CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

50-720/S-004

CHEMISTRY REVIEW(S)

OCT 20 1997

NDA SUPPLEMENT REVIEW

CHEMIST'S REVIEW	1. ORGANIZATION	2. NDA NUMBER
	DAIDP (HFD-520)	50-720

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

4. AF NUMBER

5. SUPPLEMENT(s)

NUMBER(s)	DATE(s)
S[redacted]4	7/3/97

6. NAME OF DRUG
Augmentin tablet

7. NONPROPRIETARY NAME
amoxicillin/clavulante potassium tablet

8. SUPPLEMENT(s) PROVIDES FOR:
Changing method of analysis for the release and monitoring of Augmentin tablet stability

9. AMENDMENTS AND OTHER (REPORTS, etc.) DATES
Amendment 10/1/97

10. PHARMACOLOGICAL CATEGORY
Anti-bacterial

11. HOW DISPENSED

Rx	OTC
X	

12. RELATED IND/NDA/DMF(s)

13. DOSAGE FORM(s)
Tablet (q12h)

14. POTENCY(ies)
875 mg/125 mg

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
CAS-61-336-70-7

16. RECORDS AND REPORTS

	Yes	No
CURRENT	X	
REVIEWED	X	

17. COMMENTS
This drug is the subject of a compendial monograph, USP 23, pg. 383.

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

cc: Orig: NDA 50-720
HFD-520
HFD-520/Osterberg
HFD-520/Yu
HFD-520/Makhene
HFD-520/Trostle
HFD-520/DKatague:R/D initialed /S/ 10/24/97

19. REVIEWER

NAME	SIGNATURE	DATE COMPLETED
Andrew Yu PhD	/S/	October 20, 1997

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

n/a

a. New Drug Substance

b. Other Ingredients

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)
Amoxicillin is referenced in the USP (USP 23, pg. 383) and content uniformity is an analytical release requirement of all oral products.

[redacted]

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