DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 50-785/S-003

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 30, 2003, received January 31, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Augmentin XR™ (amoxicillin/clavulanate potassium) Extended Release Tablet, 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.

We acknowledge receipt of your submissions dated March 25, May 20, and May 29, 2003.

This supplemental new drug application provides for the administration of scored Augmentin XR™ (amoxicillin/clavulanate potassium) Extended Release Tablets that have been split in half, (b)(4)----------
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We have completed our review of this supplemental new drug application and found it acceptable from the bioequivalence point. However, no changes should be made to the Augmentin XR™ tablet dissolution acceptance criteria. This supplement is approved effective on the date of this letter.

We remind you that you must comply with the 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}

James D.Vidra, Ph.D.
Chemistry Team Leader for the
Division of Anti-Infective Drug Products (HFD-520)
DNDC III, Office of New Drug Chemistry
Center for Drug Evaluation and Research

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/s/

Jim Vidra

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