

NDA 50-591/S-022

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

Dear Ms. Hackett:

Please refer to your supplemental new drug application dated April 24, 1998, received April 27, 1998, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Bactroban Ointment (mupirocin), 2%. 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 amendment dated April 13, 1999 (facsimile) which provides for revised draft labeling in accordance with the facsimile sent to you from this Division on January 21, 1999.

This supplemental new drug application provides for the following changes:

- a. Adds a "Pediatric Use" subsection as required by the December 13, 1994, Federal Register notice concerning pediatric labeling.
- b. Revises the labeling in accordance with suggestions in the approval letter for NDA 50-591/S-015 dated February 21, 1996.

We have completed the review of this supplemental 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 agreed upon labeling text. Accordingly, the supplemental application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the submitted draft labeling (package insert submitted April 13, 1999).

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 supplement NDA 50-591/S-022." Approval of this submission by FDA is not required before the labeling is used.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Practitioner" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2  
FDA  
5600 Fishers Lane  
Rockville, MD 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 note that you have fulfilled the pediatric study requirement at this time.

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

Sincerely,

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