CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number: NDA 50761

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 50-761

APR 15 1999

SmithKline Beecham
Attention: Dennen R. Stewart, Ph.D.
Regulatory Associate, U.S. Regulatory Affairs
One Franklin Plaza
P.O. Box 7929
Philadelphia, PA 19101-7929

Dear Dr. Stewart:

Please refer to your new drug application (NDA) dated April 15, 1998, received April 16, 1998, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Amoxil® (amoxicillin) Chewable Tablets. We note that this application is subject to the exemption provisions contained in section 125(d)(2) of Title I of the FDA Modernization Act of 1997.

We acknowledge receipt of your submissions dated September 6, 1998; January 13, 1999, February 12, 1999, March 24, 1999, March 31, 1999, and April 6, 1999.

This new drug application provides for the use of Amoxil (amoxicillin) Chewable Tablets 200 mg and 400 mg in divided doses q12h.

We have completed the review of this application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the enclosed labeling text. Accordingly, the application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the enclosed labeling submitted on April 6, 1999. Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Please submit 20 copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved NDA 50-761." Approval of this submission by FDA is not required before the labeling is used.

We remind you of your Phase 4 commitment specified in your submission dated March 24, 1999. This commitment, along with any completion dates agreed upon, is listed below.

Protocols, data, and final reports should be submitted to your IND for this product and a copy of the cover letter sent to this NDA. If an IND is not required to meet your Phase 4 commitment, please submit protocols, data and final reports to this NDA as correspondence. In addition, under 21 CFR 314.82(b)(2)(vii), we request that you include a status summary of the commitment in your annual report to this NDA. The status summary should include the number of patients entered in each study, expected completion and submission dates, and any changes in plans since the last annual report. For administrative purposes, all submissions, including labeling supplements, relating to this Phase 4 commitment must be clearly designated "Phase 4 Commitment."

In addition, please submit three copies of the introductory promotional materials that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to this Division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-40
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

As of April 1, 1999, all applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred (63 *FR* 66632). We are waiving the pediatric study requirement for this application.

Please submit one market package of the drug product when it is available.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, contact Mr. Steve Trostle, Project Manager, at 301-827-2125.

Sincerely,

/S/

MD
4/15/05

Janice Soreth, M.D.
Acting Director
Division of Anti-Infective Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

Enclosure

cc:
Archival NDA 50-761
HFD-520/Div. Files
HF-2/MedWatch (with labeling)
HFD-002/ORM (with labeling)
HFD-40/DDMAC (with labeling)
HFD-95/DDMS (with labeling)
HFD-104/ADRA (with labeling)
HFD-520/JCintron
HFD-520/Act.Div.Director/JSoreth 4/15/99
HFD-520/Dep.Director/LGavrilovich
HFD-520/Team Leader MO/MAlbuerne 4/12/99
HFD-520/Medical Officer/MMakhene
HFD-520/Team Leader Microbiology/ASheldon
HFD-520/Microorganism Reviewer/SAltaie S.S. Altaie 4-14-99
HFD-520/PharmTox/KSeethaler
HFD-520/Team Leader PharmTox/ROsterberg
HFD-830/Team Leader Chemistry/DKatague 4/15/99
HFD-830/ Chemistry/AYu 4/13/99
HFD-830/DNDC Division Director
HFD-880/Team Leader Biopharmaceutics/FPelsor 4/13/99
HFD-880/ Biopharmaceutics Reviewer/HSun
DISTRICT OFFICE
HFI-20/Press Office (with labeling)

Concurrence Only:
HFD-520/CPMS/JBona

Drafted by: jrc/April 9, 1999
Initialed by:
final:
filename: N50761AP

APPROVAL (AP) (with Phase 4 Commitments)