CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

50-720/S-006

ADMINISTRATIVE DOCUMENTS AND CORRESPONDENCE

Dur. file

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 50-720/S-006

AUG 4 1998

SmithKline Beecham Pharmaceuticals
One Franklin Plaza
P.O. Box 7929
Philadelphia, PA 19101-7929

Attention: Sharon W. Shapowal, R.Ph.
Associate Director
U.S. Regulatory Affairs

Dear Ms. Shapowal:

We acknowledge receipt of your supplemental application for the following:

Name of Drug: Augmentin® (amoxicillin/clavulanate potassium)

NDA Number: 50-720

Supplement Number: S-006

Date of Supplement: July 23, 1998

Date of Receipt: July 24, 1998

Unless we find the application not acceptable for filing, this application will be filed under Section 505(b)(1) of the Act on September 22, 1998 in accordance with 21 CFR 314.101(a).

All communications concerning this NDA should be addressed as follows:

Food and Drug Administration
Division of Anti-Infective Drug Products, HFD-520
Office of Drug Evaluation IV
Center for Drug Evaluation and Research
Attention: Document Control Room
5600 Fishers Lane
Rockville, MD 20857

Sincerely,

/S/

for James D. Bona, R.Ph., M.P.H.
Chief, Project Management Staff
Division of Anti-Infective Drug Products, HFD-520
Office of Drug Evaluation IV
Center for Drug Evaluation and Research