

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

50-542/S-016

50-754/S-001

APPROVAL LETTER



NDA 50-542/S-016

NDA 50-754/S-001

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

Dear Dr. Stewart:

Please refer to your supplemental new drug applications dated July 23, 1998, received July 24, 1998, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Amoxil[®] (amoxicillin). 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 submissions dated October 12, 2001 and April 5, 2002.

These supplemental new drug applications propose to revise the Microbiology subsection of the Amoxil label by changing the susceptibility breakpoints for *Streptococcus pneumoniae*.

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 product is 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.

The final printed labeling (FPL) must be identical to the draft labeling of the Microbiology subsection, submitted April 5, 2002.

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* (January 1999). 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. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, these submissions should be designated "FPL for approved supplement NDA 50-542/S-016, NDA 50-754/S-001." Approval of these submissions by FDA is not required before the labeling is used.

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In addition, please submit three copies of the introductory promotional materials that you propose to use for this product. 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 this drug product (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 this NDA and a copy to the following address:

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

Please submit one market package of the drug product when it is available.

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
4/10/02 08:48:01 AM

**APPEARS THIS WAY
ON ORIGINAL**