CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

50-725 / S-014

Trade Name: Augmentin

Generic Name: (amoxicillin / clavulanate potassium)

Sponsor: GlaxoSmithKline

Approval Date: December 7, 2001

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

50-725 / S-014

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)	**X**

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APPLICATION NUMBER:

50-725 / S-014

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 50-725/S-014

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

Dear Ms. Maglennon,

Please refer to your supplemental new drug application dated June 14, 2001, received June 15, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Augmentin® (amoxicillin/clavulanate potassium), 7:1 powder for 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.

This "Changes Being Effected in 30 days" supplemental new drug application proposes to change the shelf-life of Augmentin® powder for oral suspension from 9 months to 12 months.

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,

{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

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/s/

David Katague
12/7/01 11:16:29 AM

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

50-725 / S-014

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**

GlaxoSmithkline
1250 South Collegeville Road,
P.O. Box 5089, Collegeville
PA 19426-0989

4. **AF NUMBER**

5. **SUPPLEMENT(s)**

NUMBER(s)	DATE(s)
SCE-014	6/14/01
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:**

Change in shelf life of Augmentin powder for oral suspension from 9 months to 12 months

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

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 $C_{15}H_{19}N_3O_5S.3H_2O$ & 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.
(See p2 for structure)

16. **RECORDS AND REPORTS**

	Yes	No
CURRENT	X	
REVIEWED	X	

16. **COMMENTS**

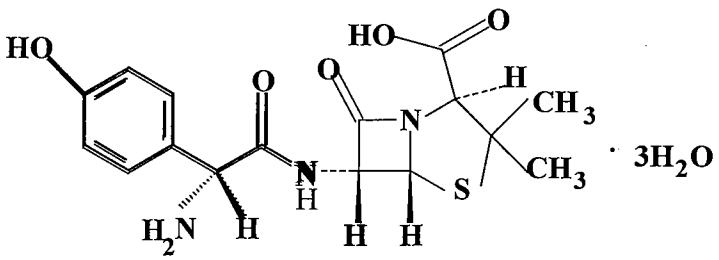
17. **CONCLUSIONS AND RECOMMENDATIONS**

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		3-DEC-2001

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



20. Components and Composition
n/a

21. Facilities and Personnel
n/a

22. Synthesis n/a

23. Raw Material Controls n/a
a. New Drug Substance
b. Other Ingredients

24. Other Firm(s)
n/a

25. Manufacturing and Processing

26. Container/Closure
n/a

27. Packaging and Labeling
n/a

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

29. **Stability**

[redacted]

30. Control Numbers
n/a

31. Samples and Results
n/a

32. Labeling

33. Establishment Inspection
n/a

34. Recalls
n/a

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/s/

Andy Yu
12/5/01 11:32:24 AM
CHEMIST

David Katague
12/5/01 01:22:02 PM
CHEMIST

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

50-725 / S-014

ADMINISTRATIVE DOCUMENTS AND CORRESPONDENCE

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 50-725/S-014

CBE-30 SUPPLEMENT

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

Dear Ms. Maglennon,

We have received your supplemental drug application submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following:

Name of Drug Product:	Augmentin® (amoxicillin/clavulanate potassium)
NDA Number:	50-725
Supplement number:	S-014
Date of supplement:	June 14, 2001
Date of receipt:	June 15, 2001

This supplemental application, submitted as "Special Supplement - Changes Being Effected in 30 days", proposes to extend the 400 mg suspension shelf-life from 9 months to 12 months.

Unless we notify you within 60 days of the receipt date that the application is not sufficiently complete to permit a substantive review, this application will be filed under section 505(b) of the Act on August 14, 2001, in accordance with 21 CFR 314.101(a).

All communications concerning this supplement should be addressed as follows:

U.S. Postal Service:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Anti-Infective Drug Products, HFD-520
Attention: Division Document Room
5600 Fishers Lane
Rockville, Maryland 20857

Courier/Overnight Mail:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Anti-Infective Drug Products, HFD-520
Attention: Division Document Room
9201 Corporate Blvd.
Rockville, Maryland 20850-3202

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

Sincerely yours,

{See appended electronic signature page}

Frances LeSane
Chief, Project Management Staff
Division of Anti-Infective Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

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/s/

Frances LeSane
9/27/01 11:20:01 AM