CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:
50-755

Trade Name: Augmentin ES-600 Powder for Oral Suspension

Generic Name: amoxicillin/clavulanate potassium

Sponsor: GlaxoSmithKline

Approval Date: June 22, 2001

Indications: Provides for the use of Augmentin ES-600 for the Treatment of Pediatric Patients with Recurrent or Persistent Acute Otitis Media due to *S. pneumoniae, H. influenzae, or M. catarrhalis*

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	Included	Pending Completion	Not Prepared	Not Required
Approval Letter	X			
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Final Printed Labeling	X			
Medical Review(s)	X			
Chemistry Review(s)	X			
EA/FONSI				
Pharmacology Review(s)	X			
Statistical Review(s)	X			
Microbiology Review(s)	X			
Clinical Pharmacology Biopharmaceutics Review(s)				
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APPLICATION NUMBER:

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APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 50-755

GlaxöSmithKline
Attention: Cynthia D'Ambrosio, Ph.D.
Associate Director, U.S. Regulatory Affairs
One Franklin Plaza
P.O. Box 7929
Philadelphia, Pennsylvania 19101-7929

Dear Dr. D'Ambrosio:

Please refer to your new drug application (NDA) dated October 31, 1997, received October 31, 1997, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Augmentin ES™ (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 submissions dated February 1, March 2, and 30, April 19, May 22, June 11, and 14, 2001. Your submission of December 21, 2000 constituted a complete response to our October 5, 2000 action letter.

This new drug application provides for the use of Augmentin ES-600™ (amoxicillin/clavulanate potassium) powder for oral suspension for the treatment of pediatric patients with recurrent or persistent acute otitis media due to *S. pneumoniae* (penicillin MICs ≤ 2µg/mL), *H. influenzae* (including β-lactamase-producing strains), or *M. catarrhalis* (including β-lactamase-producing strains) characterized by the following risk factors:

- antibiotic exposure for acute otitis media within the preceding 3 months, and either of the following:
  - age ≤ 2 years
  - daycare attendance

We have completed the review of this application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon enclosed labeling text. We note, as agreed to in your submission dated June 20, 2001, the proprietary name of this product will be Augmentin ES-600™. Accordingly, the application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert). Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Please submit the copies of final printed labeling (FPL) electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no 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 NDA 50-755." Approval of this submission by FDA is not required before the labeling is used.

Be advised that, as of April 1, 1999, all applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred (63 *FR* 66632). We note that you have fulfilled the pediatric study requirement for the age group 3 months through 12 years. Additionally, we are waiving the pediatric study requirement for the age groups 0-3 months and 12-16 years.

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

Please submit one market package of the drug product when it is available.

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

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.
Acting Director
Division of Anti-Infective Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

Enclosure (18 pages)