DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 50-785/S-005

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

Dear Dr. D'Ambrosio:

Please refer to your supplemental new drug application dated January 23, 2004, received on January 23, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Augmentin XR™ (amoxicillin/clavulanate potassium) Extended Release Tablets, 1000 mg/62.5 mg. 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.

This "Changes Being Effected" supplemental new drug application provides for revised labeling to comply with the Final Rule entitled "Labeling Requirements for Systemic Antibacterial Drug Products Intended for Human Use" (68FR 6062, February 6, 2003).

We also note the following additional changes:

1. In the first sentence of the DESCRIPTION section, "(amoxicillin/clavulanate)" has been deleted after "AUGMENTIN XR".
2. From the third paragraph of the INDICATIONS AND USAGE section, the sentence, "Once the results are known, therapy should be adjusted appropriately." was removed.
3. In the PRECAUTIONS section, under Information for Patients, the sentence, "The entire prescribed course of therapy should be completed, even if you begin to feel better after a few days," was deleted and "Discard any unused medicine" was moved to the end of the required text.

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

Please submit the copies of 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 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 supplement NDA 50-785/S-005." Approval of this submission by FDA is not required before the labeling is used.
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

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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