DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 50-755/S-010

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

Dear Dr. Stewart:

Please refer to your supplemental new drug application dated December 5, 2003, received December 8, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Augmentin ES-600™ (amoxicillin/clavulanate potassium) 600 mg/5 mL for Oral Suspension. 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 19, 2004.

This supplemental application revises the **ADVERSE REACTIONS** and **OVERDOSAGE** sections of the labeling to add information about the occurrence of tooth discoloration and crystalluria.

We also note the following editorial changes:

1. Removal of information (Direction for Mixing Oral Suspension and How Supplied) for the 50 mL, 100 mL, and 150 mL bottle sizes because they are no longer produced.
2. The word "Suspension" is replaced with "Reconstitution" in the heading of the table in Directions for Mixing Oral Suspension section.
3. In the References section, the National Committee for Clinical Laboratory Standards references (1-3) have been updated to the current editions.

We have completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the submitted labeling (text for the package insert dated May 19, 2004), and must be formatted in accordance with the requirements of 21 CFR 201.66.

Please submit the 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-010". Approval of this submission by FDA is not required before the labeling is used.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), 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 reporting requirements for an approved NDA (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

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

/s/

Janice Soreth

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