DEPARTME ·F HEALTH & HUMAN SERVICES

Health Service

Food and Drug Administration
Rockville MD 20857

AUG 28 1997

TRANSMITTED VIA FACSIMILE

Dave Garbe
Director, Scientific Information and Medical Compliance
Allergan
2525 Dupont Drive
P.O. Box 19534
Irvine, CA 92623-9534

RE: NDA 20-600
Tazorac (tazarotene topical gel) 0.05%, 0.1%
MACMIS ID #5758

Dear Mr. Garbe:

Reference is made to Allergan's July 25, 1997, FDA Form 2253 submissions for (tazarotene topical gel) 0.05%, 0.1%. The Division of Drug Marketing, Advertising and Communications (DDMAC) has reviewed these submissions and finds the following items to be in violation of the Federal Food, Drug, and Cosmetic Act and the applicable regulations:

- Dear Pharmacist Letter (TAZ016)
- Dear Pharmaceutical Buyer Letter (TAZ017)
- Sell Sheet (TAZ 007)

Specifically, DDMAC has identified the following violations.

Lack of Fair Balance

- The statement "...the most commonly reported adverse effects with Tazorac gel were...pruritus, burning/stinging, erythema, and irritation" is misleading because it omits important adverse events associated with the use of Tazorac. For example, worsening of psoriasis was reported more frequently than irritation in clinical trials, yet it is not mentioned in these promotional pieces. The approved product labeling (PI), lists the following adverse events, occurring in 10 to 30% of patients, in descending order: pruritus, burning/stinging, erythema, worsening of psoriasis, irritation, and skin pain.

Misleading Efficacy Rates

- The claims "With treatment success rates of up to 70%..." and "treatment success rates of up to 70% in stable plaque psoriasis..." are misleading because they omit material facts and present information from a study in a way that implies the study is more representative than it really is. Specifically, the omission of a definition for the term "treatment success" (improvement greater than or equal to 50% compared to baseline at the end of 12 weeks of treatment) implies that Tazorac cures psoriasis in 70% of patients who used it in clinical trials. However, the study cited in support of the claim evaluated both strengths of Tazorac on specific knee/elbow and trunk/limb target lesions, and the 70% peak treatment success rate was achieved only on trunk/limb target lesions with the 0.1% strength. Target lesions on the trunk/limbs reached a treatment success rate of up to 35% with control vehicle in the same study.

Misleading Therapeutic Efficacy Claims

- The claim "...therapeutic efficacy that may last as long as 12 weeks after the end of treatment..." is misleading because it omits material facts. The vehicle also showed beneficial therapeutic effect for up to 12 weeks following treatment. Thus, it is misleading to claim beneficial therapeutic effect for up to 12 weeks following treatment without presenting that vehicle and active control drugs also showed a beneficial therapeutic effect for this time frame.

- The tag-line "Relief that lasts," contained in the sell sheet, is misleading because it implies that Tazorac demonstrates a sustained post treatment therapeutic effect and lacks contextual information needed to adequately define what is meant by the claim.

Allergan has notified DDMAC that the materials cited above were distributed on a one time basis before DDMAC provided comments on other materials submitted voluntarily by Allergan for DDMAC's review and comment. Since Allergan has stated that it has ceased distribution of the materials, DDMAC considers this issue closed. However, DDMAC will continue to monitor Allergan's promotional materials and may determine that other remedial measures will be necessary to fully correct any false and/or misleading messages by Allergan.

If Allergan has any questions or comments, please contact 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 Allergan that only written communications are considered official.

In all future correspondence regarding this particular matter, please refer to MACMIS ID #5758 in addition to the NDA number.

Sincerely,

Mark W. Askine, R.Ph.
Regulatory Review Officer
Division of Drug Marketing,
Advertising and Communications