

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

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20-885/S002

20-710/S007

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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.

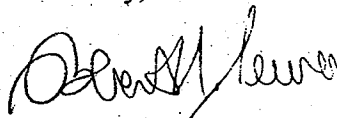
These "Changes Being Effected in 30 days" supplemental new drug applications provide for the use of paroxetine hydrochloride hemihydrate drug substance manufactured at your firm's Cork, Ireland facility.

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

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

17.1

JUL 18 2000

ST REVIEW
SUPPLEMENT

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

00
IS

3. SUPPLEMENT NUMBERS/DATES:
letter date: 05-JUL-2000
stamp date: 06-JUL-2000

AB

4. AMENDMENTS/REPORTS/DATES:
5. RECEIVED BY CHEMIST: 11-JUL-2000

6. APPLICANT NAME & ADDRESS

7. NAME OF DRUG:

SmithKline Beecham Pharmaceuticals
1250 S. Collegeville Road
Collegeville, PA 19426-0989
Paxil® Oral Suspension (NDA 20-710)
Paxil® Capsules (NDA 20-885)
Paxil® CR Tablets (NDA 20-936)
paroxetine HCl hemihydrate
see 2000 USAN dictionary
see above item 7
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
Anti-depressant, Treatment of Obsessive
Compulsive Disorder, Panic Disorder, Social
Anxiety Disorder

8. NONPROPRIETARY NAME:
9. CHEMICAL NAME/STRUCTURE:
10. DOSAGE FORM(S):
11. POTENCY:

12. PHARMACOLOGICAL CATEGORY:

13. HOW DISPENSED:

14. RECORDS & REPORTS CURRENT:

15. RELATED IND/NDA/DMF:

X (Rx) (OTC)
 X Yes No

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.

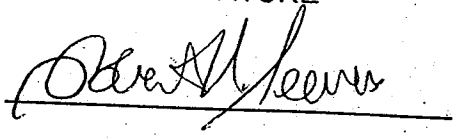
18. CONCLUSIONS & RECOMMENDATIONS: The requested new drug substance manufacturing site is identical to that approved recently for NDA 20-031/SCM-025. The site has received an Acceptable cGMP status. The supplements may be approved.

REVIEWER NAME

SIGNATURE

DATE COMPLETED

Robert H. Seevers



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

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	Brand Name: PAXIL (PAROXETINE HCL)	
1250 SOUTH COLLEGEVILLE RD UP	10/20/30/40MG CAP	
COLLEGEVILLE, PA 194260989	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)	DMF No: (b) (4)
SMITH KLINE BEECHAM PHARMA	AADA No:
CURRAGHBINNY	
COUNTY CORK, , EI	

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

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

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20-936/S004

20-885/S002

20-710/S007

**ADMINISTRATIVE and CORRESPONDENCE
DOCUMENTS**



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,

John S. Purvis 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

NDA 20-936/004

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cc:

Original NDA 20-936/004

HFD-120/Div. Files

HFD-120/CSO/David

filename:

SUPPLEMENT ACKNOWLEDGEMENT

0005 / 1 100



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

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Dr. Russell Katz, Director
July 5, 2000
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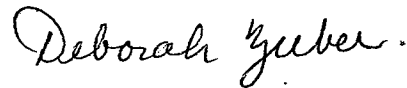
Reference is also made to NDA 20-031, Paxil® (paroxetine hydrochloride hemihydrate) Tablets, 10 mg, 20 mg, 30 mg and 40 mg and to the Supplement S-025 approved by FDA on May 17, 2000. Supplement S-025 was approved for the SmithKline Beecham Pharmaceuticals Cork, Ireland facility to manufacture ^{(b) (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 drug 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
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)

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