DEPART. T OF HEALTH & HUMAN SERVICES

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Food and Drug Administration
Rockville MD 20857

AUG 7 1997

TRANSMITTED VIA FACSIMILE

Norman T. Miller
Senior Director, Regulatory Affairs
Monarch Pharmaceuticals, Inc.
355 Beecham Street
Bristol, TN 37620

RE: **NDA 18-299**
Viroptic Ophthalmic Solution 1% Sterile
MACMIS # 5677

Dear Mr. Miller:

This letter is in reference to Monarch Pharmaceuticals, Inc.'s (Monarch) submission, dated July 23, 1997, of promotional materials under cover of Form FDA 2253 for Viroptic Ophthalmic Solution 1% Sterile. This submission included a brochure identified as 1-0258-1 and titled, "Classics that work." The Division of Drug Marketing, Advertising and Communications (DDMAC) regards the brochure to be lacking in fair balance or otherwise misleading under the Federal Food, Drug, and Cosmetic Act and its implementing regulations. Our specific objections follow:

Fair Balance

The brochure describes the benefits, indications, and dosage recommendations for Viroptic, but does not include any information relating to the product's side effects and contraindications, or other risk information. The brochure also includes a similar presentation of the benefits, indications, and dosage recommendations for Cortisporin Ophthalmic Ointment Sterile.

Monarch should cease immediately using this brochure and all other materials that are lacking fair balance. In all future promotional materials DDMAC requests that Monarch present balancing risk information in a manner comparable in prominence and readability to the presentation of information relating to the effectiveness of the drug.

Monarch should respond to DDMAC regarding this issue by August 21, 1997, detailing its disposition of these promotional materials.

If you have any questions, please contact me by telephone at (301) 827-2831, by facsimile at (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.

In all future correspondence regarding this matter, please refer to MACMIS # 5677 and NDA 18-299.

Sincerely,

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