DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 50-575/S-035
NDA 50-597/S-042
NDA 50-725/S-023
NDA 50-726/S-017

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 applications dated December 3, 2003, received December 5, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Augmentin® (amoxicillin/clavulanate potassium) 125 mg/5 mL and 250 mg/5 mL Powder for Oral Suspension (NDA 50-575), Augmentin® (amoxicillin/clavulanate potassium) 125 mg and 250 mg Chewable Tablets (NDA 50-597), Augmentin® (amoxicillin/clavulanate potassium) 200 mg/5 mL and 400 mg/5 mL Powder for Oral suspension (NDA 50-725), and Augmentin® (amoxicillin/clavulanate potassium) 200 mg and 400 mg Chewable Tablets (NDA 50-726). 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.

We acknowledge receipt of your submissions dated May 19, 2004.

These supplemental applications revise the **ADVERSE REACTIONS** section, **Renal** and **Miscellaneous** subsections, and the **OVERDOSAGE** section of the labeling to add information about the occurrence of tooth discoloration and crystalluria.

We also note the following editorial changes:

1. The unit "µg" has been replaced with "mcg".
2. The format of the word "AUGMENTIN" is presented in capital letters and the possessive use of the brand name has been removed.

We have completed our review of these applications, as amended. These applications are 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 copies of final printed labeling (FPL) electronically to each application 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 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, these submissions should be designated "FPL for approved supplements NDA 50-575/S-035, NDA 50-597/S-042, 50-725/S-023 and 50-726/S-017." Approval of these submissions by FDA is not required before the labeling is used.

If a letter communicating important information about these drug products (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

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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