CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

20-936/S004
20-885/S002
20-710/S007

Trade Name: Paxil CR
Paxil Capsules
Paxil Oral Suspension

Generic Name: (paroxetine hydrochloride)

Sponsor: SmithKline Beecham Pharmaceuticals

Approval Date: July 18, 2000

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:
20-936/S004
20-885/S002
20-710/S007

CONTENTS

Reviews / Information Included in this NDA Review.

Approval Letter	X
Other Action Letters	
Labeling	
REMS	
Summary Review	
Officer/Employee List	
Office Director Memo	
Cross Discipline Team Leader Review	
Medical Review(s)	
Chemistry Review(s)	X
Environmental Assessment	
Pharmacology Review(s)	
Statistical Review(s)	
Microbiology Review(s)	
Clinical Pharmacology/Biopharmaceutics Review(s)	
Other Reviews	
Risk Assessment and Risk Mitigation Review(s)	
Proprietary Name Review(s)	
Administrative/Correspondence Document(s)	X

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

20-936/S004

20-885/S002

20-710/S007

APPROVAL LETTER

JUL 18 2000

NDA 20-710/SCM-007
NDA 20-885/SCM-002
NDA 20-936/SCM-004

SmithKline Beecham Pharmaceuticals
Attention: Deborah Zuber
Assistant Director, U.S. Regulatory Affairs
1250 S. Collegeville Road
PO Box 5089
Collegeville, PA 19426-0989

Dear Ms. Zuber:

Please refer to your supplemental new drug applications dated July 5, 2000, received July 6, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Paxil® (paroxetine hydrochloride hemihydrate) Oral Suspension, Paxil® (paroxetine hydrochloride hemihydrate) Capsules 10, 20, 30, 40 mg, and Paxil® (paroxetine hydrochloride hemihydrate) CR tablets 12.5 and 25 mg .

These "Changes Being Effected in 30 days" supplemental new drug applications provide for the use of paroxetine hydrochloride hemihydrate drug substance manufactured at your firm's Cork, Ireland facility.

We have completed the review of these supplemental applications and they are approved.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Paul David, R.Ph., Regulatory Project Manager, at (301) 594-5530.

Sincerely,

7/18/00

Robert H. Seevers, Ph.D.
Chemistry Team Leader, Psychiatric Drugs for the
Division of Neuropharmacological Drug Products,
(HFD-120)
DNDC I, Office of New Drug Chemistry
Center for Drug Evaluation and Research

cc:
Archival NDAs 20-710, 20-885, 20-936
HFD-120/Div. Files
HFD-120/P.David
HFD-120/R.Seevers

Drafted by: rhs/July 18, 2000
Initialed by:
final:
filename: 20710S07.WPD

APPROVAL (AP)

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

20-936/S004

20-885/S002

20-710/S007

CHEMISTRY REVIEW(S)

12.1

JUL 18 2000

ST REVIEW
SUPPLEMENT

1. ORGANIZATION: HFD-120
2. NDA: 20-710/SCM-007
20-885/SCM-002
[redacted]

3. SUPPLEMENT NUMBERS/DATES:
letter date: 05-JUL-2000
stamp date: 06-JUL-2000
4. AMENDMENTS/REPORTS/DATES:
5. RECEIVED BY CHEMIST: 11-JUL-2000

6. APPLICANT NAME & ADDRESS: SmithKline Beecham Pharmaceuticals
1250 S. Collegeville Road
Collegeville, PA 19426-0989

7. NAME OF DRUG: Paxil® Oral Suspension (NDA 20-710)
Paxil® Capsules (NDA 20-885)
Paxil® CR Tablets (NDA 20-936)

8. NONPROPRIETARY NAME: paroxetine HCl hemihydrate
9. CHEMICAL NAME/STRUCTURE: see 2000 USAN dictionary
10. DOSAGE FORM(S): see above item 7
11. POTENCY: Paxil® Oral Suspension (NDA 20-710) 10mg/5mL
Paxil® Capsules (NDA 20-885) 10, 20, 30, 40 mg
Paxil® CR Tablets (NDA 20-936) 12.5, 25 mg

12. PHARMACOLOGICAL CATEGORY: Anti-depressant, Treatment of Obsessive Compulsive Disorder, Panic Disorder, Social Anxiety Disorder

13. HOW DISPENSED: X (R_x) _____ (OTC)
14. RECORDS & REPORTS CURRENT: X Yes _____ No
15. RELATED IND/NDA/DMF:

16. **SUPPLEMENT PROVIDES FOR:** the use of paroxetine HCl hemihydrate drug substance manufactured at the firm's Cork, Ireland site.

17. COMMENTS: The same change was approved for Paxil® (paroxetine HCl hemihydrate) Tablets 10, 20, 30, 40 mg: NDA 20-031/SCM-025 on May 17, 2000. The Cork, Ireland site was submitted to EES for each of the supplements in the present review on July 6, 2000. It was deemed Acceptable for each of the supplements on July 12, 2000, based on profile.

18. CONCLUSIONS & RECOMMENDATIONS: The requested new drug substance manufacturing site is identical to that approved recently for NDA 20-031/SCM-025. The site has received an Acceptable cGMP status. The supplements may be approved.

REVIEWER NAME	SIGNATURE	DATE COMPLETED
Robert H. Seevers	Robert H. Seevers	7/18/00

As 20-710, 20-885, 20-936
A 20-710, 20-885, 20-936 Division Files
D-120/RSeevers
D-120/PDavid

FDA CDER EES
ESTABLISHMENT EVALUATION REQUEST
SUMMARY REPORT

Application: NDA 20885/002
Priority: 3S
Org Code: 120
Stamp: 06-JUL-2000 Regulatory Due: 06-JAN-2001
Action Goal:
District Goal: 02-DEC-2000
Applicant: SKB PHARMS
1250 SOUTH COLLEGEVILLE RD UP
COLLEGEVILLE, PA 194260989
Brand Name: PAXIL (PAROXETINE HCL)
10/20/30/40MG CAP
Established Name:
Generic Name: PAROXETINE HCL
Dosage Form: CAP (CAPSULE)
Strength: 10, 20, 30, 40 MG

FDA Contacts:			
P. DAVID	(HFD-120)	301-594-2850	, Project Manager
R. SEEVERS	(HFD-120)	301-594-2850	, Review Chemist
R. SEEVERS	(HFD-120)	301-594-2850	, Team Leader

Overall Recommendation:

ACCEPTABLE on 12-JUL-2000 by M. EGAS (HFD-322) 301-594-0095

Establishment (b) (4)
SMITH KLINE BEECHAM PHARMA
CURRAGHBINNY
COUNTY CORK, , EI
DMF No: (b) (4)
AADA No:

Profile: (b) (4)
OAI Status: NONE
Last Milestone: OC RECOMMENDATION
Milestone Date 12-JUL-2000
Decision: ACCEPTABLE
Reason: BASED ON PROFILE
Responsibilities: DRUG SUBSTANCE MANUFACTURER

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

20-936/S004

20-885/S002

20-710/S007

ADMINISTRATIVE and CORRESPONDENCE DOCUMENTS

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-936/S-004

SmithKline Beecham Pharmaceuticals
1250 South Collegeville Road
P.O. Box 5089
Collegeville,PA 19426-0989

JUN 11 2000

Attention: Deborah Zuber
Assistant Director U.S. Regulatory Affairs

Dear Ms. Zuber:

We acknowledge receipt of your supplemental application for the following:

Name of Drug: Paxil CR Tablets

NDA Number: 20-936

Supplement Number: 004

Date of Supplement: 05-Jul-00

Date of Receipt: 06-Jul-00

Unless we find the application not acceptable for filing, this application will be filed under Section 505(b)(1) of the Act on 04-Sep-2000 in accordance with 21 CFR 314.101(a).

All communications concerning this NDA should be addressed as follows:

Center for Drug Evaluation and Research
Division of Neuropharmacological Drug Products, HFD-120
Office of Drug Evaluation I
Attention: Document Control Room 4008
5600 Fishers Lane
Rockville, MD 20857

Sincerely,

Robert N. Reeves for 7/11/00

John S. Purvis
Chief, Project Management Staff
Division of Neuropharmacological Drug Products, HFD-120
Office of Drug Evaluation I
Center for Drug Evaluation and Research

cc:
Original NDA 20-936/004
HFD-120/Div. Files
HFD-120/CSO/David

filename:

SUPPLEMENT ACKNOWLEDGEMENT

NDA NO. 20-936 REF NO. SCM-004
NDA SUPPL FOR Manufacturing

SmithKline Beecham
Pharmaceuticals

July 5, 2000

NDA SUPPLEMENT

ORIGINAL

NDA 20-710
Paxil® (paroxetine hydrochloride hemihydrate) Oral Suspension
NDA 20-885
Paxil® (paroxetine hydrochloride hemihydrate) Capsules, 10 mg, 20 mg, 30 mg and 40 mg
NDA 20-936
Paxil® (paroxetine hydrochloride hemihydrate) CR Tablets, 12.5 mg and 25 mg

Russell Katz, M.D., Director
Food and Drug Administration
Division of Neuropharmacological
Drug Products, Room 4037
1451 Rockville Pike
Woodmont 2
Rockville, Maryland 20852

CENTER FOR DRUG EVALUATION AND RESEARCH

JUL 06 2000

RECEIVED HFD-120

Re: Chemistry, Manufacturing and Controls Supplement
"Changes Being Effected – 30 Days"
Implementation Date – August 5, 2000

Dear Dr. Katz:

Reference is made to the following SmithKline Beecham Pharmaceuticals' approved New Drug Applications:

- NDA 20-710, Paxil® (paroxetine hydrochloride hemihydrate) Oral Suspension
- NDA 20-885, Paxil® (paroxetine hydrochloride hemihydrate) Capsules, 10 mg, 20 mg, 30 mg and 40 mg
- NDA 20-936, Paxil® (paroxetine hydrochloride hemihydrate) CR Tablets, 12.5 mg and 25 mg

000001

F:\Paxil\PAtoPaxil\1

1250 S. Collegeville Road, PO Box 5089, Collegeville, PA 19426-0989. Telephone (610) 917 7000. Fax (610) 917 7707.

Reference is also made to NDA 20-031, Paxil® (paroxetine hydrochloride hemihydrate) Tablets, 10 mg, 20 mg, 30 mg and 40 mg and to the Supplement S-025 approved by FDA on May 17, 2000. Supplement S-025 was approved for the SmithKline Beecham Pharmaceuticals Cork, Ireland facility to manufacture (b) (4) of the paroxetine drug substance.

SmithKline Beecham is requesting the approval of drug substance manufactured by the Cork, Ireland facility with respect to each of the above cited NDA drug products. Each of these NDAs cross-reference the dug substance section to the original Paxil® Tablet NDA 20-031. Please reference the data provided in NDA 20-031, Supplement S-025.

The implementation date is August 5, 2000.

We trust the agency will find this submission satisfactory; however, if there are any questions, please do not hesitate to contact me at (610) 917-6884.

Sincerely,

Deborah Zuber.

Deborah Zuber
Assistant Director
U.S. Regulatory Affairs

cc: District Office Copies:
NDA 20-710- Rochelle Kimmel, DEIO (full copy)
Debra Pagano, Philadelphia District Office (cover letter)
NDA 20-885 - Rochelle Kimmel, DEIO (full copy)
Debra Pagano, Philadelphia District Office (cover letter)
NDA 20-936 - Rochelle Kimmel, DEIO (full copy)
Debra Pagano, Philadelphia District Office (cover letter)