



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 50-564/S-049
NDA 50-720/S-022

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. D'Ambrosio:

Please refer to your supplemental new drug applications dated December 4, 2006, received December 4, 2006, 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.

These "Changes Being Effected" labeling supplements provide for inclusion of a Geriatric Use subsection in the labeling for the unbranded amoxicillin/clavulanate potassium products.

We completed our review of these applications and they are approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text, submitted on December 4, 2006.

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). 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 50-564/S-049 and NDA 50-720/S-022."

If you issue a letter communicating important information about these drug products (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to the NDA and a copy to the following address:

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MEDWATCH
Food and Drug Administration
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

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) 796-1400.

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

**This is a representation of an electronic record that was signed electronically and
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/s/

Kathrine Laessig
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