

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

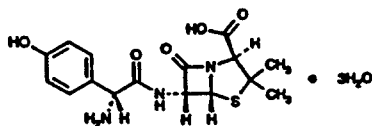
50-720/S-008

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	
SEP 23 1999		5. SUPPLEMENT (s)
		NUMBER (s) DATE (s) 5/28/99

8. SUPPLEMENT(s) PROVIDES FOR: 9. AMENDMENTS AND OTHER
(REPORTS, etc.) DATES
Potassium clavulante, a drug substance Amendment 8-4-99
now produced by a ~~_____~~

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. **COMMENTS** This supplement involves strain change of the fermenting organism in the referenced DMFs (consult was attached from Duu-Gong Wu, HFD-510, Please refer to review for NDA 50564/S036 dated 9/20/99 for a full detailed bundled review with attached consult).

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/DKataque:R/D initialed

NAME
Andrew Yu PhD

REVIEWER SIGNATURE

DATE COMPLETED
21-SEP-1999

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