

050755\_5003

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# CENTER FOR DRUG EVALUATION AND RESEARCH

## Approval Package

***APPLICATION NUMBER:***

**50-755 / S-003**

***Trade Name:*** Augmentin ES- 600

***Generic Name:*** Amoxicillin/clavulanate potassium

***Sponsor:*** GlaxoSmithKline

***Approval Date:*** May 12, 2003

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*APPLICATION NUMBER:*

**50-755 / S-003**

## CONTENTS

<b>Reviews / Information Included in this NDA Review.</b>
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<b>Approval Letter</b>	<b>X</b>
<b>Not Approvable Letter</b>	
<b>Final Printed Labeling</b>	<b>X</b>
<b>Medical Review(s)</b>	
<b>Chemistry Review(s)</b>	
<b>EA/FONSI</b>	
<b>Pharmacology Review(s)</b>	
<b>Statistical Review(s)</b>	
<b>Microbiology Review(s)</b>	
<b>Clinical Pharmacology/ Biopharmaceutics Review(s)</b>	
<b>Administrative and Correspondence Document(s)</b>	

# **CENTER FOR DRUG EVALUATION AND RESEARCH**

***APPLICATION NUMBER:***

**50-755 / S-003**

**APPROVAL LETTER**



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville MD 20857

NDA 50-755/S-003

GlaxoSmithKline  
Attention: Deneen Stewart, Ph.D.  
Assistant Director, U.S. Regulatory Affairs  
One Franklin Plaza  
P.O. Box 7929  
Philadelphia, PA 19101-7929

Dear Dr. Stewart:

Please refer to your supplemental new drug application dated April 5, 2002, received April 8, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Augmentin ES-600<sup>®</sup> (amoxicillin/clavulanate potassium) powder for oral suspension. We note that this application is subject to the exemption provisions contained in section 125(d)(2) of Title I of the FDA Modernization Act of 1997.

We acknowledge receipt of your submission dated May 8, 2003.

This "Changes Being Effected" supplemental new drug application proposes revision to the PRECAUTIONS and ADVERSE REACTIONS sections of the label on the basis of safety.

We have completed the review of this supplemental application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug products are safe and effective for use as recommended in the agreed upon labeling text. Accordingly, this supplemental application is approved effective on the date of this letter.

Please submit the final printed labeling (FPL) electronically according to the Guidance for Industry titled "Providing Regulatory Submissions in Electronic Format – NDA". Alternatively, you may submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 50-755/S-003". Approval of this submission by FDA is not required before the labeling is used.

In addition, please submit three copies of the introductory promotional materials that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to this Division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42  
Food and Drug Administration  
5600 Fishers Lane  
Rockville, Maryland 20857

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2  
FDA  
5600 Fishers Lane  
Rockville, MD 20857

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}*

Janice M. Soreth, M.D.  
Director  
Division of Anti-Infective Drug Products  
Office of Drug Evaluation IV  
Center for Drug Evaluation and Research

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**This is a representation of an electronic record that was signed electronically and  
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/s/

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Janice Soreth  
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