DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 50-542/S-019
NDA 50-754/S-004
NDA 50-760/S-003
NDA 50-761/S-003

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 May 15, 2001, received May 17, 2001, 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) 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.

We acknowledge receipt of your submission dated May 8, 2003.

These "Changes Being Effected" supplemental new drug applications provide for revisions to the **ADVERSE REACTIONS** section of the package insert, specifically, the addition of **acute general exanthematous pustulosis** to the Hypersensitivity subsection, and the addition of a new subsection entitled "**Miscellaneous**", describing **tooth discoloration**.

We have completed the review of these supplemental applications, as amended, and have concluded that adequate information has been presented to demonstrate that the drug products are safe and effective for use as recommended in the agreed upon labeling text. Accordingly, these supplemental applications are approved effective on the date of this letter.

Please submit the copies of final printed labeling (FPL) electronically to each application 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, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 50-542/S-019, NDA 50-754/S-004, NDA 50-760/S-003, and NDA 50-761/S-003". Approval of these submissions by FDA is not required before the labeling is used.

In addition, please submit three copies of the introductory promotional materials that you propose to use for these products. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to this Division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

If a letter communicating important information about these drug products (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to these NDA's and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Susmita Samanta, M.D., Regulatory Project Manager, at (301) 827-2125.

Sincerely,

{See appended electronic signature page}

Janice M. Soreth, M.D.
Director
Division of Anti-Infective Drug Products
Office of Drug Evaluation IV
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

5/12/03 03:21:54 PM