CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number:NDA 50-746

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 50-746

SmithKline Beecham Pharmaceuticals
Attention: Debra Hackett
Manager, U.S. Regulatory Affairs
One Franklin Plaza
P.O. Box 7929
Philadelphia, PA 19101

DEC 11 1997

Dear Ms. Hackett:

Please refer to your new drug application dated December 12, 1996, received December 12, 1996, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Bactroban (mupirocin calcium cream, 2%) Cream. We note that this product is subject to the exception provisions of Section 125 (2) of Title 1 of the FDA Modernization Act of 1997.

We acknowledge receipt of your submissions dated February 28, July 21, October 1 and 29, November 4 and 21, 1997 and your facsimiles dated December 1, 5, 9, and 10, 1997. The User Fee goal date for this application is December 12, 1997.

This new drug application provides for the treatment of secondarily infected traumatic skin lesions (up to 10 cm in length or 100 cm^2 in area) due to susceptible strains of *Staphylococcus aureus* and *Streptococcus pyogenes*.

We have completed the review of this application, including the submitted draft labeling, 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 marked-up draft labeling. Accordingly, the application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the enclosed marked-up draft labeling. Marketing the product with FPL that is not identical to this draft labeling 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 "FINAL PRINTED LABELING" for approved NDA 50-746. Approval of this submission by FDA is not required before the labeling is used.

Should additional information relating to the safety and effectiveness of the drug become available, revision of that labeling may be required.

We remind you of your Phase 4 commitments specified in your facsimile dated December 9,

1997. These commitments, along with any completion dates agreed upon, are listed below.

You may contact the Division for further guidance on the above requirements.

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. Should an IND not be required to meet your Phase 4 commitments, please submit protocol, data, and final reports to this NDA as correspondences. In addition, we request under 21 CFR 314.81(b)(2)(vii) that you include in your annual report to this application, a status summary of each commitment. 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 these Phase 4 commitments must be clearly designated "Phase 4 Commitments."

Additionally, an evaluation of the usefulness of *in vitro* release rate determination for assessing post-approval formulation and manufacturing changes for the 2% cream formulation is strongly encouraged.

Please submit three copies of the introductory promotional material 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 material and the package insert directly to:

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

Validation of the regulatory methods has not been completed. At the present time, it is the policy of the Center not to withhold approval because the methods are being validated. Nevertheless, we expect your continued cooperation to resolve any problems that may be identified.

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, please contact Maureen Dillon-Parker, Project Manager, at (301) 827-2125.

Sincerely yours,

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

ENCLOSURE - Labeling (5 pages)