DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

FOI

JUL 16 1998

Transmitted Via Facsimile

Lisa McGrady, R.A.C.
Regulatory Affairs Associate
Ciba Vision Corporation
11460 Johns Creek Parkway
Duluth, Georgia 30136

RE: NDA 20-037
Voltaren Ophthalmic (diclofenac sodium) 0.1% Sterile Ophthalmic Solution
MACMIS ID# 6737

Dear Ms. McGrady:

This letter is in reference to Ciba Vision Corporation's (Ciba Vision) promotional campaign for Voltaren Ophthalmic (diclofenac sodium) 0.1% Sterile Ophthalmic Solution. Based on materials and information the Division of Marketing, Advertising and Communications (DDMAC) has reviewed as part of its monitoring program, Ciba Vision published an advertisement in the April 15, 1998, issue of Ocular Surgery News for its product Voltaren that made misleading claims in violation of the Federal Food, Drug and Cosmetic Act and its implementing regulations.

Corneal Re-epithelialization

In the advertisement, Ciba Vision claims that use of Voltaren "achieves complete and normal corneal re-epithelialization equivalent to placebo." DDMAC considers this claim to be misleading because Voltaren and other non-steroidal anti-inflammatory drugs delay healing. Thus, although Voltaren may achieve complete and normal corneal re-epithelialization equivalent to placebo, it may take longer to re-epithelialize corneal tissue than placebo.

Reduction in Analgesics Use

In the advertisement, Ciba Vision claims that the use of Voltaren "significantly reduces oral narcotic use." DDMAC considers this statement to be misleading without substantial evidence (i.e., adequate and well-controlled studies) regarding the use of narcotics (generally defined as opiates) in clinical trials with Voltaren.

Post-Marketing Requirements

> Further, DDMAC notes that these promotional materials were not submitted to the Food and Drug Administration as required by the post-marketing requirements for a new drug application (21 CFR 314.81(b)(3)(i)). This regulation requires that specimens of all advertisements and promotional labeling for prescription drug products be submitted under cover of Form FDA 2253 at the time of initial dissemination for promotional labeling or at the time of initial publication for advertisements.

Ciba Vision should immediately discontinue the use of the above advertisement and any other promotional materials that make similar false or misleading claims for Voltaren. Ciba Vision should respond to DDMAC regarding this misleading advertisement by July 30, 1998.

If you have any questions, please contact the undersigned by telephone at (301) 827-2831, facsimile (301) 594-6771, or by written communication at the Division of Drug Marketing, Advertising, and Communications, HFD-40; Room 17B-20; 5600 Fishers Lane; Rockville, MD 20857. DDMAC reminds Ciba Vision that only written communications are considered official.

In all future correspondence regarding this matter, please refer to MACMIS # 6737 and NDA 20-037.

Sincerely,

/S/

Warren F. Rumble
Regulatory Review Officer
Division of Drug Marketing,
Advertising and Communications