

CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

50-725 / S-010

Trade Name: Augmentin

Generic Name: (amoxicillin / clavulanate potassium)

Sponsor: GlaxoSmithKline

Approval Date: May 3, 2001

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

50-725 / S-010

CONTENTS

Reviews / Information Included in this NDA Review.

Approval Letter	X
Approvable Letter	
Final Printed Labeling	
Medical Review(s)	
Chemistry Review(s)	X
EA/FONSI	
Pharmacology Review(s)	
Statistical Review(s)	
Microbiology Review(s)	
Clinical Pharmacology/ Biopharmaceutics Review(s)	
Administrative and Correspondence Document(s)	

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

50-725 / S-010

APPROVAL LETTER



NDA 50-720/S-011
NDA 50-564/S-039
NDA 50-726/S-009
NDA 50-725/S-010

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

Dear Ms. Maglennon:

Please refer to your supplemental new drug applications dated June 30, 2000, received June 30, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Augmentin[®] (amoxicillin/clavulanate potassium) BID Tablets (NDA 50-720), Augmentin[®] (amoxicillin/clavulanate potassium) TID Tablets (NDA 50-564), Augmentin[®] (amoxicillin/clavulanate potassium) BID Chewable Tablets (NDA 50-726) and Augmentin[®] (amoxicillin/clavulanate potassium) 7:1 BID Oral Suspension. We note that these applications are subject to the exemption provisions contained in section 125(d)(2) of Title I of the FDA Modernization Act of 1997.

These supplemental new drug applications provide information to allow for the use of amoxicillin trihydrate, manufactured at their facility in _____

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.

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

**This is a representation of an electronic record that was signed electronically and
this page is the manifestation of the electronic signature.**

/s/

David Katague
5/3/01 04:16:21 PM

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

50-725 / S-010

CHEMISTRY REVIEW(S)

WITHHOLD 3 **PAGE(S)**

B4

Chemistry Review

**This is a representation of an electronic record that was signed electronically and
this page is the manifestation of the electronic signature.**

/s/

Andy Yu
5/2/01 12:17:54 PM
CHEMIST

David Katague
5/2/01 12:53:38 PM
CHEMIST