

**CENTER FOR DRUG EVALUATION AND RESEARCH**

*APPLICATION NUMBER:*

**50-720/S-004**

**ADMINISTRATIVE DOCUMENTS**  
**AND**  
**CORRESPONDENCE**



Food and Drug Administration  
Rockville MD 20857

**NDA 50-720/S-004-**

JUL 9 1997

SmithKline Beecham Pharmaceuticals  
1250 S. Collegeville Road, P. O. Box 5089  
Collegeville, PA 19426-0989

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

Dear Ms. Maglennon:

We acknowledge receipt of your supplemental application for the following:

Name of Drug: Augmentin® (amoxicillin/clavulanate potassium) (q12h) Tablets

NDA Number: 50-720

Supplement Number: ~~50-720/S-004~~

Date of Supplement: July 3, 1997

Date of Receipt: July 7, 1997

Unless we find the application not acceptable for filing, this application will be filed under Section 505(b)(1) of the Act on September 5, 1997 in accordance with 21 CFR 314.101(a).

All communications concerning this NDA should be addressed as follows:

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

Sincerely,

*ST/bv JB 07/07/97*

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