER: Lucia C. Tang

5. PREVIOUS DOCUMENTS:

Previous Documents	Document Date
Original submission	7-15-2002
Minor amendment	1-13-2003
Addendum to minor amendment	2-10-2003

6. SUBMISSION(S) BEING REVIEWED:

Submission(s) Reviewed	Document Date
Labeling amendment	11-19-2003
Minor amendment	12-31-2003
Labeling amendment	01-28-2004
Telephone Amendment	04-28-2004

7. NAME & ADDRESS OF APPLICANT:

Name: Par Pharmaceutical, Inc.

Address: One Ram Ridge Road, Spring Valley, NY 10977

Representative: Julie Szozda

Telephone: 201-802-4131

8. DRUG PRODUCT NAME/CODE/TYPE:

a) Proprietary Name: N/A
b) Non-Proprietary Name (USAN): Fluoxetine Hydrochloride Oral Solution

Chemistry Review Data Sheet

9. LEGAL BASIS FOR SUBMISSION:

Innovator Product: Prozac® Liquid, 20 mg/5mL
Innovator Company: Eli Lilly & Co.
US Patent 4,314,081 Expiration Date: 2/02/01
US Patent 4,626,549 Expiration Date: 12/02/03
US Patent 4,626549*PED Expiration Date: 6/02/04

There exist no listed exclusivities for the referenced drug product, Prozac, for NDA #20-101

10. PHARMACOL. CATEGORY:

Antidepressant

11. DOSAGE FORM:

Oral Solution

12. STRENGTH/POTENCY:

20 mg (base) /5 mL

13. ROUTE OF ADMINISTRATION:

Oral

14. Rx/OTC DISPENSED: _x__Rx ___OTC

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

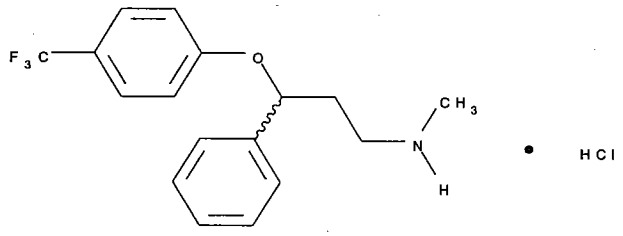
_____SPOTS product – Form Completed

____x_Not a SPOTS product

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

Fluoxetine Hydrochloride

Formula: $C_{17}H_{18}F_3NO.HCl$; Molecular weight: 345.79



(∀)-*N*-Methyl-3-phenyl-3-[(α,α,α-trifluoro-*p*-tolyl)oxy]propylamine monohydrochloride. CAS [59333-67-4]

17. RELATED/SUPPORTING DOCUMENTS:

A. DMFs:

DMF #	TYPE	HOLDER	ITEM REFERENCED	CODE[1]	STATUS[2]	DATE REVIEW COMPLETED	COMMENTS
	II			1	SAT	4-1-04	L. Tang
	III			4			
	III			4			
	III			4			
	III			4			
	III			4			
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Microbiology	N/A		
EES	Acceptable	9-19-02	S.Ferguson
Methods Validation	N/A, USP items		
Labeling	Satisfactory	3-2-04	A.Vezza
Bioequivalence	Waiver granted	3-31-03	G. Singh
EA	Categorical Exclusion		Per 21 CFR
Radiopharmaceutical			

19. ORDER OF REVIEW

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

APPEARS THIS WAY
ON ORIGINAL

Redacted 13 page(s)

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confidential commercial

information from

CHEMISTRY REVIEW #4

Expiration date:

—— expiration (tentative) date with 1, 2, 3 months accelerated stability data (40°C /75% R.H.) and 3 month room temperature stability data (25°C/ 60%RH) on batch No.:A030675 for 4-oz amber —— container/closure package size on invert and upright positions.

30. CONTROL NUMBERS: N/A

31. SAMPLES AND RESULTS/METHODS VALIDATION STATUS

Both the drug substance and the finished product are USP items. Method validation will not be requested.

32. LABELING

Satisfactory per A. Vezza reviewed on 3-2-2004.

33. ESTABLISHMENT INSPECTION
Satisfactory

EER was requested for ———————————————— and Par Pharmaceutical, Inc. by S. Shepperson on July 17 , 2002 and found acceptable on September 19, 2002.

34. BIOEQUIVALENCY/MICROBIOLOGY STATUS

Bio –Waiver is granted and reviewed on 3-31-03 per G Singh.

35. ENVIRONMENTAL IMPACT CONSIDERATIONS/CATEGORICAL EXCLUSION:

Categorical exemption requested per 21 CFR 25.31 (a).

CHEMISTRY REVIEW TEMPLATE

Chemistry Assessment Section

CC: ANDA 76-458
ANDA DUP
DIV FILE
Field Copy

Endorsements:

HFD-647/LTang/4-1-2004 U.V. Venkataram for

HFD-647/UVenkataram/04-04-04;4.30.04 U.V. Venkataram 5/5/04

HFD-647/SShepperson/5-3-04 SShepperson 5/7/04

F/T by rad//5/3/04

76458N04.RLT/disk LCT D#2

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CHEMISTRY REVIEW - APPROVAL