CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

50-725 / S-003

Trade Name: Augmentin

Generic Name: (amoxicillin / clavulanate potassium)

Sponsor: GlaxoSmithKline

Approval Date: February 19, 1998

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

50-725 / S-003

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 50-725/S-003

Smithkline Beecham Pharmaceuticals
1250 S. Collegeville Road
P.O. Box 5089
Collegeville, PA 19426-0989

FEB 19 1998

Attention: Thomas M. Hogan

Dear Mr. Hogan:

Please refer to your supplemental new drug application dated January 10, 1998, received January 13, 1998, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Augmentin Suspension(amoxicillin/clavulanate potassium suspension), 200 mg/5 mL and 400 mg/ 5 mL. We note that this application is subject to the exception provisions of Section 125(d)(2) of Title 1 of the FDA Modernization Act of 1997.

We also acknowledge receipt of your submission dated February 4, 1998. The User Fee goal date for this application is July 13, 1998.

The supplemental application provides for utilization of

We have completed the review of this supplemental application and it is approved.

This approval afffects only those changes specifically submitted in this supplemental application. Other changes that may have been approved or are pending evaluation are not 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, please contact Mr. Stephen T. Trostle, Regulatory Health Project Manager, at (301) 827-2125.

Sincerely yours,

David B. Katague

David B. Katague, Ph.D.
Chemistry Team Leader, DNDC-III
Division of Anti-Infective Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

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APPLICATION NUMBER:

50-725 / S-003

CHEMISTRY REVIEW(S)

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

3. NAME & ADDRESS OF APPLICANT
Smithkline Beecham Pharmaceuticals
1250 S. Collegeville Road P.O. Box 5089
Collegeville, PA 19426-0989

4. AF NUMBER

FEB 19 1998

5. SUPPLEMENT(s)
NUMBER(s) DATE(s)
SCM-003 1/10/98

6. NAME OF DRUG
Augmentin Suspension

7. NONPROPRIETARY NAME
amoxicillin/clavulanate potassium Suspension

8. SUPPLEMENT(s) PROVIDES FOR:

9. AMENDMENTS AND OTHER (REPORTS, etc.) DATES
Amendment 2/4/98

10. PHARMACOLOGICAL CATEGORY
Anti-bacterial

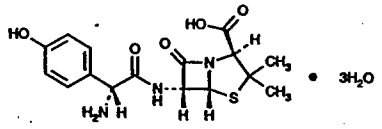
11. HOW DISPENSED
X
Rx OTC

12. RELATED IND/NDA/DMF(s)

13. DOSAGE FORM(s)
Powder for Suspension

14. POTENCY(ies)
200 mg/5 mL and 400 mg/5 mL

15. CHEMICAL NAME AND STRUCTURE
(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. M.W. 419.46
Potassium (Z)-(2R,5R)-3-(2-hydroxyethylidene)-7-oxo-4-oxa-1-azabicyclo[3.2.0]-heptane-2-carboxylate M.W. 237.25



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

17. COMMENTS
This drug is referenced in USP 23, pg. 103.

18. CONCLUSIONS AND RECOMMENDATIONS
Recommend approval letter to issue for this supplement.

cc: Orig: NDA 50-725
HFD-520 HFD-520/Makhene
HFD-520/Osterberg HFD-520/Trostle
HFD-520/Yu HFD-520/DKatague:R/D initialed DSK 2/19/98

19. REVIEWER

NAME	**SIGNATURE**	**DATE COMPLETED**
Andrew Yu PhD		February 10, 1998

DISTRIBUTION ORIGINAL JACKET REVIEWER DIVISION FILE

20. Components and Composition

n/a

21. Facilities and Personnel

n/a

22. Synthesis

n/a

23. Raw Material Controls

a. New Drug Substance n/a

b. Other Ingredients Adequate

[redacted]

24. Other Firm(s)
n/a

25. Manufacturing and Processing

n/a

26. Container/Closure

n/a

27. Packaging and Labeling

n/a

28. Laboratory Controls (In-process and Finished Dosage Form)

n/a

29. Stability

n/a

30. Control Numbers

n/a

31. Samples and Results

n/a

a. Validation

b. Market Package

32. Labeling

n/a

33. Establishment Inspection

n/a

34. Recalls

n/a