CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

50-720/S-008

APPROVAL LETTER

D.F./50-120

NDA 50-564/S-036
NDA 50-575/S-027
NDA 50-597/S-032
NDA [redacted]
NDA 50-726/S-006
NDA 50-725/S-006
NDA 50-590/S-036
NDA 50-658/S-006

SEP 23 1999

SmithKline Beecham Pharmaceutical
Attention: Ms. Sharon Maglennon
Assistant Director,
Regulatory Affairs, North America
1250 S. Collegeville Road
P.O. Box 5089
Collegeville, PA 19426-0989

APPEARS THIS WAY
ON ORIGINAL

Dear Ms. Maglennon:

Please refer to your supplemental new drug applications dated May 28, 1999, received May 28, 1998, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Augmentin® (amoxicillin/clavulanate potassium) Tablets, NDA 50-564; Augmentin® (amoxicillin/clavulanate potassium) 4:1 Powder for Oral Suspension, NDA 50-575; Augmentin® (amoxicillin/clavulanate potassium) Chewable Tablets, NDA 50-597; Augmentin® (amoxicillin/clavulanate potassium) BID Tablets, NDA 50-720; Augmentin® (amoxicillin/clavulanate potassium) BID Chewable Tablets, NDA 50-726; Augmentin® (amoxicillin/clavulanate potassium) 7:1 Powder for BID Oral Suspension, 50-725; Timentin® (sterile ticarcillin disodium and clavulanate potassium), NDA 50-590; Timentin® (sterile ticarcillin disodium and clavulanate potassium) for Injection in Plastic Container, PL 2040, NDA 50-658.We note that this application is 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 August 4, 1999.

These supplemental new drug applications provide for the use of a new strain of [redacted]. The new strain was developed by using [redacted] technology to [redacted].

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

We remind you of your commitment to place in your long-term stability program, the first commercial batch (es) of drug substance. In addition, please commit the first commercial batch of drug product manufactured from the drug substance with the new process into your long term stability program and report the stability data in your annual report as it becomes available.

In addition, update the proposed changes in your drug master files affected.

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, Senior Regulatory Management Officer/Project Manager, at (301) 827-2125.

Sincerely,

/S/

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

APPEARS THIS WAY
ON ORIGINAL