CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

50-720/S-012

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 Beehcam Pharmaceutics
1250 South Collegeville Road,
P.O. Box 5089, Collegeville
PA 19426-0989

4. **AF NUMBER**

5. **SUPPLEMENT(s)**
NUMBER(s) DATE(s)
[redacted] 10/20/00
CBE-30

6. **NAME OF DRUG**
Augmentin Tablet

7. **NONPROPRIETARY NAME**
Amoxicillin/Clavulanate Potassium tablet

8. **SUPPLEMENT(s) PROVIDES FOR:**

An expansion of the [redacted] Amoxicillin trihydrate. [redacted] All equipment remains of the same design and operating principle.

9. **AMENDMENTS AND OTHER (REPORTS, etc.) DATES**

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**

Amoxicillin Trihydrate $C_{15}H_{19}N_3O_5S.3H_2O$ & Clavulanate Potassium $C_8H_8KNO_5$
(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 50-725/SCS-013 dated 4/10/01 by A. Yu

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

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

NAME	**REVIEWER SIGNATURE**	**DATE COMPLETED**
Andrew Yu PhD		10-APRR-2001

/s/

Andy Yu
4/10/01 03:07:43 PM
CHEMIST

David Katague
4/10/01 03:32:19 PM
CHEMIST

APPEARS THIS WAY
ON ORIGINAL