

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

50-720/S-007

CHEMISTRY REVIEW(S)

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

3. NAME & ADDRESS OF APPLICANT **4. AF NUMBER**
 Smithkline Beecham Pharmaceuticals
 1250 South Collegeville Road,
 P.O. Box 5089, Collegeville
 PA 19426-0989

5. SUPPLEMENT(s)
NUMBER(s) DATE(s)
~~50-720~~ 7/31/98

6. NAME OF DRUG **7. NONPROPRIETARY NAME**
 Augmentin Tablet Amoxicillin/Clavulanate
 Potassium tablet

8. SUPPLEMENT(s) PROVIDES FOR: **9. AMENDMENTS AND OTHER**
 (REPORTS, etc.) **DATES**

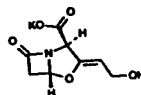
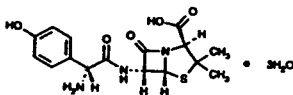
Method, specification & other changes in
 Potassium clavulanate in DMFs 4349 & 7048

10. PHARMACOLOGICAL **11. HOW DISPENSED** **12. RELATED**
CATEGORY **IND/NDA/DMF(s)**
 Anti-bacterial X DMF 4349 & 7048
 Rx OTC

13. DOSAGE FORM(s) **14. POTENCY(ies)**
 Tablet 875 mg

15. CHEMICAL NAME AND STRUCTURE

Amoxicillin Trihydrate C₁₅H₁₉N₃O₅·3H₂O & Clavulanate Potassium C₈H₈KNO₅
 (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 refers to changes in the DMFs
 for potassium clavulanate which are reviewed separately.

18. CONCLUSIONS AND RECOMMENDATIONS

Recommend approval letter to issue for this supplement.

cc: Orig: NDA 50-720 HFD-520/Garilovich
 HFD-520 HFD-520/Markene
 HFD-520/Osterberg HFD-520/Trostle
 HFD-520/Yu HFD-520/DKatague

NAME **REVIEWER SIGNATURE** **DATE COMPLETED**
 Andrew Yu PhD *[Signature]* 31-JAN-1999

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) n/a
- 29. Stability
n/a
- 30. Control Numbers
n/a
- 31. Samples and Results
n/a
- 32. Labeling
n/a
- 33. Establishment Inspection
n/a
- 34. Recalls
n/a

**APPEARS THIS WAY
ON ORIGINAL**