CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

50-720/S-016

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 50-542/S-020
NDA 50-754/S-007
NDA 50-761/S-006
NDA 50-760/S-006
NDA 50-564/S-044
NDA 50-597/S-040
NDA 50-575/S-033
NDA [redacted]
NDA 50-726/S-015
NDA 50-725/S-018
NDA 50-755/S-004

APPEARS THIS WAY
ON ORIGINAL

GlaxoSmithKline
Attention: Stephen M. LoCastro
Assistant Director, Regulatory Affairs
1250 South Collegeville Road
P.O. Box 5089
Collegeville, Pennsylvania 19426-0989

Dear Mr. LoCastro:

Please refer to your supplemental new drug applications dated June 3, 2002, received June 5, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Amoxil® (amoxicillin) Chewable Tablets (tid) (50-542/S-020), Amoxil® (amoxicillin) Tablets (bid) (50-754/S-007), Amoxil (amoxicillin) Chewable Tablets (bid) (50-761/S-006), Amoxil® (amoxicillin) Suspension (bid) (50-760/S-006), Augmentin® (amoxicillin/clavulanate potassium) Tablets (tid) (50-564/S-044), Augmentin® (amoxicillin/clavulanate potassium) Chewable Tablets (tid) (50-597/S-040), Augmentin® (amoxicillin/clavulanate potassium) 4:1 Powder for Oral Suspension (tid) (50-575/S-033), Augmentin® (amoxicillin/clavulanate potassium) Tablets (bid) (50-720/S-016), Augmentin® (amoxicillin/clavulanate potassium) Chewable Tablets (bid) (50-726/S-015), Augmentin® (amoxicillin/clavulanate potassium) 7:1 Oral Suspension (bid) (50-725/S-018), and Augmentin ES-600™ (amoxicillin/clavulanate potassium) 14:1 Oral Suspension (bid).

These "Changes Being Effected" supplemental new drug applications provide for an update of the [redacted] manufacturing and controls for amoxicillin trihydrate drug substance. The update is an amendment, made March 29, 2002, to DMF [redacted].

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}

Chi Wan Chen, Ph.D.
Acting Chemistry Team Leader for the
Division of Anti-Infective Drug Products, (HFD-520) and
Director
DNDC III, Office of New Drug Chemistry
Center for Drug Evaluation and Research

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/s/

Chi Wan Chen
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