

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

50-720/S-005

ADMINISTRATIVE DOCUMENTS
AND
CORRESPONDENCE



Food and Drug Administration
Rockville MD 20857

NDA 50-720/S-005

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

Attention: Thomas M. Hogan
Director, U.S. Regulatory Affairs

JAN 22 1998

Dear Mr. Hogan:

We acknowledge receipt of your supplemental application for the following:

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

NDA Number: 50-720

Supplement Number: S-005

Date of Supplement: January 10, 1998

Date of Receipt: January 13, 1998

Unless we find the application not acceptable for filing, this application will be filed under Section 505(b)(1) of the Act on March 14, 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,

J.D. Bona
1/20/98

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

CDER Establishment Evaluation Report
for January 26, 1998

Application: NDA ~~50720/005~~ Priority: 3S Org Code: 520
Stamp: 13-JAN-1998 Regulatory Due: 13-JUL-1998 Action Goal: District Goal: 08-MAY-1998
Applicant: SKB PHARMS Brand Name: AUGMENTIN
7929 Established Name:
PHILADELPHIA, PA 191017929 Generic Name: AUGMENTIN
Dosage Form: TAB (TABLET)
Strength: 875

FDA Contacts: A. YU, (HFD-520) 301-827-2143 , Review Chemist
J. TIMPER JR (HFD-520) 301-827-2193 , Team Leader

Overall Recommendation:

ACCEPTABLE on 22-JAN-1998 by S. FERGUSON (HFD-324) 301-827-0062

Establishment

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DMF No:
AADA No:

Profile: CTL OAI Status: NONE
Last Milestone: OC RECOMMENDATION
Milestone Date 22-JAN-1998
Decision: ACCEPTABLE
Reason:

Responsibilities: _____

**APPEARS THIS WAY
ON ORIGINAL**