

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

50-720/S-009

CHEMISTRY REVIEW(S)

CHEMIST'S REVIEW	1. ORGANIZATION DAIDP (HFD-520)	2. NDA NUMBER 50-720
3. NAME & ADDRESS OF APPLICANT Smithkline Beecham Pharmaceuticals 1250 South Collegeville Road, P.O. Box 5089, Collegeville PA 19426-0989	4. AF NUMBER	
5. SUPPLEMENT(s) NUMBER(s) DATE(s) 8-005 7/26/99		

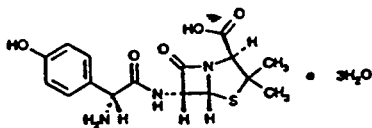
6. NAME OF DRUG Augmentin Tablet	7. NONPROPRIETARY NAME Amoxicillin/Clavulanate Potassium tablet
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8. SUPPLEMENT(s) PROVIDES FOR: Modification of the process of extraction of	9. AMENDMENTS AND OTHER (REPORTS, etc.) DATES
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10. PHARMACOLOGICAL CATEGORY Anti-bacterial	11. HOW DISPENSED X Rx OTC	12. RELATED IND/NDA/DMF(s) DMF 4349
13. DOSAGE FORM(s) Tablet	14. POTENCY(ies) 875 mg	

15. CHEMICAL NAME AND STRUCTURE

Amoxicillin Trihydrate $C_{15}H_{19}N_3O_5S \cdot 3H_2O$ & 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.
Potassium (Z)-(2R,5R)-3-(2-hydroxyethylidene)-7-oxo-4-oxa-1-azabicyclo[3.2.0]-heptane-2-carboxylate



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

17. COMMENT Please refer to NOA 50-524/SCS-037 for details dated 11/9/99

18. CONCLUSIONS AND RECOMMENDATIONS

Recommend approval letter to issue for this supplement.

cc: Orig: NDA 50-720	HFD-520/Gavrilovich
HFD-520	HFD-520/Markhene
HFD-520/Osterberg	HFD-520/Cintron
HFD-520/Yu	HFD-520/DKatague:R/D initialed

NAME
Andrew Yu PhD

REVIEWER SIGNATURE

DATE COMPLETED
9-NOV-1999

/S/

/S/ 11/9/99