CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

50-720/S-005

CHEMISTRY REVIEW(S)

DIV

NDA SUPPLEMENT REVIEW FEB 11 1998

CHEMIST'S REVIEW	1. ORGANIZATION	2. NDA NUMBER
	DAIDP (HFD-520)	[redacted]

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)
SC[redacted]	1/10/98

6. NAME OF DRUG
Augmentin tablet

7. NONPROPRIETARY NAME
amoxicillin/clavulanate potassium tablet

8. SUPPLEMENT(s) PROVIDES FOR:
The site change of microbiologic and excipient release tests of Augmentin tablets

9. AMENDMENTS AND OTHER (REPORTS, etc.) DATES
Amendment 2/4/98

10. PHARMACOLOGICAL CATEGORY
Anti-bacterial

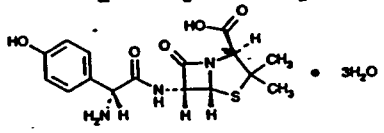
11. HOW DISPENSED
X
Rx OTC

12. RELATED IND/NDA/DMF(s)

13. DOSAGE FORM(s)
Tablet (bid)

14. POTENCY(ies)
875 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
Potassium (Z)-(2R,5R)-3-(2-hydroxyethylidene)-7-oxo-4-oxa-1-azabicyclo[3.2.0]-heptane-2-carboxylate M.W. 237.25



16. RECORDS AND REPORTS

	Yes	No
CURRENT	X	
REVIEWED	X	

17. COMMENTS
This drug is referenced in USP 23, pg. 100.

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

cc: Orig: NDA 50-720
HFD-520 HFD-520/Makhene
HFD-520/Osterberg HFD-520/Trostle
HFD-520/Yu HFD-520/DKatague:R/D initialed __

/S/ 2/11/98

19.

NAME	REVIEWER SIGNATURE	DATE COMPLETED
Andrew Yu PhD	/S/	February 10, 1998

for /S/

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**

a. New Drug Substance n/a

b. Other Ingredients Adequate

The supplement is submitted to request a site change for excipient release and testing required for Augmentin tablets manufacturing. The new testing site will be:

[ ]

_____ (Drug Establishment _____ was inspected and found to be acceptable by OC (EER attached). A full description of the water testing and raw material testing performed by _____ is provided in attachement 3 and amended on 2/4/98.

[ ]

A certification from _____ verifying they are in conformance with cGMP is provided in attachment 4.

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)

n/a

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