DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 50-564/S-048
NDA 50-720/S-021

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

Dear Dr. D'Ambrosio:

Please refer to your supplemental new drug applications dated August 25, 2004, received August 26, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for AUGMENTIN® (amoxicillin/clavulanate potassium) Tablets, 250 mg/125 mg and 500 mg/125 mg (NDA 50-564) and AUGMENTIN® (amoxicillin/clavulanate potassium) Tablets, 875mg/125 mg (NDA 50-720). 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 also acknowledge receipt of your submissions dated July 26, 2005.

These supplements provide for inclusion of a Geriatric Use subsection in the labeling for Augmentin Tablets in accordance with 21CFR 201.57(f)(10), paragraphs (ii)(B) and (iii)(B).

We completed our review of these applications, as amended, and they are approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

Please submit an electronic version of the FPL 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. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate these submissions "**FPL for approved supplement NDA 50-564/S-048, NDA 50-720/S-021**." Approval of these submissions 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, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

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}

Janice M. Soreth, M.D.
Director
Division of Anti-Infective and Ophthalmology 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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