CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

50-720/S-005

APPROVAL LETTER

DIV

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

NDA 50[redacted]

Food and Drug Administration
Rockville MD 20857

FEB 11 1998

Thomas M. Hogan
Director
U.S. Regulatory Affairs
SmithKline Beecham
1250 S. Collegeville Road,
P.O. Box 5089
Collegeville, PA 19426-0989

Dear Mr. Hogan:

Reference is made to your supplemental New Drug Application (NDA) dated January 10, 1998 submitted under section 505(b) of the Federal Food, Drug Cosmetic Act for Augmentin (amoxicillin/clavulanate potassium) Tablet, 875 mg. We note that this application is subject to the exception provisions of Section 125(d)(2) of Title 1 of the FDA Modernization Act of 1997.

The supplemental application provides for utilization of _____ to perform microbiological testing for drug product excipients and capsule shell.

We have completed our review of this supplemental application and it is approved effective as of the date of this letter.

This approval affects only those changes specifically submitted in this supplemental application. Other changes that may have been approved or are pending evaluation are not affected.

We remind you that you must comply with the requirements set forth under 21 CFR 314.80 and 314.81 for an approved NDA.

Sincerely yours,

/S/ 2/11/98 for /S/

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