CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

50-542/S-017
50-754/S-002
50-760/S-001
50-761/S-001

APPROVAL LETTER

DIV. P. 50-197

MAY 16 2000

NDA 50-542/S-017
[redacted]
NDA 50-760/S-001
NDA 50-761/S-001

SmithKline Beecham
Attention: Dennen Stewart, Ph.D.
Regulatory Associate, Regulatory Affairs
One Franklin Plaza
P.O. Box 7929
Philadelphia, PA 19101-7029

Dear Dr. Stewart:

Please refer to your supplemental new drug applications dated July 30, 1999, received August 2, 1999, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Amoxil ®(amoxicillin) Chewable Tablets, NDA 50-542; Amoxil® (amoxicillin) Tablets, NDA 50-754; Amoxil® (amoxicillin) for Oral Suspension, NDA 50-760; Amoxil ® (amoxicillin) 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 September 24, 1999.

These "Changes Being Effected " supplemental new drug applications provide for labeling changes to revise the ADVERSE REACTION section of the labeling.

We have completed the review of these supplemental applications 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 submitted final printed labeling (package insert submitted July 1999, AM; L18A 9416802). Accordingly, the supplemental applications are approved effective on the date of this letter.

In addition, it is recommended that at the next printing of the labeling the word " anaphylactic" in the first sentence of the WARNINGS section be written in upper case.

Please submit 20 copies of the FPL as soon as it is available, in no case more than 30 days after it is printed, to each application. 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 supplements NDA 50-542/S-017, 50-754/S-002, 50-760/S-001, 50-761/S-001." 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 inserts directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-40
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 Practitioner" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to these NDAs 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 CDR. Jose R. Cintron, USPHS, R.Ph., M.A., Project Manager, at (301) 827-2125.

Sincerely,

/S/

Gary K. Chikami, M.D.
Director
Division of Anti-Infective Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research