

**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

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## *APPLICATION NUMBER:*

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**20-885/S002**

**20-710/S007**

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*APPLICATION NUMBER:*

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**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.

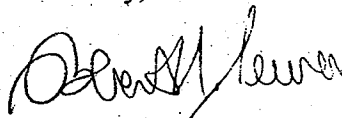
These "Changes Being Effected in 30 days" supplemental new drug applications provide for the use of paroxetine hydrochloride hemihydrate drug substance manufactured at your firm's Cork, Ireland facility.

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

5. APPLICANT NAME & ADDRESS

4. AMENDMENTS/REPORTS/DATES:  
5. RECEIVED BY CHEMIST: 11-JUL-2000  
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)  
paroxetine HCl hemihydrate  
see 2000 USAN dictionary  
see above item 7

NONPROPRIETARY NAME:  
1. CHEMICAL NAME/STRUCTURE:  
0. DOSAGE FORM(S):  
1. 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  
Anti-depressant, Treatment of Obsessive  
Compulsive Disorder, Panic Disorder, Social  
Anxiety Disorder

2. PHARMACOLOGICAL CATEGORY:

X (Rx) \_\_\_\_\_ (OTC)  
X Yes \_\_\_\_\_ No

3. HOW DISPENSED:

4. RECORDS & REPORTS CURRENT:

5. RELATED IND/NDA/DMF:

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

7. 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.

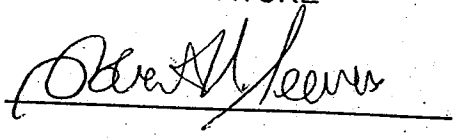
8. CONCLUSIONS & RECOMMENDATIONS: The requested new drug substance manufacturing site is identical to that approved recently for NDA 20-031/SCM-025. The site has received an Acceptable cGMP status. The supplements may be approved.

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**

*APPLICATION NUMBER:*

**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 Manufacturers

# 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**

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Dr. Russell Katz, Director  
July 5, 2000  
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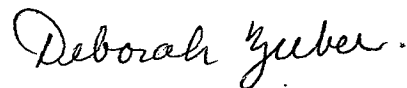
Reference is also made to NDA 20-031, Paxil® (paroxetine hydrochloride hemihydrate) Tablets, 10 mg, 20 mg, 30 mg and 40 mg and to the Supplement S-025 approved by FDA on May 17, 2000. Supplement S-025 was approved for the SmithKline Beecham Pharmaceuticals Cork, Ireland facility to manufacture (b) (4) 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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