CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

50-725 / S-008

Trade Name: Augmentin

Generic Name: (amoxicillin / clavulanate potassium)

Sponsor: GlaxoSmithKline

Approval Date: June 5, 2000

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APPLICATION NUMBER:

50-725 / S-008

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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APPLICATION NUMBER:

50-725 / S-008

APPROVAL LETTER

NDA 50-725/S-008

SmithKline Beecham Pharmaceuticals
Attention: Thomas M. Hogan
Director, U.S. Regulatory Affairs
1250 South Collegeville Road
P.O. Box 5089
Collegeville, Pennsylvania 19426-0989

Dear Mr. Hogan:

Please refer to your supplemental new drug application dated February 11, 2000, received February 14, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Augmentin® (amoxicillin/clavulanate potassium) 7:1 powder for BID Oral Suspension. We note that this application is subject to the exemption provisions contained in section 125(d)(2) of Title I of the FDA Modernization Act of 1997.

[ ]

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, call Susmita Samanta, M.D., Regulatory 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

cc:
Archival NDA 50-725
HFD-520/Div. Files
HFD-520/S.Samanta
HFD-520/A.Yu/D.Katague
HFD-520/F.Lesane/L.Gavrilovich
HFD-830/DNDC Division Director
DISTRICT OFFICE

For concurrence only:
Frances V. Lesane, CPMS/HFD-520

Drafted by: SS/June 6, 2000
Initialed by:DK/June 6, 2000
AU/June 6, 2000
FL/June 6, 2000
final:SS/June 6, 2000
filename:50725.S8.6600.doc

APPROVAL (AP)

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

50-725 / S-008

CHEMISTRY REVIEW(S)

NDA SUPPLEMENT REVIEW

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

JUN - 5 2000

5. SUPPLEMENT(s) NUMBER(s) DATE(s)
SCS-008 2/11/00

6. NAME OF DRUG
Augmentin powder
for oral suspension

7. NONPROPRIETARY NAME
Amoxicillin/clavulante potassium
powder for oral suspension

8. SUPPLEMENT(s) PROVIDES FOR:

9. AMENDMENTS AND OTHER (REPORTS, etc.) DATES

[redacted]

11. CATEGORY
Anti-bacterial

HOW DISPENSED
X
Rx OTC

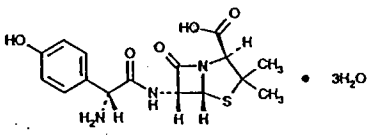
12. PHARMACOLOGICAL RELATED IND/NDA/DMF(s)

13. DOSAGE FORM(s)
Powder for
Oral suspension

14. POTENCY(ies)
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

18. CONCLUSIONS AND RECOMMENDATIONS

Recommend approval letter to issue for this supplement.

cc: Orig: NDA 50-725
HFD-520
HFD-520/Osterberg
HFD-520/Yu
HFD-520/Gavrilovich
HFD-520/Markhene
HFD-520/Cintron/S.SAMANTA
HFD-520/DKatague:R/D initialed DBK 6/5/00

NAME	REVIEWER SIGNATURE	DATE COMPLETED
Andrew Yu PhD	Andrew Yu	June 5 2000

WITHHOLD 2 PAGE(S)

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Chemistry Review 1