CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

50-720/S-013

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 50-754/S-006
NDA 50-760/S-005
NDA 50-761/S-005
NDA 50-564/S-041
NDA 50-720/S-014

GlaxoSmithKline
Attention: David Urquhart
Senior Regulatory Associate
1250 South Collegeville Road
P.O. Box 5089
Collegeville, PA 19426-0989

Dear Mr. Urquhart,

Please refer to your supplemental new drug applications dated October 31, 2001, received November 5, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Amoxil® (amoxicillin) 500 mg Tablets (50-754), Amoxil® (amoxicillin) 200 mg/5 mL and 400 mg/5 mL Oral Suspension (50-760), Amoxil® (amoxicillin) 200 mg and 400 mg Chewable Tablets (50-761), Augmentin® (amoxicillin/clavulanate potassium) 500 mg Tablets (50-564) and Augmentin® (amoxicillin/clavulanate potassium) 875/125 mg Tablets (50-720). 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 "Changes Being Effected" supplemental new drug applications provide for reduction of the expiration dating period and amendment of the approved, routine commercial stability protocols.

We have completed the review of these supplemental applications, and they are approved.

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}

David B. Katague, Ph.D.
Chemistry Team Leader for the
Division of Anti-Infective Drug Products, (HFD-520)
DNDC III, Office of New Drug Chemistry
Center for Drug Evaluation and Research

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/s/

Shrikant Pagay
5/1/02 06:58:27 PM
Signed for Dr. Katague

APPEARS THIS WAY
ON ORIGINAL