DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service FCI

Food and Drug Administration
Rockville MD 20857

SEP 29 1998

TRANSMITTED VIA FACSIMILE

Eric Loukas, Esquire
3 M Pharmaceuticals
3M Center Building 270-3A-01
St. Paul, MN 55144-1000

RE: NDA# 20-723
Aldara (imiquimod) Cream, 5%
MACMIS ID #6714

Dear Mr. Loukas:

The Division of Drug Marketing, Advertising and Communications (DDMAC) has reviewed a broadcast advertisement that promotes 3M Pharmaceuticals' (3M) product, Aldara Cream. This broadcast advertisement was submitted to the Food and Drug Administration in accordance with 21 CFR 314.81, and was transmitted on FDA Form 2253. As stated during a September 25, 1998, meeting between representatives from DDMAC and 3M, DDMAC has determined that the referenced broadcast advertisement is false and misleading in violation of the Federal Food, Drug, and Cosmetic Act and the applicable regulations.

Specifically, DDMAC objects to the following:

Inadequacy of Risk Information

The advertisement does not adequately present the important adverse events associated with the use of Aldara Cream, nor appropriately communicate the frequency with which such events occur, e.g., burning 26%, edema (swelling) 17%, and soreness 3%. Further, DDMAC believes that it is important to disclose that study participants experienced fungal infections.

In addition, the advertisement fails to provide sufficient context for the claim that sexual contact should be avoided. This important public health message should be accompanied by information regarding the fact that Aldara Cream must be used 3 times a week, left on the skin for 6-10 hours, and that therapy must continue until there is total clearance or for a maximum of 16 weeks. It is also important that consumers know that the treatment area

should be washed with mild soap and water and that the product may weaken condoms and diaphragms.

Unsupported Claims

DDMAC also believes that the claim, "help take the suffering out of genital warts" is misleading. Since Aldara Cream is not a cure for genital warts, it is clear that the suffering continues. Further, the adverse events associated with this product, i.e., burning, itching, pain, soreness, etc., would not support any explicit or implicit claim that a patient is no longer suffering as a result of administering this product.

Fair Balance

Since 3 M has focused on the issue of pain as a means of distinguishing this product from other treatment modalities, it is important that the claim, "few people complained of pain" be qualified with the actual number of adverse events, as set forth in the approved labeling for the product.

The claim regarding how conveniently and effectively Aldara Cream treats external genital warts, in conjunction with the implied comparisons of burning, cutting and freezing, would be misleading without additional contiguous, contextual information about the fact that new warts may appear. The current claim of "not a cure" is too distant from the initial claims of burning, cutting and freezing. In addition, total clearance with Aldara Cream was only achieved in about half of the study participants. Therefore, it is important that there be a prominent qualifying statement regarding the fact that Aldara Cream does not work for everyone.

DDMAC also believes that the graphics in this advertisement are misleading because they imply, without necessary contextual information, that this product is convenient and easy to use, particularly as compared to other treatment options. Without the complete information regarding the dosage regimen, including the duration of therapy, such symbolic suggestions are misleading.

Further, these graphics also imply that casual sexual intimacy is assured by the use of this product and that there is no need to worry about the transmission of the virus. The simple audio disclosure concerning Aldara's unknown effect on transmission does not overcome the impact of the visuals.

Adequate Provision

DDMAC recommends that the information about how to obtain the full prescribing information (PI) be more prominent in order to help assure that the viewer has an ample opportunity to note such information.

DDMAC is concerned that most of these issues were communicated to 3M in a June 30, 1998 letter, in response to 3M's request for comments on a storyboard and video clip. We request that 3M immediately discontinue the broadcast of this violative advertisement and the dissemination of any associated print pieces, including, but not limited to, journal advertisement AL-243R and the college newspaper advertisement AL1925.

3M should provide a written response to the undersigned no later than October 5, 1998, affirming that the referenced broadcast advertisement was stopped and the date that such occurred, and stating a plan of action for the discontinuation of all violative print material. This response should be forwarded to the Division of Drug Marketing, Advertising and Communications, 5600 Fishers Lane, Rm 17B-20, HFD-40, Rockville, Maryland 20857. 3M is further advised that DDMAC is continuing its evaluation of 3M's promotional campaign for Aldara Cream and, if there are other violations, such will be subsequently addressed under separate cover.

DDMAC reminds 3M that only written communications are considered official.

In all future correspondence regarding this particular matter, please refer to MACMIS ID# 6714, in addition to the NDA number.

Sincerely,

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