CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

50-720/S-007

ADMINISTRATIVE DOCUMENTS AND CORRESPONDENCE

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 50-720/S-007

NOV 9 1998

SmithKline Beecham Pharmaceuticals
1250 South Collegeville Road
P.O. Box 5089
Collegeville, PA 19426

Attention: Sharon Maglennon
Assistant Director
U.S. Regulatory Affairs

Dear Ms. Maglennon:

We acknowledge receipt of your supplemental application for the following:

Name of Drug: Augmentin® (q12h) (Amoxicillin/Clavulanate Potassium)

NDA Number: 50-720

Supplement Number: S-007

Date of Supplement: July 31, 1998

Date of Receipt: August 3, 1998

Unless we find the application not acceptable for filing, this application will be filed under Section 505(b)(1) of the Act on October 2, 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 11-3-98

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