CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-411

CHEMISTRY REVIEW(S)

NDA 21-411

Strattera™ (Atomoxetine HCl)

Eli Lilly and Company

Gurpreet Gill-Sangha, Ph.D.

DIVISION OF NEUROPHARMACOLOGICAL DRUG PRODUCTS

Review of Chemistry, Manufacturing, and Controls

3 page(s) have been removed because it contains trade secret and/or confidential information that is not disclosable.

Chemistry Review Data Sheet

1. NDA 21-411

2. REVIEW #: 3

3. REVIEW DATE: November 14, 2002

4. REVIEWER: Gurpreet Gill-Sangha, Ph.D.

5. PREVIOUS DOCUMENTS:

Previous Documents	Document Date
Original	October 11, 2001
N(BC) Amendment	January 16, 2002
N(BL) Amendment	January 31, 2002
N(BC) Amendment	April 15, 2002
N(BC) Amendment	May 8, 2002
N(BC) Amendment	May 22, 2002
N(BC) Amendment	May 29, 2002
CMC Review #1	July 16, 2002
CMC Review #2	August 7, 2002

6. SUBMISSION(S) BEING REVIEWED:

Submission(s) Reviewed	Document Date
Response to Approvable Letter	September 26, 2002
N(BC) Amendment	October 10, 2002
N(BC) Amendment	October 23, 2002
N(BC) Amendment	October 31, 2002

7. NAME & ADDRESS OF APPLICANT:

Name:	Eli Lilly and Company
Address:	Lilly Corporate Center, Indianapolis, IN 46285
Representative:	Gregory T. Brophy, Ph.D., Director, US Regulatory Affairs
Telephone:	(317) 277-3799

8. DRUG PRODUCT NAME/CODE/TYPE:

a) Proprietary Name: Strattera™
b) Non-Proprietary Name (USAN): Atomoxetine HCl
c) Code Name/# (ONDC only): LY139603
d) Chem. Type/Submission Priority (ONDC only):

- Chem. Type: 1
- Submission Priority: S

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

10. PHARMACOL. CATEGORY: Treatment of ADHD in children, adolescents and adults

11. DOSAGE FORM: Capsule

12. STRENGTH/POTENCY: 5, 10, 18, 25, 40 and 60 mg

13. ROUTE OF ADMINISTRATION: Oral

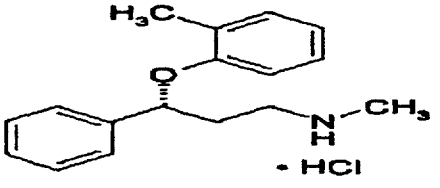
14. Rx/OTC DISPENSED: _X__Rx ___OTC

15. SPOTS (SPECIAL PRODUCTS ON-LINE TRACKING SYSTEM)[Note27]:

_____SPOTS product – Form Completed
__X__Not a SPOTS product

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

CA Name:	Benzenepropanamine, N-methyl-γ-(2-methylphenoxy)-, hydrochloride, (-)
USAN Name:	(-)-*N*-methyl-3-phenyl-3-(*o*-tolyloxy)-propylamine hydrochloride
Non-Proprietary Name:	Atomoxetine Hydrochloride
Chemical Formula:	$C_{17}H_{21}NO$ .HCl
Molecular Weight:	291.82
CAS registry #:	82248-59-7
Structure:	



17. RELATED/SUPPORTING DOCUMENTS:

A. DMFs: None for this review

DMF #	TYPE	HOLDER	ITEM REFERENCED	CODE[1]	STATUS[2]	DATE REVIEW COMPLETED	COMMENT

[1] Action codes for DMF Table:
1 – DMF Reviewed.
Other codes indicate why the DMF was not reviewed, as follows:
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[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: NA

DOCUMENT	APPLICATION NUMBER	DESCRIPTION

18. STATUS:

CONSULTS/ CMC RELATED REVIEWS	RECOMMENDATION	DATE	REVIEWER
Biometrics	Acceptable	June 17, 2002	Ning Li, Ph.D.
EES	Acceptable	October 3, 2002	FDA Compliance
Pharm/Tox	*Approvable* Pending	*August 5, 2002* N/A	*Ikram Elayan, Ph.D.* Ikram Elayan, Ph.D.
Biopharm	Acceptable	June 19, 2002	Hong Zhao, Ph.D.
LNC	USAN available	NA	NA
Methods Validation	Pending		Gurpreet Gill-Sangha, Ph.D.
OPDRA	Acceptable	March 22, 2002	Marci Lee, Pharm.D.
EA	Acceptable, categorical exclusion granted as per information from Eli Lilly in this NDA	As per CMC Review #1 July 16, 2002	Gurpreet Gill-Sangha, Ph.D.
Microbiology	Acceptable	November 14, 2002	Bryan Riley, Ph.D.

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/s/

Gurpreet Gill-Sangha
11/14/02 11:30:04 AM
CHEMIST

MC Review #3

Thomas Oliver
11/14/02 12:12:40 PM
CHEMIST

NDA 21-411

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Gurpreet Gill-Sangha, Ph.D.

DIVISION OF NEUROPHARMACOLOGICAL DRUG PRODUCTS

Review of Chemistry, Manufacturing, and Controls

Table of Contents

Chemistry Review Data Sheet

1. NDA 21-411

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4. REVIEWER: Gurpreet Gill-Sangha, Ph.D.

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FDA's EES Report	August 5, 2002

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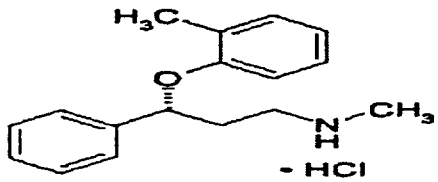

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Microbiology	NA		

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06-AUG-2002 FDA CDER EES Page 1 of 4
ESTABLISHMENT EVALUATION REQUEST
DETAIL REPORT

Application: NDA 21411/000 Action Goal:
Stamp: 12-OCT-2001 District Goal: 13-JUN-2002
Regulatory Due: 12-AUG-2002 Brand Name: [redacted] (ATOMOXETINE HCL)
Applicant: LILLY Estab. Name:
LILLY CORPORATE CENTER Generic Name: ATOMOXETINE HCL
INDIANAPOLIS, IN 46285
Priority: S Dosage Form: (CAPSULE)
Org Code: 120 Strength: 5,10,18,25,40 & 60-MG

Application Comment: THE DRUG SUBSTANCE, ATOMOXETINE HYDROCHLORIDE, WILL BE MANUFACTURED AT ELI LILLY S.A. - IRISH BRANCH, KINSALE, CO. CORK IRELAND. THE KINSALE FACILITY WILL ALSO CONDUCT IN-PROCESS & FINAL DS CONTROL TESTING. (on 02-NOV-2001 by L. ROCCA (HFD-810) 301-594-5357)

FDA Contacts: A. HUMMINAY WEIKEL (HFD-120) 301-594-5535 , Project Manager
G. GILL SANGHA , Review Chemist
H. PATEL (HFD-810) 301-594-2570 , Team Leader

Overall Recommendation: WITHHOLD on 05-AUG-2002 by R. WOODS (HFD-324) 301-827-0062

Establishment: 1819470
ELI LILLY AND CO
LILLY CORP CTR/WHITE RIVER PKY/EAST DR
INDIANAPOLIS, IN 46200

DMF No: AADA:
Responsibilities: FINISHED DOSAGE PACKAGER
Profile: CHG OAI Status: OAI ALERT
Estab. Comment: PACKAGING AND LABELING OF THE FINISHED CAPSULES ATOMOXETINE 5, 10, 18, 25, 40 & 60 MG WILL BE CONDUCTED AT LILLY'S TECHNOLOGY CENTER IN INDIANAPOLIS, IN. PRIMARY, SUPPORTING AND OTHER STABILITY STUDIES OF THE FINISHED DOSAGE FORM WILL BE CONDUCTED AT LILLY'S TECHNOLOGY CENTER IN INDIANAPOLIS, IN. (on 02-NOV-2001 by L. ROCCA (HFD-810) 301-594-5357)

Milestone Name	Date	Req. Type	Insp. Date	Decision & Reason	Creator
SUBMITTED TO OC	02-NOV-2001				ROCCAL
OC RECOMMENDATION	05-NOV-2001			ACCEPTABLE	FERGUSONS
OC RECOMMENDATION	05-AUG-2002			BASED ON PROFILE WITHHOLD EIR REV-NONCONCUR W/DISTRICT	WOODSR

THIS WITHHOLD IS ACTUALLY BASED ON A REVIEW OF AN FDA-483 ISSUED AT THE END OF A 4/8 - 5/30/02 OAI EI FOR WHICH THE DISTRICT HAS RECOMMENDED AN INJUNCTION. GMP DEFICIENCIES EXIST IN THE FIRM'S QUALITY SYSTEM THAT COULD EFFECT PACKAGING OPERATIONS. RELEVANT FDA-483 OBSERVATIONS READ - THE QUALITY CONTROL UNIT DOES NOT ASSURE THAT ALL ERRORS, UNEXPLAINED DISCREPANCIES AND DEVIATIONS FROM ESTABLISHED PROCEDURES AND SPECIFICATIONS ARE FULLY INVESTIGATED IN A TIMELY MANNER. ADDITIONALLY AND SPECIFIC TO THIS PRODUCT, GMP DEFICIENCIES IN PACKAGING OPERATIONS LACK EVIDENCE OF ADEQUATE INVESTIGATION.

Establishment: 1813682
ELI LILLY CO/TIPPECANOE
BOX 685 LILLY RD
LAFAYETTE, IN 47902

DMF No: AADA:
Responsibilities: DRUG SUBSTANCE MANUFACTURER
DRUG SUBSTANCE OTHER TESTER
Profile: CSN OAI Status: NONE
Estab. Comment: TIPPECANOE SITE IS CURRENTLY MANUFACTURING THE API. LILLY

06-AUG-2002 FDA CDER EES Page 2 of 4
ESTABLISHMENT EVALUATION REQUEST
DETAIL REPORT

PROPOSES TO TRANSFER API MANUFACTURING TO IRELAND SITE DURING MID-REVIEW OF NDA. IRELAND IS ACCEPTABLE BASED ON PROFILE FROM EES. TIPPERCANOE SITE SHOULD BE INSPECTED FOR API MANUFACTURING ALSO BEACUSE IT IS THE CURRENT MANUFACTURER OF API AND ALL THE API LOTS IN THE NDA ARE FORM THIS SITE. (on 26-NOV-2001 by G. GILL SANGHA ())

Milestone Name	Date	Req. Type	Insp. Date	Decision & Reason	Creator
SUBMITTED TO OC	26-NOV-2001				GILLSANGHA
SUBMITTED TO DO	26-NOV-2001	PB			DAMBROGIOJ
ASSIGNED INSPECTION	30-NOV-2001	PB			MROBINSO
INSPECTION SCHEDULED	11-DEC-2001		29-MAR-2002		MROBINSO
INSPECTION PERFORMED	23-APR-2002		18-APR-2002		MROBINSO
GMP & PAI EI REPORTED DEVIATIONS NOT LIKELY TO AFFECT PRODUCT QUALITY. EIR WILL BE CLASSIFIED VAI.					
DO RECOMMENDATION	23-APR-2002			ACCEPTABLE INSPECTION	MROBINSO
EI DATED 4/1-18/2002 WILL BE CLASSIFIED VAI.					
OC RECOMMENDATION	23-APR-2002			ACCEPTABLE DISTRICT RECOMMENDATION	DAMBROGIOJ
INSPECTION PERFORMED	17-MAY-2002		18-APR-2002		MROBINSO
DO RECOMMENDATION	28-MAY-2002			ACCEPTABLE INSPECTION	MROBINSO
EI 4/1-18/02 WAS CLASSIFIED VAI.					
OC RECOMMENDATION	28-MAY-2002			ACCEPTABLE DISTRICT RECOMMENDATION	ADAMSS

Profile: CTL OAI Status: NONE
Estab. Comment:

Milestone Name	Date	Req. Type	Insp. Date	Decision & Reason	Creator
SUBMITTED TO OC	02-NOV-2001				ROCCAL
SUBMITTED TO DO	05-NOV-2001	GMP			FERGUSONS
DO RECOMMENDATION	23-APR-2002			ACCEPTABLE	MROBINSO
				INSPECTION	
GMP AND PAI INSPECTION 4/1-18/2002 INCLUDED LABORATORY COVERAGE AND WILL BE CLASSIFIED VAI.					
OC RECOMMENDATION	23-APR-2002			ACCEPTABLE	DAMBROGIOJ
				DISTRICT RECOMMENDATION	

Establishment: 2619243
ELI LILLY INDUSTRIES INC
12.6 KM 65TH INFANTRY RD
CAROLINA, PR 00985

DMF No: AADA:

Responsibilities: FINISHED DOSAGE MANUFACTURER
FINISHED DOSAGE PACKAGER

Profile: CHG OAI Status: NONE

Estab. Comment: CAPSULES ATOMOXETINE 5, 10, 18, 25, 40 & 60 MG WILL BE MANUFACTURED AT LILLY'S CAROLINA, PR FACILITY. PACKAGING & LABELING OF THE FINISHED CAPSULES ATOMOXETINE 5, 10, 18, 25, 40 & 60 WILL BE CONDUCTED AT LILLY'S CAROLINA, PR FACILITY. IN-PROCESS & CONTROL TESTING OF THE FINISHED DOSAGE FORM WILL BE CONDUCTED AT LILLY'S CAROLINA, PR FACILITY. PRIMARY, SUPPORTING & OTHER STABILITY STUDIES OF THE FINISHED DOSAGE FORM WILL BE CONDUCTED AT LILLY'S CAROLINA, PR FACILITY. (on 02-NOV-2001 by L. ROCCA (HFD-810) 301-594-5357)

Milestone Name	Date	Req. Type	Insp. Date	Decision & Reason	Creator
SUBMITTED TO OC	02-NOV-2001				ROCCAL
SUBMITTED TO DO	05-NOV-2001	PS			FERGUSONS
ASSIGNED INSPECTION	13-NOV-2001	PS			MTORRES
INSPECTION SCHEDULED	01-APR-2002		15-JUN-2002		MTORRES
INSPECTION PERFORMED	14-JUN-2002		07-JUN-2002		MTORRES
DO RECOMMENDATION	14-JUN-2002			ACCEPTABLE	MTORRES
				INSPECTION	
VALIDATION FOR 60 MG COVERED AND NO DEFICIENCIES FOUND.					
OC RECOMMENDATION	14-JUN-2002			ACCEPTABLE	FERGUSONS
				DISTRICT RECOMMENDATION	

Establishment: 9611006
ELI LILLY SA (ELANCO)
KINSALE, COUNTY CORK, EI

DMF No: AADA:

Responsibilities: DRUG SUBSTANCE MANUFACTURER

Profile: CSN OAI Status: NONE

Estab. Comment: THE DRUG SUBSTANCE, ATOMOXETINE HYDROCHLORIDE, WILL BE MANUFACTURED AT ELI LILLY S.A. - IRISH BRANCH, KINSALE, CO. CORK IRELAND. THE KINSALE FACILITY WILL ALSO CONDUCT IN-PROCESS & FINAL DS CONTROL TESTING. (on 02-NOV-2001 by L. ROCCA (HFD-810) 301-594-5357)

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SUBMITTED TO OC	02-NOV-2001				ROCCAL
OC RECOMMENDATION	05-NOV-2001			ACCEPTABLE	DAMBROGIOJ
				BASED ON PROFILE	

Establishment: 9615231

06-AUG-2002 FDA CDER EES Page 4 of 4
ESTABLISHMENT EVALUATION REQUEST
DETAIL REPORT

LILLY RESEARCH LABORATORIES DIV ELI LILLY AND CO
3650 DANFORTH AVENUE
SCARBOROUGH, ONTARIO, CA M1W 2E8
DMF No: AADA:
Responsibilities: FINISHED DOSAGE STABILITY TESTER
Profile: CTL OAI Status: NONE
Estab. Comment: THE ANALYTICAL LABORATORIES OF ELI LILLY CANADA WILL CONDUCT PRIMARY, SUPPORTING AND OTHER STABILITY STUDIES OF THE FINISHED DOSAGE FORM. (on 05-NOV-2001 by L. ROCCA (HFD-810) 301-594-5357)

Milestone Name	Date	Req. Type	Insp. Date	Decision & Reason	Creator
SUBMITTED TO OC	05-NOV-2001				ROCCAL
SUBMITTED TO DO	06-NOV-2001	GMP			DAMBROGIOJ
ASSIGNED INSPECTION	06-NOV-2001	GMP			GARCIAM
INSPECTION SCHEDULED	22-MAR-2002		12-APR-2002		IRIVERA
INSPECTION SCHEDULED	08-APR-2002		12-APR-2002		GARCIAM
INSPECTION PERFORMED	16-APR-2002		12-APR-2002		IRIVERA
INSPECTION PERFORMED	20-MAY-2002		12-APR-2002		GARCIAM

DO RECOMMENDATION	04-JUN-2002	ACCEPTABLE INSPECTION	ADAMSS
OC RECOMMENDATION	04-JUN-2002	ACCEPTABLE DISTRICT RECOMMENDATION	DAMBROGIOJ

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/s/

Gurpreet Gill-Sangha
8/7/02 09:09:45 AM
CHEMIST
CMC Review #2

Thomas Oliver
8/7/02 09:22:45 AM
CHEMIST

NDA 21-411

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Gurpreet Gill-Sangha, Ph.D.

DIVISION OF NEUROPHARMACOLOGICAL DRUG PRODUCTS

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	September 9, 1981

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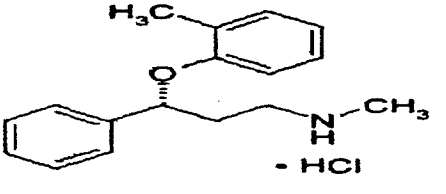

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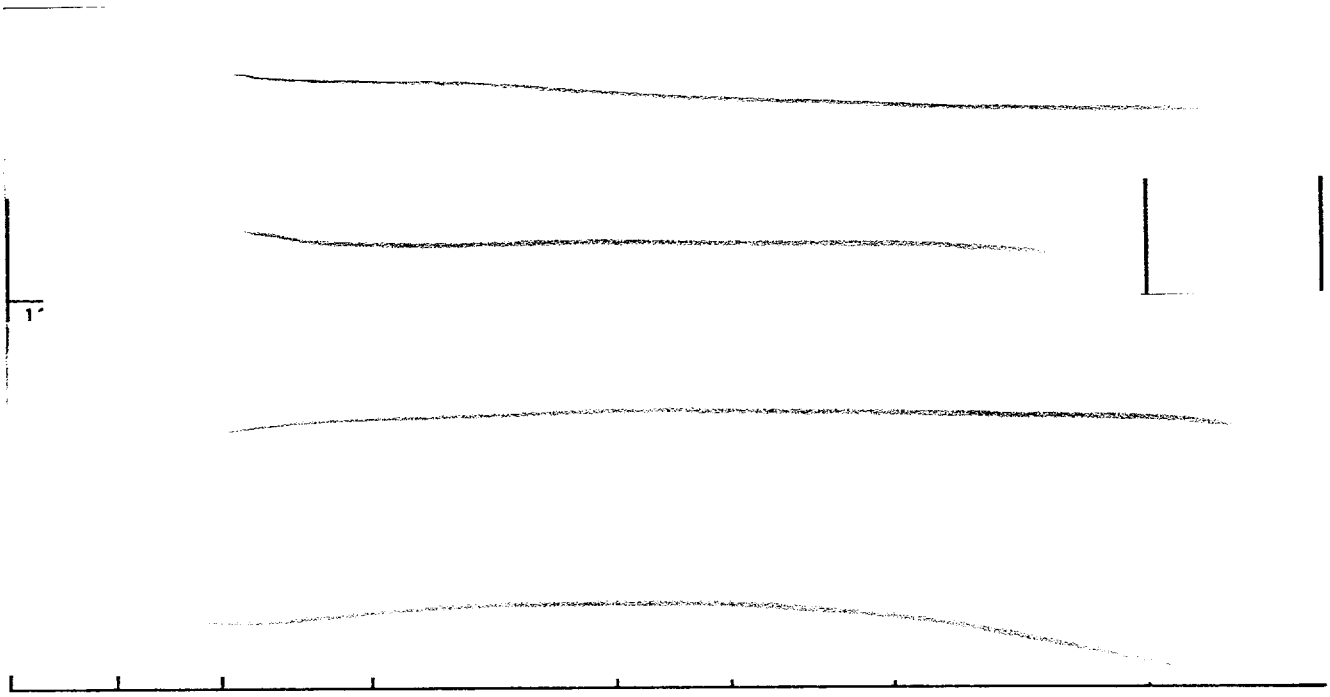

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APPEARS THIS WAY
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/s/

Gurpreet Gill-Sangha
7/16/02 04:29:55 PM
CHEMIST

CMC Review #1

Thomas Oliver
7/16/02 04:32:45 PM
CHEMIST