DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 50-542/S-023
NDA 50-754/S-010
NDA 50-760/S-009
NDA 50-761/S-009

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 July 29, 2005, received July 29, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for:

Amoxil® (amoxicillin) 125 mg and 250 mg Chewable Tablets (NDA 50-542),

Amoxil® (amoxicillin) 500 mg and 875 mg Tablets (NDA 50-754),

Amoxil® (amoxicillin) 200 mg and 400 mg for Oral Suspension (NDA 50-760), and

Amoxil® (amoxicillin) 200 mg and 400 mg Chewable Tablets (NDA 50-761)

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 supplemental new drug applications provide for the inclusion of a "Geriatric use" subsection in the package insert labeling.

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. The final printed labeling must be identical to the enclosed labeling.

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 50-542/023, NDA 50-754/010, NDA 50-760/S-009, 50-761/S-009**." 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 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}

Janice M. Soreth, M.D.
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 this page is the manifestation of the electronic signature.

/s/

Janice Soreth

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