

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

50-720/S-013

CHEMISTRY REVIEW(S)

NDA SUPPLEMENT REVIEW

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) 80-10/31/01
6. NAME OF DRUG Augmentin Tablet	7. NONPROPRIETARY NAME Amoxicillin/Clavulanate Potassium tablet	CBE-30
8. SUPPLEMENT (s) PROVIDES FOR:	9. AMENDMENTS AND OTHER (REPORTS, etc.) DATES	
_____ of the expiration dating period and to amend the routine commercial stability protocol.		
10. PHARMACOLOGICAL CATEGORY Anti-bacterial	11. HOW DISPENSED X Rx OTC	12. RELATED IND/NDA/DMF (s) DMF 13207
13. DOSAGE FORM (s) Tablet	14. POTENCY (ies) 875 mg	
15. CHEMICAL NAME AND STRUCTURE		
<u>Amoxicillin Trihydrate</u> C ₁₅ H ₁₉ N ₃ O ₅ S.3H ₂ O & Clavulanate Potassium C ₈ H ₈ KNO 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	Please refer to bundled review 50-754/SCE-006 dated 30-APR-2002 by A. Yu for full review.	
18. CONCLUSIONS AND RECOMMENDATIONS		
Recommend approval letter to issue for this supplement.		
cc: Orig: NDA 50-720	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		30-APR-2002

**APPEARS THIS WAY
ON ORIGINAL**

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

/s/

Andy Yu
4/30/02 05:58:55 PM
CHEMIST

Shrikant Pagay
4/30/02 06:23:23 PM
CHEMIST
Signed for Dr. Katague

**APPEARS THIS WAY
ON ORIGINAL**