CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

50-720/S-001

CHEMISTRY REVIEW(S)

NDA SUPPLEMENT REVIEW MAY 13 1996

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, PO Box 5089
Collegeville, PA 19426-0989

4. AF NUMBER

5. SUPPLEMENT(s) NUMBER(s) DATE(s)
SCM-001 3/27/96

6. NAME OF DRUG
Augmentin

7. NONPROPRIETARY NAME
Amoxicillin/Clavulanate Potassium

8. SUPPLEMENT(s) PROVIDES FOR:

SCM-001: For re-instating the the use of — facility for the —

9. AMENDMENTS AND OTHER (REPORTS, etc.) DATES
none

10. PHARMACOLOGICAL CATEGORY
Antimicrobial

11. HOW DISPENSED
XXX
Rx OTC

12. RELATED IND/NDA/DMF(s)

13. DOSAGE FORM(s)
Tablet

14. POTENCY(ies)
Amoxicillin 875 mg/Clavulanate potassium 125mg/Tablet

15. CHEMICAL NAME AND STRUCTURE

Amoxicillin $C_{16}H_{19}N_3O_5S.3H_2O$
(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 Registry No. 61336-70-7

Clavulanate potassium C_8H_8KNO5
Potassium (Z)-(2R,5R)-3-(2-hydroxyethylidene)-7-oxo-4-oxa-1-azabicyclo[3.2.0]-heptane-2-carboxylate
m.w. 237.25
CAS Registry No. 61177-45-5

16. RECORDS AND REPORTS

	Yes	No
CURRENT		
REVIEWED	Yes	No

17. COMMENTS
This drug is the subject of a compendial monograph, USP 23, page 104. See items 20-34 for detailed comments.

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

cc: Orig: NDA 50-720
HFD-520
HFD-520/Buko
HFD-520/SPagay
HFC-130/JAllen
HFD-520/Roberts
HFD-520/Cintron
HFD-520/SBRoy:R/D initialed /S/ 5/13/96

19. REVIEWER

NAME	SIGNATURE	DATE COMPLETED
Shrikant Pagay, Ph.D.	/S/	5/10/96

DISTRIBUTION ORIGINAL JACKET REVIEWER DIVISION FILE

20. Components and Composition: NA

21. Facilities and Personnel: NA

22. Synthesis: NA

23. Raw Material Controls: NA
    a. New Drug Substance
    b. Other Ingredients

24. Other Firm(s): NA

25. Manufacturing and Processing: NA

26. Container/Closure: NA

27. Packaging and Labeling: NA

28. Laboratory Controls (In-process and Finished Dosage Form): NA

29. Stability: NA

30. Control Numbers: NA

31. Samples and Results: NA
    a. Validation
    b. Market Package

32. Labeling: NA

33. Establishment Inspection

    On February 2, 1996, the firm withdrew the [redacted] facility as a source of [redacted] since it was outside the 2 year compliance period (GMP inspection) and consequently had an impact on the approvability of the NDA application. The facility was inspected on March 14, 1996 and the inspection was satisfactory (report attached - [redacted].

34. Recalls: NA