

**CENTER FOR DRUG EVALUATION AND RESEARCH**

*APPLICATION NUMBER:*

**50-720/S-016**

**CHEMISTRY REVIEW(S)**

**NDA Supplement Review**  
**Chemistry, Manufacturing, and Controls**  
**Division of Anti-Infective Drug Products (HFD-520)**

1. NDA NUMBER/SUPPLEMENT: 50-720/SCS-016

CBE-0

2. REVIEW: # 1

3. REVIEW DATE(s): 12/02/02 STAMP DATE: 6/5/02; DUE DATE: 12/5/02

4. SUPPLEMENT PROVIDES FOR: an update of the \_\_\_\_\_ manufacturing and controls of amoxicillin trihydrate drug substance. The update is an amendment, made March 29, 2002, to DMF \_\_\_\_\_

6. PREVIOUS DOCUMENTS: None

7. SUBMISSION(S) BEING REVIEWED: Original Supplement

8. NAME AND ADDRESS OF APPLICANT      GlaxoSmithKline  
1250 South Collegeville Road  
P. O. Box 5089  
Collegeville, PA 19426-0989  
S. LoCastro (610)-917-6457

9. DRUG PRODUCT NAME:

Proprietary Name : Augmentin Chewable tablet

Nonproprietary Name: Amoxicillin / Clavulanate Potassium chewable tablet

10. PHARMACOLOGICAL CATEGORY: Anti-bacterial

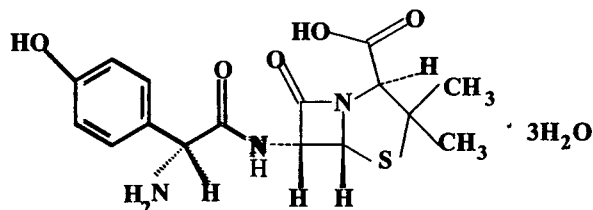
11. DOSAGE FORM: Chewable Tablet

12. STRENGTH/POTENCY: 125 and 250 mg

13. ROUTE OF ADMINISTRATION: Oral

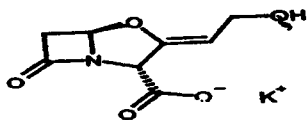
14. Rx/OTC DISPENSED:  Rx     OTC

15. CHEMICAL NAME, CHEMICAL STRUCTURE, MOLECULAR FORMULA, and MOL. WT.  
Amoxicillin Trihydrate: (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; CAS: [61-336-70-7]; MW419.46; C<sub>15</sub>H<sub>19</sub>N<sub>3</sub>O<sub>5</sub>·3H<sub>2</sub>O



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Clavulanate Potassium: Potassium(Z)-(2R,5R)-3-(2-hydroxyethyldene)-7-oxo-4-oxa-1-zabicyclo[3.2.0]heptane-2-carboxylate Clavulanate potassium; CAS: [61177-45-5]; MW: 237.25; C<sub>8</sub>H<sub>8</sub>KNO<sub>5</sub>;



**16. RELATED/SUPPORTING DOCUMENTS:** This supplement is bundled with the following 12 supplements: 50-755/S-004, 50-542/S-020, 50-564/S-044, 50-575/S-033, 50-597/S-040, 50-725/S-018, 50-726/S-015, 50-754/S-007, 50-760/S-006, 50-761/S-006, ANDA 62-226S-029 and 62-216/S-028. See lead review for NDA 50-755/S-004 for details.

**17. COMMENTS:** DMF is a Type II DMF referenced for the proposed change of this supplement. The applicant is See lead review for NDA 50-755/SCS-004.

**18. CONCLUSIONS AND RECOMMENDATIONS:** It is recommended that an approval letter be issued for this supplement.

cc:  
HFD-520/Samanta  
HFD-800/M. Folkendt

HFD-830/Dunn  
HFD-520/Yu

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/s/

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LaVaughn Wilbur  
12/2/02 03:46:08 PM  
SECRETARY

Andy Yu  
12/2/02 03:55:20 PM  
CHEMIST

Bonnie Dunn  
12/2/02 04:22:20 PM  
CHEMIST

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