CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

50-720/S-008

ADMINISTRATIVE DOCUMENTS AND CORRESPONDENCE

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 50-720/S-008

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

JUN 4 1999

Attention: Sharon Maglennon
Assistant Director, Regulatory Affairs-North America

Dear Ms. Maglennon:

We acknowledge receipt of your supplemental application for the following:

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

NDA Number: 50-720

Supplement Number: S-008

Date of Supplement: May 28, 1999

Date of Receipt: May 28, 1999

Unless we find the application not acceptable for filing, this application will be filed under Section 505(b)(1) of the Act on July 27, 1999 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/ 6/4/99

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

P.F.

MEMORANDUM

Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research

Date: June 9, 1999

Re: Supplemental NDAs: 50-564/S-036, 50-575/S-027, 50-597/S-032, 50-720/S-008, 50-726/S-006, 50-725/S-006, 50-590/S-036, and 50-658/S-006
NDAs: 50-755 and 50-765
ANDA 62-691

I called Sharon Maglennon of SmithKline Beecham at 610-917-6457. I notified her that the submissions dated May 28, 1999, to the above applications, which were designated as "Special Supplement-Changes Being Effect," should now be considered as supplements requiring prior approval. This determination was made after further discussions by our staff. She stated that she understood and that she would notify the effected manufacturing sites to not implement the changes contained in the May 28, 1999 submission (to the above applications) until they are approved by the Agency. SB may request a follow-up teleconference for clarification.

/S/

Stephen T. Trostle
Regulatory Health Project Manager
Division of Anti-Infective
Drug Products, HFD-520

cc:

NDA Arch (for each above NDA/ten total)
HFD-520
HFD-520/TL/Chem/DKatague
HFD-520/Chem/AYu
HFD-520/RHPM/STrostle
HFD-510/TL/Chem/DWu
HFD-640/MAnderson
OGD/HFD-600/ANDA Arch (62-691)