CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

NDA 20-710/S-004

Name:	Paxil Tablets and Oral Suspension
Generic:	paroxetine hydrochloride
Sponsor:	GlaxoSmithKline
Approval Date:	02/23/1999

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 20-710/S-004

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CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 20-710/S-004

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-710/SCS-004

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

FEB 23 1999

Dear Ms. Zuber:

Please refer to your supplemental new drug application dated December 23, 1998, received December 28, 1998, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Paxil (paroxetine hydrochloride) oral suspension.

We acknowledge receipt of your submission dated January 6, 1999.

We note that this supplement was submitted as a 'Special Supplement - Changes Being Effected' under 21 CFR 314.70(c).

This supplemental new drug application provides for addition of an alternate manufacturing of a [ ] batch size for the drug product and updating the antifoam component, [ ] simethicone emulsion, to a [ ] source. Your submission stated January 22, 1999 as the implementation date for the change(s).

We have completed the review of this supplemental application and it is 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, contact Paul David, R.Ph., Regulatory Management Officer, at (301) 594-2850.

Sincerely,

Robert H. Seevers 2/23/99

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 NDA 20-710
HFD-120/Div. Files
HFD-120/P.David
DISTRICT OFFICE

Drafted by: rhs/February 22, 1999
Initialed by:
final:
filename: 20710S04.WPD

APPROVAL (AP)

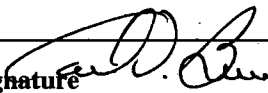
CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 20-710/S-004

CHEMISTRY REVIEW(S)

FEB 23 1999

CHEMIST'S REVIEW	1. ORGANIZATION HFD-810@110	2. NDA Number 20-710
3. Name and Address of Applicant (City & State) SmithKline Beecham Pharmaceuticals 1250 South Collegeville Road P. O. Box 5089 Collegeville, PA 19426-0989		4. Supplement(s) Number(s) Date(s) SCS-004 December 23, 1998 SCS-004 (BC) January 6, 1999
5. Drug Name Paxil®	6. Nonproprietary Name paroxetine hydrochloride	7. Amendments & Other (reports, etc) – Dates SCS-004 (BC) January 6, 1999 (minor correction)
8. Supplement provides for the addition of an alternate manufacturing of a [ ] batch size and updating the antifoam component [ ] simethicone emulsion to a [ ] [ ] source for drug product. The supplement is a CBE.		
9. Pharmacological Category antidepressant	10. How Dispensed Rx X OTC	11. Related IND(s)/ NDA(s)/DMF(s)
12. Dosage Form(s) oral suspension	13. Potency(ies) 10mg/5mL	
13. Chemical Name and Structure See last page of this review.		15. Records/Reports Current Yes X No Reviewed Yes X No
16. Comments See Comments Continued on the next page.		
17. Conclusions and Recommendations Since the data submitted supports the proposed changes, we recommend approval for this supplement. The standard letter should be written.		
18. REVIEWER		
Name Carl J. Berninger, Ph.D.	Signature 	Date Completed 2/23/99
Distribution: Original Jacket x Reviewer x Division File x PM x		
CJB File Name c:\sup-rev\ 20710s04.doc	R/D init: R. Seevers 	

Redacted 3 page(s)

of trade secret and/or

confidential commercial

information from

Chemistry Review

ESTABLISHMENT EVALUATION REQUEST
DETAIL REPORT

Application: NDA 20710/000
Stamp: 03-APR-1996
Regulatory Due: 16-NOV-1997
Applicant: SKB PHARMS
1250 SOUTH COLLEGEVILLE RD
COLLEGEVILLE, PA 19426
Priority: 3S
Org Code: 120

Action Goal:
District Goal:
Brand Name: PAXIL (PAROXETINE) ORAL SUSPENSION 10MG
Estab. Name:
Generic Name: PAROXETINE

Dosage Form: (SUSPENSION)
Strength: 10MG/5ML

Application Comment:
FDA Contacts: M. ZARIFA (HFD-120) 301-594-2850 , Review Chemist

Overall Recommendation: ACCEPTABLE on 17-JUN-1997 by M. EGAS (HFD-322) 301-594-0095

Establishment: 9610176
SMITH KLINE BEECHAM PHARMACEUTICALS
CURRAGHBINNY CO CORK
, , EI
DMF No: [redacted] AADA:
Responsibilities: DRUG SUBSTANCE MANUFACTURER
Profile: CSN OAI Status: NONE
Estab. Comment:

Milestone Name	Date	Req. Type	Insp. Date	Decision & Reason	Creator
SUBMITTED TO OC	21-MAY-1996				EES_CONV
OC RECOMMENDATION	03-JUN-1996			ACCEPTABLE BASED ON PROFILE	EES_CONV

Establishment: 9612240
SMITHKLINE BEECHAM
MANOR RD WEST RH10 2QJ
CRAWLEY, ENGLAND - WEST SUSSEX, UK
DMF No: AADA:
Responsibilities: FINISHED DOSAGE MANUFACTURER
Profile: LIQ OAI Status: NONE
Estab. Comment: MFG; NME PRODUCT (on 24-AUG-1996 by EES_CONV)

Milestone Name	Date	Req. Type	Insp. Date	Decision & Reason	Creator
SUBMITTED TO OC	21-MAY-1996				EES_CONV
SUBMITTED TO DO	19-SEP-1996	PS			EGASM
ASSIGNED INSPECTION	22-JAN-1997	PS			EGASM
INSPECTION PERFORMED	05-MAR-1997		05-MAR-1997		EGASM
DO RECOMMENDATION	17-JUN-1997			ACCEPTABLE INSPECTION	EGASM
OC RECOMMENDATION	17-JUN-1997			ACCEPTABLE DISTRICT RECOMMENDATION	EGASM

Establishment: 9610449
SMITHKLINE BEECHAM CHEMICALS
AYRSHIRE, SCOTLAND
, IRVINE, UK
DMF No: 5288 AADA:
Responsibilities: DRUG SUBSTANCE MANUFACTURER
Profile: CSN OAI Status: NONE
Estab. Comment:

Milestone Name	Date	Req. Type	Insp. Date	Decision & Reason	Creator

SUBMITTED TO OC	21-MAY-1996		EES_CONV
OC RECOMMENDATION	03-JUN-1996	ACCEPTABLE BASED ON PROFILE	EES_CONV

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 20-710/S-004

ADMINISTRATIVE and CORRESPONDENCE DOCUMENTS

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-710/S-004

SmithKline Beecham Pharmaceuticals
1250 S. Collegeville Road
Collegeville, PA 19426

JAN 11 1999

Attention: Deborah E. Zuber, Assistant Director

Dear Ms. Zuber:

We acknowledge receipt of your supplemental application for the following:

Name of Drug: Paxil Oral Suspension

NDA Number: 20-710

Supplement Number: S-004

Date of Supplement: December 23, 1998

Date of Receipt: December 28, 1998

Unless we find the application not acceptable for filing, this application will be filed under Section 505(b)(1) of the Act on February 26, 1999 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,

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

cc:
Original NDA 20-710/004
HFD-120/Div. Files
HFD-120/CSO/David

filename: C:\WPWIN61\TEMPLATE\FDA\20-710.004

SUPPLEMENT ACKNOWLEDGEMENT

SmithKline Beecham

ORIGINAL

January 6, 1999

NDA 20-710
Paxil® (paroxetine hydrochloride) Oral Suspension

Paul Leber, M.D., Director
Division of Neuropharmacological
Drug Products (HFN-120, Room 10B-45)
Center for Drug Evaluation and Research
Office of Drug Evaluation I
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Re: Amendment to Special Supplement for Paxil Oral Suspension

Dear Dr. Leber:

Reference is made to the approved NDA 20-710, Paxil® (paroxetine hydrochloride) Oral Suspension and to the Special Supplement "Changes Being Effected" submitted December 23, 1998.

This amendment to the supplement provides for a typographical correction in Section 4, Method of Manufacture, 4.2, Process Monograph, Operation 1: Preparation of[ ] Suspension, Step / due to a statement which was inadvertently omitted. Step / should read, [ ] [ ]. For ease of replacement, attached is the corrected page.

If you have any questions regarding this submission, please contact the undersigned at (610) 917-6884.

Sincerely,

Lynn Kruger for

Deborah E. Zuber
Assistant Director
U.S. Regulatory Affairs

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

SmithKline Beecham

ORIGINAL

December 23, 1998

NDA NO. 20-710 REF NO. SCS-004
NDA SUPPL FOR Control

NDA 20-710
Paxil® (paroxetine hydrochloride) Oral Suspension
Supplemental NDA

Paul Leber, M.D., Director
Division of Neuropharmacological
Drug Products (HFN-120, Room 10B-45)
Center for Drug Evaluation and Research
Office of Drug Evaluation I
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

CENTER FOR DRUG EVALUATION AND RESEARCH

DEC 28 1998

RECEIVED HFD-120

NDA SUPPLEMENT

Re: Special Supplement "Changes Being Effected" Paxil Oral Suspension

Dear Dr. Leber:

Reference is made to the approved NDA 20-710, Paxil® (paroxetine hydrochloride) Oral Suspension.

This supplement provides for the addition of an alternate manufacturing of a [ ] batch size and updating the antifoam component [ ] simethicone emulsion to a [ ] source. This submission contains the inclusion of the flow diagram, revised process monograph and representative equipment list for the [ ] batch size. Also included in this submission is the unexecuted batch record for the [ ] batch size in Appendix 1 and the Technical File for [ ] Simethicone emulsion in Appendix 2.

This change will be effective 30 days from date of submission.

If you have any questions regarding this submission, please contact the undersigned at (610) 917-6884.

Sincerely,

Deborah E. Zuber

Deborah E. Zuber
Assistant Director
U.S. Regulatory Affairs

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000001

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