CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

50-720/S-013

ADMINISTRATIVE DOCUMENTS AND CORRESPONDENCE

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 50-754/S-006
NDA 50-761/S-005
NDA 50-760/S-005
NDA [redacted]
NDA 50-564/S-041

CBE-30 SUPPLEMENT

GlaxoSmithKline
Attention: David Urquhart
Senior Regulatory Associate
1250 South Collegeville Road
P.O. Box 5089
Collegeville, PA 19426-0989

Dear Mr. Urquhart,

We have received your supplemental drug applications submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following:

Names of Drug Product: Amoxil® (amoxicillin) 500 mg and 875 mg Tablets (50-754)
Amoxil® (amoxicillin) 200 mg and 400 mg Chewable Tablets (50-761)
Amoxil® (amoxicillin) 200 mg/5 mL and 400 mg/5 mL Oral Suspension (50-760)
Augmentin® (amoxicillin/clavulanate potassium) 875/125 mg Tablets (50-720)
Augmentin® (amoxicillin/clavulanate potassium) 250 mg and 500 mg Tablets (50-564)

NDA Numbers
and Supplement numbers: 50-754/ S-006, 50-761/S-005, 50-760/S-005, 50-720/S-013, 50-564/S-041

Date of supplements: October 31, 2001

Date of receipt: November 5, 2001

This supplemental application was submitted as a "Supplement - Changes Being Effected in 30 days." The appropriateness of reporting the proposed change(s) as changes being effected in 30 days is under review.

Unless we notify you within 60 days of the receipt date that the application is not sufficiently complete to permit a substantive review, this application will be filed under section 505(b) of the Act on January 4, 2002 in accordance with 21 CFR 314.101(a).

All communications concerning this supplement should be addressed as follows:

U.S. Postal Service:
Food and Drug Administration
Center for Drug Evaluation and Research
Division of Anti-Infective Drug Products, HFD-520
Attention: Division Document Room
5600 Fishers Lane
Rockville, Maryland 20857

Courier/Overnight Mail:
Food and Drug Administration
Center for Drug Evaluation and Research
Division of Anti-Infective Drug Products, HFD-520
Attention: Division Document Room
9201 Corporate Blvd.
Rockville, Maryland 20850-3202

If you have any question, call Susmita Samanta, Regulatory Project Manager, at (301) 827-2125.

Sincerely yours,

{See appended electronic signature page}

Frances LeSane
Chief, Project Management Staff
Division of Anti-Infective Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

APPEARS THIS WAY
ON ORIGINAL

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Frances LeSane
1/23/02 04:47:32 PM