# CENTER FOR DRUG EVALUATION AND RESEARCH

***APPLICATION NUMBER:***

# 50-720/S-012

# ADMINISTRATIVE DOCUMENTS AND CORRESPONDENCE

DEPARTMENT OF HEALTH & HUMAN SERVICES Div File Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 50-720/S-012

NOV - 9 2000

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

Attention: sharon Maglennon, Assistant Director North America Regulatory Affairs

Dear Ms. Maglennon:

We acknowledge receipt of your supplemental application for the following:

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

NDA Number: 50-720

Supplement Number: S-012

Date of Supplement: October 20, 2000

Date of Receipt: October 23, 2000

Unless we find the application not acceptable for filing, this application will be filed under Section 505(b)(1) of the Act on December 22, 2000 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/

Frances V. Le Sane
Chief, Project Management Staff
Division of Anti-Infective Drug Products, HFD-520
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

cc:
Original NDA 50-720/S-012
HFD-520/Div. Files
HFD-520/CSO/S. Samanta

SUPPLEMENT ACKNOWLEDGEMENT

APPEARS THIS WAY
ON ORIGINAL