DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

FOI

OCT - 6 1998

TRANS ITTED VIA FACSI ILE

Mr. James P. Thompson
Manager
Worldwide Regulatory Affairs
Dermik Laboratories, Inc.
500 Arcola Road
P.O. Box 5096
Collegeville, PA 19426-0107

RE: NDA #50-557
Benzamycin Topical (erythromycin and benzoyl peroxide gel)
AC IS ID # 7122

Dear Mr. Thompson:

The Division of Drug Marketing, Advertising and Communications (DDMAC), as part of its routine monitoring and surveillance program, has reviewed a labeling piece that promotes Dermik Laboratories, Inc.'s (Dermik) product, Benzamycin. This piece, identified as BZMO198PED1, was submitted on Form FDA 2253 on August 6, 1998. DDMAC has determined that this piece is in violation of the Federal Food, Drug, and Cosmetic Act and the implementing regulations.

Specifically, DDMAC objects to Dermik's presentation of the risks associated with the use of Benzamycin. The referenced piece states, "Adverse reactions infrequently reported include dryness, erythema and pruritus." However, such disclosure is not presented with a prominence and readability that is reasonable comparable to the claims of effectiveness. In addition, the labeling for Benzamycin contains additional adverse events, including urticarial reactions. Dermik's failure to disclose, at a minimum, this important adverse event, causes this piece to be misleading.

Further, since this is labeling, Dermik is reminded that the full prescribing information must be disseminated with the piece.

In order to address these objections, Dermik should immediately discontinue the referenced piece and any other pieces that contain the same or similar violations. In addition, Dermik should notify the undersigned by October 16, 1998, regarding Dermik's willingness to comply with the above stated request.

If Dermik has any questions, please contact the undersigned by facsimile at 301-594-6759, or by written correspondence at the Food and Drug Administration, Division of Drug Marketing, Advertising and Communications, 5600 Fishers Lane, HFD-40, Room 17B-20, Rockville, MD 20857.

DDMAC reminds Dermik that only written communications are considered official.

In all future correspondence regarding this particular matter, please refer to MACMIS # 7122, in addition to the NDA number.

Sincerely,

Minnie Baylor-Henry, R.Ph., J.D.
Director