CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

50-725 / S-007

Trade Name: Augmentin

Generic Name: (amoxicillin / clavulanate potassium)

Sponsor: GlaxoSmithKline

Approval Date: November 19, 1999

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50-725 / S-007

CONTENTS

Reviews / Information Included in this NDA Review.

Approval Letter	X
Approvable Letter	
Final Printed Labeling	
Medical Review(s)	
Chemistry Review(s)	**X**
EA/FONSI	
Pharmacology Review(s)	
Statistical Review(s)	
Microbiology Review(s)	
Clinical Pharmacology/ Biopharmaceutics Review(s)	
Administrative and Correspondence Document(s)	

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APPROVAL LETTER

8.1

NDA 50-564/S-037
NDA 50-575/S-028
NDA 50-597/S-033
NDA 50-720/S-009
NDA 50-726/S-007
NDA 50-725/S-007
NDA 50-590/S-037
NDA 50-658/S-007

NOV 19 1999

SmithKline Beecham Pharmaceutical
Attention: Ms. Sharon Maglennon
Assistant Director,
Regulatory Affairs, North America
1250 S. Collegeville Road
P.O. Box 5089
Collegeville, PA 19426-0989

Dear Ms. Maglennon:

Please refer to your supplemental new drug applications dated July 26, 1999, received July 26, 1999, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Augmentin® (amoxicillin/clavulanate potassium) Tablets, NDA 50-564; Augmentin® (amoxicillin/clavulanate potassium) 4:1 Powder for Oral Suspension, NDA 50-575; Augmentin® (amoxicillin/clavulanate potassium) Chewable Tablets, NDA 50-597; Augmentin® (amoxicillin/clavulanate potassium) BID Tablets, NDA 50-720; Augmentin® (amoxicillin/clavulanate potassium) BID Chewable Tablets, NDA 50-726; Augmentin® (amoxicillin/clavulanate potassium) 7:1 Powder for BID Oral Suspension, 50-725; Timentin® (sterile ticarcillin disodium and clavulanate potassium), NDA 50-590; Timentin® (sterile ticarcillin disodium and clavulanate potassium) for Injection in Plastic Container, PL 2040, NDA 50-658.We note that these applications are subject to the exemption provisions contained in section 125(d)(2) of Title I of the FDA Modernization Act of 1997.

These supplemental new drug applications provide for three changes to the extraction

[redacted]

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

We remind you of your commitment to place in your long-term stability program, the first commercial batch (es) of drug substance. In addition, please commit the first commercial batch of drug product manufactured from the drug substance with the new process into your long-term stability program and report the stability data in your annual report, as it becomes available.

In addition, update the proposed changes in your drug master files affected.

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 CDR. Jose R. Cintron, USPHS, Senior Regulatory Management Officer/Project Manager, at (301) 827-2125.

Sincerely,

David B. Katague, Ph.D.
Chemistry Team Leader for the
Division of Anti-Infective Drug Products,
(HFD-520)
DNDC III, Office of New Drug Chemistry
Center for Drug Evaluation and Research

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

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CHEMISTRY REVIEW(S)

8.1

NDA SUPPLEMENT REVIEW

NOV 9 1999

CHEMIST'S REVIEW	1. ORGANIZATION	2. NDA NUMBER
1	DAIDP (HFD-520)	50-725

3. NAME & ADDRESS OF APPLICANT

Smithkline Beehcam Pharmaceutics
1250 South Collegeville Road,
P.O. Box 5089, Collegeville
PA 19426-0989

4. AF NUMBER

5. SUPPLEMENT(s)
NUMBER(s) DATE(s)
SCS-008 7/26/99
7

6. NAME OF DRUG	7. NONPROPRIETARY NAME
Augmentin powder for oral suspension	Amoxicillin/clavulante potassium powder for oral suspension

8. SUPPLEMENT(s) PROVIDES FOR:

9. AMENDMENTS AND OTHER (REPORTS -tc.) DATES

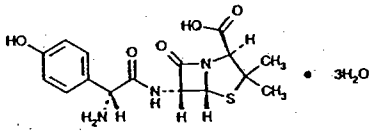
10. PHARMACOLOGICAL

11. CATEGORY	HOW DISPENSED	12. RELATED IND/NDA/DMF(s)
Anti-bacterial	X Rx OTC	

13. DOSAGE FORM(s)	14. POTENCY(ies)
Powder for Oral suspension	200/28.5 and 400/57.5 mg/5ml

15. CHEMICAL NAME AND STRUCTURE

Amoxicillin Trihydrate $C_{15}H_{19}N_3O_5S.3H_2O$ & Clavulanate Potassium $C_8H_8KNO_5$
(2S,5R,6R)-6-[(R)-(-)-2-amino-2-(p-hydroxyphenyl)acetamido]-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0] heptane-2-carboxylic acid trihydrate.
CAS-61-336-70-7 M.W. 419.46



16. RECORDS AND REPORTS

	Yes	No
CURRENT	X	
REVIEWED	X	

17. COMMENTS This is a bundled review, please refer to NDA 50-564/SCS-037 review issued on 11/9/99 for details.

18. CONCLUSIONS AND RECOMMENDATIONS

Recommend approval letter to issue for this supplement.

cc: Orig: NDA 50-725 HFD-520/Gavrilovich
HFD-520 HFD-520/Markhene
HFD-520/Osterberg HFD-520/Cintron
HFD-520/Yu HFD-520/DKatague:R/D initialed DBK 11/9/99

VOM

NAME	REVIEWER SIGNATURE	DATE COMPLETED
Andrew Yu PhD	andrew yu	9-NOV-1999