

**CENTER FOR DRUG EVALUATION AND RESEARCH**

***APPLICATION NUMBER:***

**50-720/S-012**

**APPROVAL LETTER**



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville MD 20857

NDA 50-542/S-018  
NDA 50-754/S-003  
NDA 50-761/S-002  
NDA 50-760/S-002  
NDA 50-564/S-040  
NDA 50-597/S-036  
NDA 50-575/S-030  
~~NDA 50-720/S-012~~  
NDA 50-726/S-011  
NDA 50-725/S-013

SmithKline Beecham Pharmaceuticals  
Attention: Sharon Maglennon  
Assistant Director, North America Regulatory Affairs  
1250 South Collegeville Road  
P.O. Box 5089  
Collegeville, Pennsylvania 19426-0989

Dear Ms. Maglennon:

Please refer to your supplemental new drug applications dated October 20, 2000, received October 23, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Amoxil<sup>®</sup> (amoxicillin) Chewable Tablets (tid) (50-542/S-018), Amoxil<sup>®</sup> (amoxicillin) Tablets (bid) (50-754/S-003), Amoxil (amoxicillin) Chewable Tablets (bid) (50-761/S-002), Amoxil<sup>®</sup> (amoxicillin) Suspension (bid) (50-760/S-002), Augmentin<sup>®</sup> (amoxicillin/clavulanate potassium) Tablets (tid) (50-564/S-040), Augmentin<sup>®</sup> (amoxicillin/clavulanate potassium) Chewable Tablets (tid) (50-597/S-036), Augmentin<sup>®</sup> (amoxicillin/clavulanate potassium) 4:1 Powder for Oral Suspension (tid) (50-575/S-030), Augmentin<sup>®</sup> (amoxicillin/clavulanate potassium) Tablets (bid) (50-720/S-012), Augmentin<sup>®</sup> (amoxicillin/clavulanate potassium) Chewable Tablets (bid) (50-726/S-011), Augmentin<sup>®</sup> (amoxicillin/clavulanate potassium) 7:1 Oral Suspension (bid) (50-725/S-013).

These "Changes Being Effected" supplemental new drug applications propose an expansion of the SB \_\_\_\_\_ facility.

We have completed the review of these supplemental applications, and they are approved.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

NDA 50-542/S-018  
NDA 50-754/S-003  
NDA 50-761/S-002  
NDA 50-760/S-002  
NDA 50-564/S-040  
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NDA 50-575/S-030  
NDA 50-720/S-012  
NDA 50-726/S-011  
NDA 50-725/S-013

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If you have any questions, call Susmita Samanta, M.D., Regulatory Project Manager, at (301) 827-2125.

Sincerely,

*{See appended electronic signature page}*

David B. Katague, Ph.D.  
Chemistry Team Leader for the  
Division of Anti-Infective Drug Products, (HFD-520)  
DNDC III, Office of New Drug Chemistry  
Center for Drug Evaluation and Research

**APPEARS THIS WAY  
ON ORIGINAL**

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/s/

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David Katague

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ON ORIGINAL**