



NDA 50-785/S-007

GlaxoSmithKline
Attention: Edward M. Yuhas, Ph.D.
Senior Director, Regulatory Affairs, Antibacterials
One Franklin Plaza
P.O. Box 7929
Philadelphia, PA 19101-7929

Dear Dr. Yuhas:

Please refer to your supplemental new drug applications dated December 11, 2006, received December 11, 2006, 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 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 this application and it is 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 11, 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 50-785/S-007.”

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
12/10/2008 11:27:01 AM