CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

50-720/S-004

APPROVAL LETTER

DIV

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 50-720/SGS-[redacted]

Smithkline Beecham Pharmaceuticlas
1250 S. Collegeville Road, P.O. Box 5089
Collegeville, PA 19426-0989

OCT 20 1997

Attention: Sharon M. Maglennon

Dear Ms. Maglennon:

Please refer to your supplemental new drug application dated July 3, 1997, received July 7, 1997, submitted under section 507 of the Federal Food, Drug, and Cosmetic Act for Augmentin (amoxicillin/potassium clavulanate) Tablets, 875 mg.

We also acknowledge receipt of your amendment to the submission dated October 1, 1997. The User Fee goal date for this application is January 7, 1998.

The supplemental application provides for modification of the assay method which incorporates the modified sample size, for the release and stability monitoring of the drug product.

We have completed the review of this supplemental application and it is 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, please contact Steve Trostle, Project Manager , at (301) 827-2125.

Sincerely yours,

/S/

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