CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

50-725 / S-011

Trade Name: Augmentin

Generic Name: (amoxicillin / clavulanate potassium)

Sponsor: GlaxoSmithKline

Approval Date: November 27, 2000

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

50-725 / S-011

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)	

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

50-725 / S-011

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 50-725/S-011

SmithKline Beecham Pharmaceuticals
Attention: Sharon Maglennon
Assistant Director, North America Regulatory Affairs
1250 South Collegeville Road
P.O. Box 5089
Collegeville, Pennsylvania 19426-0989

Dear Ms. Maglennon:

Please refer to your supplemental new drug application dated July 25, 2000, received July 26, 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) 827-2149.

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

/s/

David Katague
11/27/00 10:41:53 AM

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

50-725 / S-011

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

5. SUPPLEMENT(s)
NUMBER(s) DATE(s)
SCS-011 7/25/00

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

10. PHARMACOLOGICAL CATEGORY
Anti-bacterial

11. HOW DISPENSED
X
Rx OTC

12. 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/Samanta
HFD-520/DKatague:R/D initialed

NAME	REVIEWER SIGNATURE	DATE COMPLETED
Andrew Yu PhD		NOV 14 2000

20. Components and Composition
n/a

21. Facilities and Personnel
n/a

22. Synthesis

WITHHOLD 2 PAGE(S)

B4

Chemistry Review

/s/

Andy Yu
11/16/00 09:22:51 AM
CHEMIST

Dave, please sign and notify PM to issue approval letter

David Katague
11/16/00 09:39:58 AM
CHEMIST