CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

50-720/S-007

APPROVAL LETTER

DF

NDA 50-564/S-035
NDA 50-575/S-026
NDA 50-597/S-031
NDA [redacted]
NDA 50-725/S-005
NDA 50-726/S-005
NDA 50-590/S-035
NDA 50-658/S-005

FEB - 1 1999

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

Dear Ms. Maglennon:

Please refer to your supplemental new drug applications dated July 31, 1998, received August 3, 1998, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Augmentin® (amoxicillin/clavulanate potassium) Tablet, NDA 50-564/S-035; Augmentin® (amoxicillin/clavulanate potassium) Powder for Oral Suspension, NDA 50-575/S-026; Augmentin® (amoxicillin/clavulanate potassium) Chewable Tablets, NDA 50-597/S-031; Augmentin® (amoxicillin/clavulanate potassium) BID Tablets, NDA 50-720/S-007; Augmentin® (amoxicillin/clavulanate potassium) BID Oral Suspension, NDA 50-725/S-005; Augmentin® (amoxicillin/clavulanate potassium) BID Chewable Tablets, NDA 50-726/S-005; Timentin® (sterile ticarcillin disodium and clavulanate potassium), NDA 50-590/S-035; Timentin® (sterile ticarcillin disodium and clavulanate potassium) for Injection in Plastic Container, PL 2040, NDA 50-658/S-005. 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 amendment to DMFs 4349 and 7048 dated January 29, 1999.

We note that these supplements were submitted as 'Special Supplement - Changes Being Effected' under 21 CFR 314.70(c).

These supplemental new drug applications provide for Annual updates of DMF 4349 and 7048, specifically changes in the analytical methods, specifications and various other control changes used in the manufacture of clavulanate potassium bulk drug substance.

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, contact Mr. Jose R. Cintron, R.Ph., M.A., and Senior Regulatory Management Officer, at (301) 827-2125.

Sincerely,

/S/

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

APPEARS THIS WAY
ON ORIGINAL