DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

FOI

TRANSMITTED VIA FACSIMILE

SEP - 9 1999

Debra Hackett
Manager
U.S. Regulatory Affairs
SmithKline Beecham Pharmaceuticals
PO Box 7929
Philadelphia, PA 19101

RE: NDA # 50-703
Bactroban Nasal (calcium mupirocin)
MACMIS ID # 8204

Dear Ms. Hackett:

The Division of Drug Marketing, Advertising, and Communications (DDMAC), as part of its routine monitoring and surveillance program, has reviewed promotional material disseminated by SmithKline Beecham Pharmaceuticals (SKB) for its product Bactroban Nasal. This material was submitted under cover of FDA Form 2253 in May, 1999. The promotional material consisted of a hospital panel (BN0461). DDMAC has determined that this promotional material is misleading in violation of the Federal, Food, Drug, and Cosmetic Act (the Act) and its implementing regulations.

Hospital panel (BN0461) is lacking in fair balance or otherwise misleading because it fails to provide any balancing information about the adverse events, contraindications, warnings, or precautions associated with the use of Bactroban Nasal. The hospital panel makes statements regarding the efficacy of the product that require the inclusion of risk information to balance the claims made. Such statements include, e.g., "Stop Methicillin-Resistant *Staphylococcus aureus* outbreaks where they originate...," "Infection protection in a tube," and "In a hospital study, Bactroban Nasal contributed to a dramatic reduction in MRSA infections and Vancomycin costs during an outbreak." Promotional materials must present information relating to side effects, contraindications, and warnings with a prominence and readability reasonably comparable with any presentation of information relating to the use or efficacy of the drug. Merely directing the reader to the complete

prescribing information at the exhibit is not sufficient to satisfy the regulatory requirement of fair balance.

In order to address this violation, DDMAC recommends that SKB take the following actions:

1. Immediately discontinue the use of the aforementioned material and any other promotional materials for Bactroban Nasal that contain the same or similar violations; and
2. Provide a written response to DDMAC of your intent to comply with the above request, a list of promotional materials containing the misleading presentation that will be discontinued, and the date of discontinuation.

SKB's response should be received no later than 10 business days from the issue date of this letter. Please address your response to the undersigned by facsimile at (301) 594-6771, or at the Food and Drug Administration, Division of Drug Marketing, Advertising, and Communications, HFD-40, Rm 17B-20, 5600 Fishers Lane, Rockville, MD 20857.

DDMAC reminds SKB that only written communications are considered official. In all future correspondence regarding this particular matter, please refer to MACMIS ID # 8704 in addition to the NDA number.

Sincerely.

/S/

Jo Ann Spearmon, Pharm.D., M.P.A.
Regulatory Review Officer
Division of Drug Marketing,
Advertising, and Communications