DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 50-575/S-037
NDA 50-597/S-044
NDA 50-725/S-025
NDA 50-726/S-019

GlaxoSmithKline
Attention: Deneen Stewart, Ph.D.
Associate 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 5, 2006, received December 5, 2006, 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.

These "Changes Being Effected" supplemental new drug applications provide for the addition of text regarding potential hypersensitivity vasculitis reactions and liver interactions (hepatitis and cholestatic jaundice) in the "ADVERSE REACTIONS" section of the label.

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

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to the enclosed labeling (text for the package insert submitted on December 5, 2006). Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission, "SPL for approved NDA 50-575/S-037, NDA 50-597/S-044, NDA 50-725/S-025, and NDA 50-026/S-019."

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
Food and Drug Administration
Suite 12B05
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, MD, Regulatory Project Manager, at 301-796-0803.

Sincerely,

{See appended electronic signature page}

Katherine A. Laessig, M.D.
Deputy Director
Division of Anti-Infective and Ophthalmology Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

Enclosure

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

/s/

Kathrine Laessig
12/4/2008 12:12:28 PM