



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville, MD 20857

NDA 50-760/S-011  
NDA 50-761/S-011  
NDA 50-754/S-012  
NDA 50-542/S-025

GlaxoSmithKline  
Attention: Deneen Stewart, Ph.D.  
Associate Director, U.S. Regulatory Affairs  
One Franklin Plaza  
P.O. Box 7929  
Philadelphia, PA 19101-7929

Dear Dr. Stewart:

Please refer to your supplemental new drug applications dated December 13, 2006, received December 13, 2006 under section 505(b) of the Federal Food, Drug, and Cosmetic Act for:

NDA 50-760/SLR-011: AMOXIL® (amoxicillin) Oral Suspension-BID  
NDA 50-761/SLR-011: AMOXIL® (amoxicillin) Chewable Tablets-BID  
NDA 50-754/SLR-012: AMOXIL® (amoxicillin) Tablets-BID; Capsules  
NDA 50-542/SLR-025: AMOXIL® (amoxicillin) Chewable Tablets

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 revisions to the **WARNINGS** and **PRECAUTIONS/Information for Patients** sections to include information on *Clostridium difficile* associated disease (CDAD).

We completed our review of these applications, as amended. These application are approved, effective on the date of this letter, for use as recommended in the content of labeling [21 CFR 314.50(1)] in structured product labeling (SPL) format submitted on December 13, 2006.

We note that your December 13, 2006 submission includes final printed labeling (FPL) for your package insert. You are responsible for assuring that the wording in this printed labeling is identical to that of the approved content of labeling in the structured product labeling (SPL) format.

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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  
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) 796-0803.

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: Labeling submitted on December 13, 2006

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

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Kathrine Laessig  
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