

CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

50-725 / S-013

Trade Name: Augmentin

Generic Name: (amoxicillin / clavulanate potassium)

Sponsor: GlaxoSmithKline

Approval Date: April 17, 2001

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50-725 / S-013

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



NDA 50-542/S-018
NDA 50-754/S-003
NDA 50-761/S-002
NDA 50-760/S-002
NDA 50-564/S-040
NDA 50-597/S-036
NDA 50-575/S-030
NDA 50-720/S-012
NDA 50-726/S-011
NDA 50-725/S-013

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 applications dated October 20, 2000, received October 23, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Amoxil[®] (amoxicillin) Chewable Tablets (tid) (50-542/S-018), Amoxil[®] (amoxicillin) Tablets (bid) (50-754/S-003), Amoxil (amoxicillin) Chewable Tablets (bid) (50-761/S-002), Amoxil[®] (amoxicillin) Suspension (bid) (50-760/S-002), Augmentin[®] (amoxicillin/clavulanate potassium) Tablets (tid) (50-564/S-040), Augmentin[®] (amoxicillin/clavulanate potassium) Chewable Tablets (tid) (50-597/S-036), Augmentin[®] (amoxicillin/clavulanate potassium) 4:1 Powder for Oral Suspension (tid) (50-575/S-030), Augmentin[®] (amoxicillin/clavulanate potassium) Tablets (bid) (50-720/S-012), Augmentin[®] (amoxicillin/clavulanate potassium) Chewable Tablets (bid) (50-726/S-011), Augmentin[®] (amoxicillin/clavulanate potassium) 7:1 Oral Suspension (bid) (50-725/S-013).

These "Changes Being Effected" supplemental new drug applications propose an expansion of the SB 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.

NDA 50-542/S-018
NDA 50-754/S-003
NDA 50-761/S-002
NDA 50-760/S-002
NDA 50-564/S-040
NDA 50-597/S-036
NDA 50-575/S-030
NDA 50-720/S-012
NDA 50-726/S-011
NDA 50-725/S-013

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If you have any questions, call Susmita Samanta, M.D., Regulatory Project Manager, at (301) 827-2125.

Sincerely,

{See appended electronic signature page}

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

**This is a representation of an electronic record that was signed electronically and
this page is the manifestation of the electronic signature.**

/s/

David Katague
4/17/01 03:35:25 PM

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APPLICATION NUMBER:

50-725 / S-013

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	4. AF NUMBER
Smithkline Beecham Pharmaceuticals 1250 South Collegeville Road, P.O. Box 5089, Collegeville PA 19426-0989	

**5. SUPPLEMENT (s)
NUMBER (s) DATE (s)**

SCS-013 10/20/00 CBE-30

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, etc.) DATES
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An expansion of the Amoxicillin trihydrate. _____
 _____ All equipment remains of the same design and operating principle.

10. PHARMACOLOGICAL CATEGORY	11. 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 C₁₅H₁₉N₃O₅S.3H₂O & Clavulanate Potassium C₈H₈KNO₅
 (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.

(See p2 for structure)

16. RECORDS AND REPORTS	
CURRENT	X
Yes	No
REVIEWED	X
Yes	No

16. COMMENTS Bundled reviews

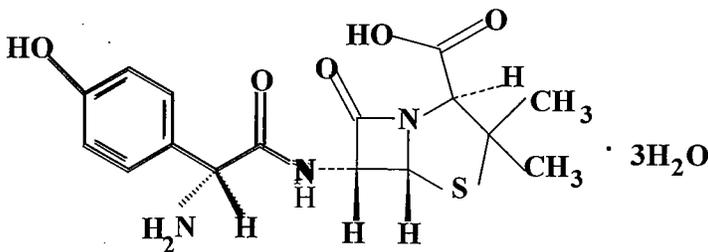
17. CONCLUSIONS AND RECOMMENDATIONS

Recommend approval letter to issue for this supplement.

cc: Orig: NDA 50-725 HFD-520/ Samanta
 HFD-520 HFD-520/Makhene
 HFD-520/Yu HFD-520/DKatague:R/D initialed

NAME	REVIEWER SIGNATURE	DATE COMPLETED
Andrew Yu PhD		10-APRR-2001

Amoxicillin trihydrate: CAS-61-336-70-7 M.W. 419.46



WITHHOLD 3 PAGE(S)

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Chemistry Review

/s/

Andy Yu
4/10/01 03:00:23 PM
CHEMIST

David Katague
4/10/01 03:26:56 PM
CHEMIST